NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

OCTOBER 2018

INTRODUCTION

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. This document also is designed to be useful to those interested in NIH grants by providing information about NIH—its organization, its staff, and its grants process. The NIHGPS is available online at https://grants.nih.gov/policy/nihgps/index.htm. This version includes many links within the document as well as links to some web resources outside of this document. Users are strongly encouraged to use the on-line version of this document to benefit from these links.

NIHGPS ORGANIZATION

The NIHGPS has three parts, which allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- ***Part I: NIH Grants—General Information.*** Part I (chapters 1 and 2) contains a glossary defining commonly used terms and abbreviations used throughout the document; describes NIH and its relationship to other organizations within the Department of Health and Human Services (HHS); specifies recipient, NIH, and other HHS staff responsibilities and outlines the grant application and review processes.
- ***Part II: Terms and Conditions of NIH Grant Awards.*** Part II (chapters 3-19) includes generally applicable terms and conditions (Part IIA). This part also specifies the terms and conditions that apply to particular types of grants, recipients, and activities that differ from, supplement, or elaborate on the standard terms and conditions (Part IIB). These requirements, in separate chapters, pertain to multiple PD/PI applications and awards; construction, modernization and major alteration and renovation grants; research training grants and fellowships; career development awards; modular applications and awards; conference grants, consortium agreements; grants to foreign and international organizations (and grants with substantial foreign components awarded to domestic organizations), grants to Federal institutions and payments to Federal employees; grants to for-profit organizations; and research patient care activities.
- ***Part III: Points of Contact.*** Part III (chapter 20) lists pertinent offices with their contact information.

CONVENTIONS

Certain conventions are followed throughout this document. The term “grant” is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term “recipient” generally is used to refer to recipients of grants and awardees of cooperative agreements; however the terms “recipient” or “awardee” also are used. “NIH” may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by NIH, including actions by its ICs, with an action by a recipient or other organization. A reference to “Part II (IIA or IIB)” or “Part III” without further elaboration means the corresponding part of the NIHGPS.

SUPERSESSION

The NIHGPS was originally published with an effective date of October 1, 1998. It was subsequently revised in 2001, 2003, 2010, 2011, 2012, 2013, March 2015, October/November 2015, 2016 and 2017. This revision of the NIHGPS is an update of the October 2017 publication. It applies to all NIH grants

and cooperative agreements for budget periods beginning on or after October 1, 2018. This version incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the GPS from October 2017. An explanation of the major changes to the NIHGPS since the previous edition is included in the *NIH Guide for Grants and Contracts* notice announcing the reissuance of the NIHGPS.

ADDITIONAL INFORMATION

The Office of Policy for Extramural Research Administration (OPERA) develops and maintains this document. Changes in statutes, regulations, or policies that take effect before the next revision of the NIHGPS will be published separately in the *NIH Guide for Grants and Contracts*. Recipients are responsible for reviewing the *NIH Guide for Grants and Contracts*, which is published on the NIH home page at http://grants.nih.gov/grants/guide/index.html, for changes and for implementing them, as appropriate. Subscribe to the *NIH Guide for Grants and Contracts* Listserv at http://grants.nih.gov/grants/guide/listserv.htm.

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PART I: NIH GRANTS—GENERAL INFORMATION

This part contains a glossary defining terms and abbreviations commonly used throughout the NIHGPS; describes NIH and its relationship to other organizations within HHS; specifies recipient, NIH, and other HHS staff responsibilities; and outlines the grant application and review processes.

1 GLOSSARY

The glossary lists acronyms and other abbreviations used in the NIHGPS. The glossary also defines terms commonly used throughout the NIHGPS. The definitions may be amplified and additional definitions may be found throughout this document and in source documents, such as applicable statutes, grants administration regulations, and OMB circulars. This is the only location in the NIHGPS where these terms are defined. If an abbreviation used in the NIHGPS is unfamiliar, the reader should consult this list for its meaning.

1.1 ABBREVIATIONS

Exhibit 1: Abbreviation and full language of acronyms used in the Grants Policy Statement

Abbreviation	Full Meaning of Abbreviation
A&R	Alteration and Renovation
ACF	Administration for Children and Families
ACH	Automated Clearinghouse
ACL	Administration for Community Living
AHRQ	Agency for Healthcare Research and Quality
AIA	American Institute of Architects
AoA	Administration on Aging
AOR	Authorized Organization Representative
APAC	Annual Payback Activities Certification
AREA	Academic Research and Enhancement Award
ASHRAE	American Society of Heating, Refrigeration and Air Conditioning Engineers
BSO	Biological Safety Officer
CDA	Career Development Award
CDC	Centers for Disease Control and Prevention
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations

Abbreviation	Full Meaning of Abbreviation
CGMO	Chief Grants Management Officer
CM	Construction Manager
CMS	Centers for Medicare and Medicaid Services
CoC	Certificate of Confidentiality
COR	Career Opportunities in Research Education and Training Program
CSR	Center for Scientific Review
DAB	Departmental Appeals Board
DCA	Division of Cost Allocation, HHS
DCGP	Division of Central Grants Processing, OER, NIH
DCIS	Departmental Contracts Information System
DEA	Drug Enforcement Administration
DEITR	Division of Extramural Inventions & Technology Resources, OPERA, OER, NIH
DES	Department of Engineering Services, NIH
DFAS	Division of Financial Advisory Services, NIH
DGCO	Division of Grants Compliance and Oversight, OPERA, OER, NIH
DGP	Division of Grants Policy, OPERA, OER, NIH
DNA	Deoxyribonucleic acid
DoC	Department of Commerce
DoD	Department of Defense
DoL	Department of Labor
DPI	Division of Program Integrity, OMA, NIH
DRR	Division of Receipt and Referral, CSR
DSMB	Data and Safety Monitoring Board
EA	Environmental Assessment
eFSR/FFR	Electronic Financial Status Report/Federal Financial Report
EIN	Entity Identification Number
EIS	Environmental Impact Statement
EO	Executive Order
eRA	Electronic Research Administration
ESI	Early Stage Investigator

Abbreviation	Full Meaning of Abbreviation
eSNAP	Electronic Streamlined Non-competing Award Process
F&A	Facilities and Administrative (costs)
FAC	Federal Audit Clearinghouse
FAIN	Federal Award Identification Number
FAR	Federal Acquisition Regulation
FCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDP	Federal Demonstration Partnership
FEMA	Federal Emergency Management Agency
FFATA	Federal Funding Accountability and Transparency Act
FFR	Federal Financial Report (SF425)
FIC	Fogarty International Center
FICA	Federal Insurance Contributions Act
FOA	Funding Opportunity Announcement
FOI	Freedom of Information
FOIA	Freedom of Information Act
FSR	Financial Status Report (SF 269 or 269A)
FTR	Federal Travel Regulation
FWA	Federalwide Assurance
GAAP	Generally Accepted Accounting Principles
GAGAS	Generally Accepted Government Accounting Standards
GeMCRIS	Genetic Modification Clinical Research Information System
GMO	Grants Management Officer
GMP	Guaranteed Maximum Price
GMS	Grants Management Specialist
GPO	Government Printing Office
GSA	General Services Administration
GWAS	Genome-wide Association Studies
hESC	Human Embryonic Stem Cells

Abbreviation	Full Meaning of Abbreviation
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIS	Indian Health Service
HPSL	Health Professional Student Loan
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilating, and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IBS	Institutional Base Salary
IC	Institute or Center
IDE	Investigational Device Exception
IHE	Institutions of Higher Education
IND	Investigational New Drug
IPA	Intergovernmental Personnel Act
IPF	Institutional Profile File
IR&D	Independent Research and Development
IRB	Institutional Review Board
IRG	Initial Review Group
IRS	Internal Revenue Service
IVF	In vitro Fertilization
K award	Career Award
Kirschstein-NRSA	Ruth L. Kirschstein National Research Service Award
LWOP	Leave Without Pay
MARC-U*STAR	Maximizing Access to Research Careers Undergraduate Student Training in Academic Research Program
MOU	Memorandum of Understanding
MTDC	Modified Total Direct Cost
NCATS	National Center for Advancing Translational Sciences
NCT	National Clinical Trial
ND	Not Discussed

Abbreviation	Full Meaning of Abbreviation
NEARC	National External Audit Review Center, OIG
NEI	National Eye Institute
NEPA	National Environmental Policy Act
NFI	Notice of Federal Interest
NFPA	National Fire Protection Association
NHSC	National Health Service Corps
NICHD	*Eunice Kennedy Shriver* National Institute for Child Health and Human Development
NIDCR	National Institute of Dental and Craniofacial Research
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIH MSID	NIH manuscript submission reference number
NIHGPS	National Institutes of Health Grants Policy Statement
NIMH	National Institute of Mental Health
NINR	National Institute on Nursing Research
NLM	National Library of Medicine
NoA	Notice of Award
NTIS	National Technical Information Service
OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights, HHS
OEP	Office of Extramural Programs, OER, NIH
OER	Office of Extramural Research, NIH
OFCCP	Office of Federal Contract Compliance Programs, DoL
OFM	Office of Financial Management, NIH
OHRP	Office for Human Research Protections, HHS
OIG	Office of the Inspector General
OIR	Office of Intramural Research, NIH
OLAW	Office of Laboratory Animal Welfare, NIH
OMA	Office of Management Assessment, NIH
OMB	Office of Management and Budget
ONR	Office of Naval Research

Abbreviation	Full Meaning of Abbreviation
OPERA	Office of Policy for Extramural Research Administration, OER, NIH
ORI	Office of Research Integrity, HHS
OSC	Other Significant Contributor
P.L.	Public Law
PA	Program Announcement
PAR	Program Announcement with Special Review Criteria
PD/PI	Program Director/Principal Investigator
pdf	portable document format
PHS	Public Health Service
PII	Personally Identifiable Information
PMC	PubMed Central
PMCID	PubMed Central Identification/reference number
PMS	Payment Management System, Payment Management Service, HHS
PO	Program Official
PSC	Payback Service Center, NIH, or Program Support Center, HHS
PTE	Pass-through Entity
R&D	Research and Development
R&R	Research and Related
RePORT	Research Portfolio Online Reporting Tool
RFA	Request for Applications
RFP	Request for Proposals
ROTC	Reserve Officer Training Corps
RPPR	Research Performance Progress Report
S&W	Salaries and Wages
SAM	System for Award Management
SAMHSA	Substance Abuse and Mental Health Services Administration
SBA	Small business Administration
SBC	Small Business Concern
SBIR	Small Business Innovation Research Program
SEP	Special Emphasis Panel

Abbreviation	Full Meaning of Abbreviation
SEVIS	Student and Exchange Visitor Information System
SF	Standard Form
SF424(R&R)	Standard Form 424 for Research and Research-Related (R&R)
SII	Successor-In-Interest
SNAP	Streamlined Non-competing Award Process
SO	Signing Official
SPOC	State Single Point of Contact
SRG	Scientific Review Group
SRO	Scientific Review Officer
STTR	Small Business Technology Transfer Program
TVPA	Trafficking Victims Protection Act
U.S.	United States
U.S.C.	United States Code
USCIS	United States Citizenship and Immigration Services
USDA	United States Department of Agriculture
USPS	United States Postal Service
VA	Department of Veterans Affairs
VAMC	VA Medical Center
VANPC	VA-Affiliated Non-Profit research Corporation
VAT	Value Added Tax
VHA	Veterans Health Administration
WIC	Women, Infants and Children

1.2 DEFINITION OF TERMS

Exhibit 2: Definitions of terms used in the Grants Policy Statement

Term	Definition
Acquisition cost	The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.
Activity code	A 3-character code used to identify a specific category of extramural research activity, applied to financial assistance mechanisms. NIH uses three funding mechanisms for extramural research awards: grants, cooperative agreements and contracts. Within each funding mechanism, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.) to differentiate the wide variety of research-related programs NIH supports. A comprehensive list of activity codes is on the NIH Web site at http://grants.nih.gov/grants/funding/ac_search_results.htm.
Additive alternative	A use of program income earned during or after the project period that permits income that is generated under a grant to be added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives. (See definitions for deductive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Administrative supplement	A request for (or the award of) additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project.
Advance payment	A payment that a Federal awarding agency or pass through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes.
Allocation	The process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives. For additional information, see Cost Considerations—The Cost Principles.
Allowable cost	A cost incurred by a recipient that is: (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; (4) consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other federally supported award (unless specifically authorized by statute). For additional information on each, see Cost Considerations—The Cost Principles.

Term	Definition
Alteration and renovation	Work that changes the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. See also definitions for Major A&R and Minor A&R.
Applicable clinical trial	Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA.
Applicable credit	Those receipts that offset or reduce direct or indirect costs. Typical examples of such transactions include purchase discounts, rebates, or allowances; recoveries or indemnities on losses, insurance refunds; and adjustments of overpayments or erroneous charges.
Application	A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. (See Application Information and Processes for detailed information about the application process, including an explanation of the types of applications).
Application type code	A single-digit code identifying the type of application received and processed. Application type codes include the following: 1=New; 2=Renewal; 3=Revision; 4=E-Extension; 5=Non-Competing Continuation; 6=Change of Organization Status (Successor-In-Interest); 7=Change of Recipient or Training Institution; 8=Change of Institute or Division (Type 5 transfer to another NIH IC); 9=Change of Institute or Division (Type 2 transfer to another NIH IC).
Appropriation Act	The statute that provides the authority for Federal agencies to incur obligations to and make payments out of the U.S. treasury for specified purposes.
Assurance	A certification by an applicant, normally included with the application or State plan, indicating that the entity is in compliance with, or that it will abide by, a particular requirement if awarded a Federal grant.
Audit finding	Deficiencies which an auditor is required by 45 CFR § 75.516(a) to report in the schedule of findings and questioned costs.
Audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings (that is, questioned costs).
Authorized organization representative	The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This individual is equivalent to the signing official in the eRA Commons, i.e., holds the SO Role.
Award	The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.
Awarding IC	The NIH IC responsible for the award, administration, and monitoring of grant supported activities.

Term	Definition
Budget	The financial plan for the project or program that the Federal awarding agency or pass-through entity approves during the Federal award process or in subsequent amendments to the Federal award. It may include the Federal and non-Federal share or only the Federal share, as determined by the Federal awarding agency or pass through entity. The approved budget specified in the NoA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the recipient in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.
Budget period	The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.
Capital assets	Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include: (1) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and (2) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).
Capital expenditures	Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life. (See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Capital Expenditures).
Carryover	Unobligated Federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated, but unliquidated, funds are not considered carryover.
Catalogue of Federal Domestic Assistance (CFDA) number	The number assigned to a Federal program in the CFDA.
CFDA program title	The title of the program under which the Federal award was funded in the CFDA.
Change in scope	An activity whereby the objectives or specific aims identified in the approved grant application are significantly changed by the recipient after award. GMO prior approval is required for a change in scope to be allowable under an award. See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Change of Scope for additional information.
Change of PD/PI	A process, usually initiated by the recipient, whereby the federally approved PD/PI is replaced by another individual, with the approval of the GMO.

Term	Definition
Change of recipient organization	Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
Chief Grants Management Officer	The Grants Management Officer within an awarding agency who is the principal Grants Officer in the agency. The Chief Grants Management Officer provides leadership to an organizational component that is responsible for the business and fiscal management of an IC's grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO.
Claim	Depending on the context, either: (1) A written demand or written assertion by one of the parties to a Federal award seeking as a matter of right: (i) The payment of money in a sum certain; (ii) The adjustment or interpretation of the terms and conditions of the Federal award; or (iii) Other relief arising under or relating to a Federal award. (2) A request for payment that is not in dispute when submitted.
Clinical research	Research with human subjects that is: 1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies. 2) Epidemiological and behavioral studies. 3) Outcomes research and health services research Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

Term	Definition
Clinical trial	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. • See Common Rule definition of research at 45 CFR 46.102(d) • See Common Rule definition of human subject at 45 CFR 46.102(f) • The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial. • An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and, treatment, prevention, and diagnostic strategies. • A *health-related biomedical or behavioral outcome* is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and, well-being or quality of life Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases: Phase I. Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely. Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
Closeout	The process by which the Federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the Federal award have been completed and takes actions as described in 45 CFR § 75.381.

Term	Definition
Cluster of programs	A grouping of closely related programs that share common compliance requirements. The types of clusters of programs are research and development (R&D), student financial aid (SFA), and other clusters. “Other clusters” are as defined by OMB in the compliance supplement or as designated by a state for Federal awards the state provides to its subrecipients that meet the definition of a cluster of programs. When designating an “other cluster,” a state must identify the Federal awards included in the cluster and advise the subrecipients of compliance requirements applicable to the cluster, consistent with 45 CFR § 75.352(a). A cluster of programs must be considered as one program for determining major programs, as described in 45 CFR § 75.518, and, with the exception of R&D as described in 45 CFR § 75.501(c), whether a program-specific audit may be elected.
Code of Federal Regulations	The codified regulations of the Federal government based on the final agency regulations published in the Federal Register.
Cognizant agency for audit	The Federal agency designated to carry out the responsibilities described in 45 CFR § 75.513(a). The cognizant agency for audit is not necessarily the same as the cognizant agency for indirect costs. A list of cognizant agencies for audit may be found at the FAC Web site.
Cognizant agency for indirect costs	The Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals developed under this part on behalf of all Federal agencies. The cognizant agency for indirect cost is not necessarily the same as the cognizant agency for audit. For assignments of cognizant agencies see the following: (1) For IHEs: 45 CFR Pt 75, Appendix III, C.11. (2) For nonprofit organizations: 45 CFR Pt 75, Appendix IV, C.2. (3) For state and local governments: 45 CFR Pt 75, Appendix V, F.1. (4) For Indian tribes: 45 CFR Pt 75, Appendix VII, D.1.
Co-Investigator	An individual involved with the PD/PI in the scientific development or execution of a project. The Co-Investigator (collaborator) may be employed by, or be affiliated with, the applicant/recipient organization or another organization participating in the project under a consortium agreement. A Co-Investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel. The designation of a Co-Investigator, if applicable, does not affect the PD/PI’s roles and responsibilities as specified in the NIHGPS, nor is it a role implying multiple PD/PI.
Commercial organization	An organization, institution, corporation, or other legal entity, including, but not limited to, partnerships, sole proprietorships, and limited liability companies, that is organized or operated for the profit or benefit of its shareholders or other owners. The term includes small and large businesses and is used interchangeably with “for-profit organization.”
Competitive revision	A request for (or the award of) additional funds during a current project period to support new or additional activities which are not identified in the current award that reflect an expansion of the scope of the grant-approved activities. Competitive revisions require peer review.
Competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award.

Term	Definition
Compliance Supplement	Appendix XI to 45 CFR 75 (previously known as the Circular A-133 Compliance Supplement).
Component	For the purposes of applications and progress reports, a component is a distinct, reviewable part of a multi-project application or progress report for which there is a business need to gather detailed information identified in the funding opportunity announcement (FOA). Components typically include general information (component organization, project period, project title, etc.), performance sites, personnel, and budget. The FOA defines the construction and naming convention for the application; the funded application defines the construction and naming convention for the progress report. Components may also be referred to as "cores" or "projects." Note, for RPPR Question G.9, the term "foreign component" is distinct from "component" as defined here. However, a "foreign component" may also be a "component" in the RPPR. (See definition of foreign component for more information).
Computing devices	Machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or ''peripherals'') for printing, transmitting and receiving, or storing electronic information. See also "supplies" and "information technology systems."
Conference (domestic or international)	A symposium, seminar, workshop, or any other organized and formal meeting, whether conducted face-to-face or via the Internet, where individuals assemble (or meet virtually) to exchange information and views or explore or clarify a defined subject, problem, or area of knowledge, whether or not a published report results from such meeting.
Conference grant	A grant whose purpose is to support activities related to the conduct of a conference (s) or defined set of conference-related activities.
Conflict of interest	Conflict of Interest is a cross-cutting issue that affects many policy areas such as peer review, financial conflict of interest, and responsible conduct of research. There are different uses of this term throughout this document. It generally means that a competing personal interest could affect, or could appear to affect, an individual's judgment or could cause the individual's impartiality to be questioned. Conflicts of Interest (actual or potential) may arise in the objective review process or in other activities or phases of the financial assistance process. See also Financial Conflict of Interest for a specific definition covering that policy area.
Consortium agreement	A formalized agreement whereby a research project is carried out by the recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific level of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship. (See Consortium Agreements chapter in IIB).

Term	Definition
Construction	Construction of new buildings or completion of shell space in existing buildings (including the installation of fixed equipment, but excluding the cost of land acquisition and off-site improvements). The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities. New construction, or activities that would change the "footprint" of an existing facility (e.g., relocation of existing exterior walls, roofs, or floors, attachment of fire escapes) is considered construction. See Construction chapter in IIB.
Consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, recipients and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants also include firms that provide professional advice or services. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Consultant Services).
Contact PD/PI	When multiple PD/PIs are designated, NIH requires that the applicant organization identify one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. See Multiple PI chapter in IIB for additional information.
Contract	A legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term as used in 45 CFR 75 does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward. See Subaward.
Contractor	An entity that receives a contract. See contract.
Cooperative agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302–6305: (1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or pass through entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal government or pass-through entity's direct benefit or use; (2) Is distinguished from a grant in that it provides for substantial involvement between the Federal awarding agency or pass-through entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. (3) The term does not include: (i) development agreement as defined in 15 U.S.C. 3710a; or (ii) An agreement that provides only: (A) Direct United States Government cash assistance to an individual; (B) A subsidy; (C) A loan; (D) A loan guarantee; or (E) Insurance.
Cost allocation plan	Central service cost allocation plan or public assistance cost allocation plan.

Term	Definition
Cost objective	A program, function, activity, award, organizational subdivision, contract, or work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, products, jobs, capital projects, etc. A cost objective may be a major function of the non-Federal entity, a particular service or project, a Federal award, or an indirect (Facilities & Administrative (F&A)) cost activity, as described in 45 CFR 75, Subpart E—Cost Principles.
Cost overrun	Any amount charged in excess of the Federal share of costs for the project period (competitive segment).
Cost principles	The government-wide principles, issued by OMB (or, in the case of commercial organizations, the Federal Acquisition Regulation [48 CFR 21], or, in the case of hospitals, 45 CFR 75, Appendix IX, "Principles For Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals"), on allowability and unallowability of costs under federally sponsored agreements. See Cost Considerations—The Cost Principles for additional details.
Cost sharing	See matching or cost sharing definition.
Cost sharing or matching alternative	An alternative use of program income whereby income accrued during the period of grant support may be used to satisfy a cost sharing or matching requirement. (See also definitions for additive alternative and deductive alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Cost-type contract	A contract or subcontract under a grant in which the contractor or subcontractor is paid on the basis of the allowable costs it incurs, with or without a fee.
Data and safety monitoring plan	For each NIH-supported clinical trial, NIH requires a data and safety monitoring plan that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the awarding IC for approval prior to the accrual of human subjects.
Debarment and suspension	The actions taken by a debarring official in accordance with OMB guidance at 2 CFR 180, "Non-procurement Debarment and Suspension," as implemented by HHS in 2 CFR 376, to exclude a person or organization from participating in grants and other non-procurement awards government-wide. If debarred or suspended, the person or organization may not receive financial assistance (under a grant, cooperative agreement, or subaward, or contract under a grant) for a specified period of time. Debarments and suspensions carried out pursuant to 2 CFR 376 are distinct from post-award suspension action by an awarding agency. (See also Public Policy Requirements and Objectives—Debarment and Suspension).
Debt collection	The process of collecting funds owed by recipients to the Federal government, which, under grants, generally are owed as a result of formal cost disallowances.
Debt instrument	A document used to record a legal obligation of one party to pay a financial obligation to another in accordance with predetermined terms and conditions.

Term	Definition
Deductive alternative	An alternative for the use of program income earned during the period of grant support under which allowable costs of the project or program to be paid by the Federal government are offset by the amount of the program income. (See also definitions for additive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Departmental Grants Appeals Board	The independent office established in the Office of the Secretary with delegated authority from the Secretary to review and decide certain disputes between recipients of HHS funds and HHS awarding agencies under 45 CFR Part 16 and to perform other review, adjudication and mediation services as assigned.
Deviation	A departure on a single-case or class basis from a regulatory or policy requirement. A single-case deviation represents a request for waiver or exception sought for one grant only that arises on a case-by-case basis. A class deviation involves more than one grant for which the same type of deviation action is being requested.
Direct costs	Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
Disallowed costs	Those charges to a Federal award that the Federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable Federal statutes, regulations, or the terms and conditions of the Federal award.
Domestic organization	A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.
Early Stage Investigator	An individual who is classified as a New Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). See definition of New Investigator.
Entity Identification Number	A three-part coding scheme of 12 characters used in PMS to identify organizations and individuals. The first character identifies the recipient as an organization or an individual. The next nine characters are the Employer Identification Number. The last two characters are a suffix to provide distinction between organizational entities that are assigned a single EIN and those that have more than one.
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000. (See also capital assets, computing devices, general purpose equipment, information technology systems, special purpose equipment, and supplies).

Term	Definition
eRA Commons	The Electronic Research Administration (eRA) Commons is a virtual meeting place where NIH extramural recipient organizations, recipients, and the public can receive and transmit information about the administration of biomedical and behavioral research. The eRA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively.
Excluded Parties List System	A public database maintained by the General Services Administration which is the official government-wide system of record for debarments, suspensions, and other exclusionary actions. (See also Public Policy Requirements and Objectives—Debarment and Suspension).
Expanded authorities	Operating authorities provided in Federal Administrative Regulations (e.g., A-110) to recipients that waive the requirement for prior approval for specified actions. NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances thus these authorities have become the NIH Standard Terms of Award. Therefore, the term Expanded Authorities is no longer used at NIH (see Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award).
Expenditure report	Means: (1) For non-construction grants, the SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report); (2) for construction grants, the SF-271 "Outlay Report and Request for Reimbursement" (or other OMB-approved equivalent report)
Expenditures	Charges made by a non-Federal entity to a project or program for which a Federal award was received. 1. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. 2. For reports prepared on a cash basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense charged; iii. The value of third-party in-kind contributions applied; and iv. The amount of cash advance payments and payments made to subrecipients. 3. For reports prepared on an accrual basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense incurred; iii. The value of third-party in-kind contributions applied; and iv. The net increase or decrease in the amounts owed by the non-Federal entity for: A. Goods and other property received; B. Services performed by employees, contractors, subrecipients, and other payees; and C. Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.

Term	Definition
Facilities and Administrative (F&A) costs (or indirect costs)	Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of F&A (indirect) costs. F&A (indirect) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.
Federal agency	An "agency" as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).
Federal Audit Clearinghouse (FAC)	The clearinghouse designated by OMB as the repository of record where non-Federal entities are required to transmit the reporting packages required by Subpart F—Audit Requirements of 45 CFR 75 Subpart F – Audit Requirements. The mailing address of the FAC is Federal Audit Clearinghouse, Bureau of the Census, 1201 E. 10th Street, Jeffersonville, IN 47132 and the web address is: https://harvester.census.gov/facweb/. Any future updates to the location of the FAC may be found at the OMB Web site.
Federal award	Depending on the context, in either paragraph (1) or (2) of this section: (1)(i) The Federal financial assistance that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 45 CFR 75.101; or (ii) The cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 45 CFR 75.101. (2) The instrument setting forth the terms and conditions. The instrument is the grant agreement, cooperative agreement, other agreement for assistance covered in paragraph (2) of Federal financial assistance, or the cost-reimbursement contract awarded under the Federal Acquisition Regulations. (3) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal government owned, contractor operated facilities (GOCOs). (4) See also definitions of Federal financial assistance, grant agreement, and cooperative agreement.
Federal award date	The date when the Federal award is signed by the authorized official of the Federal awarding agency.
Federal Award Identification Number	A unique number assigned to a financial assistance award to assist recipients in correctly reporting subawards. The public can use the FAIN and the CFDA number together to find one accurate result when searching on line in such databases as USASpending.gov and FSRS. The FAIN can be found on the notice of award. NIH implements the FAIN by deriving it from the core elements of the grant number. For example, the FAIN for 1R0lGM654321-01 would be R01GM654321.
Federal awarding agency	The Federal agency that provides a Federal award directly to another entity. See also Awarding IC.

Term	Definition
Federal Demonstration Partnership	A cooperative initiative among some Federal agencies, including NIH, selected organizations receiving Federal funding for research, and certain professional associations. Its efforts include demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs.
Federal financial assistance	1. For grants and cooperative agreements, Federal financial assistance means assistance that non-Federal entities receive or administer in the form of: i. Grants; ii. Cooperative agreements; iii. Non-cash contributions or donations of property (including donated surplus property); iv. Direct appropriations; v. Food commodities; and vi. Other financial assistance (except assistance listed in paragraph (b) of this section). 2. For Subpart F of 45 CFR 75, Federal financial assistance also includes assistance that non-Federal entities receive or administer in the form of: i. Loans; ii. Loan Guarantees; iii. Interest subsidies; and iv. Insurance. 3. Federal financial assistance does not include amounts received as reimbursement for services rendered to individuals as described in 45 CFR 75.502(h) and (i).
Federal institution	A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency. For the purposes of this document, this term is used in the context of a Federal institution as a recipient. See also Awarding IC.
Federal interest	For purposes 45 CFR 75.343 or when used in connection with the acquisition or improvement of real property, equipment, or supplies under a Federal award, the dollar amount that is the product of the: (1) Federal share of total project costs; and (2) Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs.

Term	Definition
Federal program	1. All Federal awards which are assigned a single number in the CFDA. 2. When no CFDA number is assigned, all Federal awards to non- Federal entities from the same agency made for the same purpose should be combined and considered one program. 3. Notwithstanding paragraphs (1) and (2) of this definition, a cluster of programs. The types of clusters of programs are: i. Research and development (R&D); ii. Student financial aid (SFA); and iii. ''Other clusters,'' as described in the definition of Cluster of Programs.
Federal share	The portion of the total project costs that are paid by Federal funds.
Federalwide Assurance	The Federalwide Assurance is the only type of new assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under a FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR 46, as well as the terms of assurance.
Fee	An amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as profit. (See Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee).
Financial assistance	Transfer by NIH of money or property to an eligible entity to support or stimulate a public purpose authorized by statute.
Financial conflict of interest	A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See 42 CFR 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought and Public Policy Requirements and Objectives—Financial Conflict of Interest.

Term	Definition
Foreign component	The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are: • collaborations with investigators at a foreign site anticipated to result in co-authorship; • use of facilities or instrumentation at a foreign site; or • receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component. (See Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components chapter in IIB).
Foreign organization	An entity that is: 1. A public or private organization located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance; 2. A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public; 3. A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or 4. An organization located in a country other than the United States not recognized as a *Foreign Public Entity*.
Foreign public entity	(1) A foreign government or foreign governmental entity; (2) A public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288–288f); (3) An entity owned (in whole or in part) or controlled by a foreign government; or (4) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.

Term	Definition
For-profit organization	An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. A for-profit organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. (Also see definition for small business concern).
Full-time appointment	The number of days per week and/or months per year representing full-time effort at the applicant/recipient organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.
Funding opportunity announcement	A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program. Funding opportunity announcements can be found at Grants.gov/FIND and in the *NIH Guide for Grants and Contracts*.
General purpose equipment	Equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles. See also "Equipment" and "Special Purpose Equipment."
Generally Acceptable Accounting Principles (GAAP)	The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).
Generally Accepted Government Auditing Standards (GAGAS)	Also known as the Yellow Book, generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.
Grant number	A grant number is a unique identifier for a grant composed of the application type code, activity code, Institute code, 6-digit serial number, support year and /or suffix code for the support year of the grant, or other information, such as a supplement (S1), resubmission (A1), or a fellowship's institutional allowance. In Federalwide systems (e.g., USASpending.gov, FFATA/FSRS) the Federal Award Identifier Number (FAIN) is used to identify grants for Federalwide implications. Similar to the NIH Grant Number, the FAIN consists of the activity code, Institute code, and 6-digit serial number. Sample Grant Number: 1 R01 AI 123456-01 A1 S1 Sample FAIN: R01 AI 654321

Term	Definition
Grant or grant agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302, 6304: 1. Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or passthrough entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal awarding agency or pass-through entity's direct benefit or use; 2. Is distinguished from a cooperative agreement in that it does not provide for substantial involvement between the Federal awarding agency or passthrough entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. 3. Does not include an agreement that provides only: i. Direct United States Government cash assistance to an individual; ii. A subsidy; iii. A loan; iv. A loan guarantee; or v. Insurance. See also Cooperative Agreement.
Grantee	See Recipient.
Grants Management Officer	An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. GMOs are delegated the authority from the CGMO to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards. See also Chief Grants Management Officer definition.
Grants Management Specialist	An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to recipients; and administering grants after award.
Grants.gov	Grants.gov (http://www.grants.gov/) has been designated by the Office of Management and Budget as the single access point for all grant programs offered by 26 Federal grant-making agencies. It provides a single interface for agencies to announce their grant opportunities and for all applicants to find and apply for those opportunities.

Term	Definition
Grant-supported project or activity	Those activities specified or described in a grant application or in a subsequent submission that are approved by an NIH IC for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.
Hospital	A facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state. Also includes a non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation).
Human subject	A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See Public Policy Requirements and Objectives—Human Subjects Protections).
Impact score	The impact score is the rating which is assigned to an individual application by an SRG, and designates the reviewers' assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of established review criteria. The impact score is one mechanism by which the SRG makes a recommendation to the funding component concerning the application's scientific and technical merit. Impact scores may be numeric (10 – 90) or alphabetical (ND, for example).
Improper payment	(1) Any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and (2) Includes any payment to an ineligible party, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), any payment that does not account for credit for applicable discounts, and any payment where insufficient or lack of documentation prevents a reviewer from discerning whether a payment was proper.
Indian tribe (or "federally recognized Indian tribe")	Any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.
Indirect costs	See facilities and administrative costs definition.
Information technology systems	Computing devices, ancillary equipment, software, firmware, and similar procedures, services (including support services), and related resources. See also computing devices and equipment.

Term	Definition
Innovation	Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of innovation would be new medical or biological products for improved value, efficiency, or costs.
Institute or Center	The NIH organizational component responsible for a particular grant program or set of activities. The terms “NIH IC,” or “awarding IC” are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award.
Institutional Animal Care and Use Committee	The *PHS Policy on Humane Care and Use of Laboratory Animals* incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding.
Institutional base salary	The annual compensation paid by an organization for an employee’s appointment, whether that individual’s time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties for the applicant/recipient organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages).
Institutional Review Board (IRB)	An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.
Institutions of Higher Education (IHEs)	IHE is defined at 20 U.S.C. 1001.
Intangible property	Property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).

Term	Definition
Intergovernmental Personnel Act (IPA)	The Intergovernmental Personnel Act Mobility Program provides for the temporary assignment of personnel between the Federal Government and state and local governments, colleges and universities, Indian tribe (or "federally recognized Indian tribe" governments, federally funded research and development centers, and other eligible organizations. The goal of the Intergovernmental Personnel Act mobility program is to facilitate the movement of employees, for short periods of time, when this movement serves a sound public purpose.
Internal control over compliance requirements for Federal awards	A process implemented by a non-Federal entity designed to provide reasonable assurance regarding the achievement of the following objectives for Federal award: 1. Transactions are properly recorded and accounted for, in order to: i. Permit the preparation of reliable financial statements and Federal reports; ii. Maintain accountability over assets; and iii. Demonstrate compliance with Federal statutes, regulations, and the terms and conditions of the Federal award; 2. Transactions are executed in compliance with: i. Federal statutes, regulations, and the terms and conditions of the Federal award that could have a direct and material effect on a Federal program; and ii. Any other Federal statutes and regulations that are identified in the Compliance Supplement; and iii. (3) Funds, property, and other assets are safeguarded against loss from unauthorized use or disposition.
Internal controls	A process, implemented by a non-Federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: (1) Effectiveness and efficiency of operations; (2) Reliability of reporting for internal and external use; and (3) Compliance with applicable laws and regulations.
International organization	An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.
Invention reporting	The requirement pursuant to 37 CFR 401 that recipients of contracts, grants or cooperative agreements fully disclose any subject inventions made during the performance of work under a funding agreement in order to protect the Federal government's rights.
Investigational new drug	A new drug or biological drug that is used in a clinical investigation.
Investigator-initiated research	Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees.

Term	Definition
IPF number	Institutional Profile File (IPF) number is a unique number used by NIH for tracking/reporting awards to recipient institutions.
Just-in-Time	NIH policy allows the submission of certain elements of a competing application to be deferred until later in the application process, after review when the application is under consideration for funding. Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. Through this module, institutions can electronically submit the information that is requested after the review, but before award. See Completing the Pre-Award Process—Just-In-Time Procedures for additional information.
Liquidated damages	An amount defined in a contract and chargeable against funds due to the contractor for each day the contractor fails to complete the project beyond the contract completion date.
Local government	Any unit of government within a state, including a: (1) County; (2) Borough; (3) Municipality; (4) City; (5) Town; (6) Township; (7) Parish; (8) Local public authority, including any public housing agency under the United States Housing Act of 1937; (9) Special district; (10) School district; (11) Intrastate district; (12) Council of governments, whether or not incorporated as a nonprofit corporation under state law; and (13) Any other agency or instrumentality of a multi-, regional, or intra-state or local government.
Major A&R	An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving modernization, improvement or remodeling, exceeding $500,000 in direct costs awarded for the project. Major A&R may include improvement, conversion, rearrangement, rehabilitation or remodeling. Major A&R does not apply to minor alterations, renovations or repairs funded under a research project grant or alterations or renovations funded under an NIH center grant. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants.
Matching or cost sharing	The portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). This may include the value of allowable third party in-kind contributions, as well as expenditures by the recipient.
Mechanism	Extramural awards are divided into three types of financial assistance: *grants*, *cooperative agreements* and *contracts*. A mechanism is the type of funded application or transaction used at the NIH. Within each mechanism NIH includes programs. Programs can be further refined by specific activity codes.
Merger	A legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for the recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change will apply.

Term	Definition
Micro-purchase	A purchase of supplies or services using simplified acquisition procedures, the aggregate amount of which does not exceed the micro-purchase threshold. Micro-purchase procedures comprise a subset of a non-Federal entity's small purchase procedures. The non-Federal entity uses such procedures in order to expedite the completion of its lowest-dollar small purchase transactions and minimize the associated administrative burden and cost. The micro-purchase threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1 (Definitions). Per OMB Memo M-18-18, the threshold is currently $10,000.
Minor A&R	An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving improvement or remodeling, which does not exceed $500,000 in direct costs. Minor A&R is not an allowable activity or cost under grants to individuals or grants for limited purposes, such as grants in support of scientific meetings (conference grants). Routine maintenance and repair of the organization's physical plant or its equipment is not considered A&R; these types of costs are typically treated as F&A costs.
Modernization	Alteration, renovation, remodeling, improvement, and/or repair of an existing building and the provision of equipment necessary to make the building suitable for use for the purposes of a particular program. The entire purpose of the modernization grant is to modernize biomedical research facilities. A modernization grant cannot support the conduct of any research.
Modified Total Direct Cost (MTDC)	All direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.
Modular application	A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review of the application, award, and post-award administration.
Monitoring	A process whereby the programmatic and business management performance aspects of a grant are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources.
Name change	An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.

Term	Definition
New Investigator	A PD/PI who has not previously competed successfully as a PD/PI for a substantial independent research award is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. A complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://-grants.nih.gov/grants/new_investigators/#definition. See also the definition of Early Stage Investigator.
No-cost extension	An extension of time to a project period and/or budget period to complete the work of the grant under that period, without additional Federal funds or competition. See NIH Standard Terms of Award and Prior Approval Requirements.
Non-competing continuation application/award	A financial assistance request (in the form of an application or progress report) or resulting award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants.
Non-Federal entity	A state, local government, Indian tribe, institution of higher education (IHE), or non-profit organization that carries out a Federal award as a recipient or subrecipient.
Non-Federal share	When cost sharing or matching is required as a condition of an award, the portion of allowable project/program costs not borne by the Federal government.
Non-profit organization	Any corporation, trust, association, cooperative, or other organization, not including IHEs, that: (1) Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; (2) Is not organized primarily for profit; and (3) Uses net proceeds to maintain, improve, or expand the operations of the organization.
Notice of Award	The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: 1. notifies the recipient of the award of a grant; 2. contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and, 3. provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.
Obligations	When used in connection with a non- Federal entity's utilization of funds under a Federal award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non- Federal entity during the same or a future period.
Office of Management and Budget (OMB)	The Executive Office of the President, Office of Management and Budget.

Term	Definition
OMB Circulars	Government-wide guidance issued to Heads of Federal agencies by the Director of OMB. OMB Circulars directly pertinent to grants include the following: • cost principles (OMB Circular A-21, OMB Circular A-87, and OMB Circular A-122). See Cost Considerations—The Cost Principles for additional information; • uniform administrative requirements (OMB Circular A-102 and OMB Circular A-110); • audit requirements for non-profit organizations (OMB Circular A-133). See Monitoring—Audit for additional information. These Circulars were superseded by OMB's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("Uniform Guidance") and were implemented in HHS regulation at 45 CFR Part 75.
Organization	A generic term used to refer to an Institution of Higher Education or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.
Other Significant Contributors	Individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition.
Other support	Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.
Oversight agency for audit	The Federal awarding agency that provides the predominant amount of funding directly to a non-Federal entity not assigned a cognizant agency for audit. When there is no direct funding, the Federal awarding agency which is the predominant source of pass-through funding must assume the oversight responsibilities. The duties of the oversight agency for audit and the process for any reassignments are described in 45 CFR 75.513(b).
Parent announcement	NIH-wide FOA enabling applicants to electronically submit an investigator-initiated grant application for a specific activity code, e.g., Research Project Grant (Parent R01).
Participant support costs	Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects. For the purposes of Kirschstein-NRSA programs, this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travel in accordance with NRSA Regulations.
Pass-through entity	A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.

Term	Definition
Payback	Requirement that the recipient of a NRSA postdoctoral fellowship engage in qualified research or teaching activities for a length of time equal to the period of NRSA support received. Only the first year of training incurs a payback obligation. In general, payback activity must involve at least 20 hours per week and be conducted over 12 consecutive months; special exceptions may be considered on a case-by-case basis. See Ruth L. Kirschstein National Research Service Awards—Payback for additional information.
Payment Management System	The HHS centralized grants payment system operated by the Payment Management Service, Program Support Center. Most HHS (and some other Federal government agencies') recipients receive grant payments through this system.
Peer review	The process that involves the consistent application of standards and procedures that produce fair, equitable, and objective examinations of applications based on an evaluation of scientific or technical merit or other relevant aspects of the application. The review is performed by experts (Peer Reviewers) in the field of endeavor for which support is requested. Peer review is intended to provide guidance and recommendations to the NIH individuals responsible for making award decisions.
Period of performance	The time during which the non-Federal entity may incur new obligations to carry out the work authorized under the Federal award. The Federal awarding agency or pass-through entity must include start and end dates of the period of performance in the Federal award.
Person months	The metric for expressing the effort (amount of time) PD/PI(s), faculty and other senior/key personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year, academic year, and/or summer term; and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.
Personal property	Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.
Personally Identifiable Information (PII)	Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public Web sites, and university listings. This type of information is considered to be Public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.

Term	Definition
Phase III clinical trial	As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See also clinical trial definition).
Pre-award costs	Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk, for otherwise allowable costs.
Prior approval	Written approval by an authorized HHS official, e.g., a designated IC GMO, evidencing prior consent before a recipient undertakes certain activities or incurs specific costs (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).
Profit	See definition for fee.
Program	A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs that carry out their missions through the award of grants or cooperative agreements to other organizations.
Program Director/Principal Investigator	The individual(s) designated by the applicant organization/recipient to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the official (s) at the applicant organization/recipient, or as appropriate, to a collaborating organization for the proper conduct of the project, program, or activity including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.

Term	Definition
Program income	Gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance except as provided in 45 CFR 75.307(f). (See Period of performance.) Program income includes but is not limited to income from fees for services performed, the use or rental or real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 CFR 75.307, 45 CFR 75.407 and 35 USC §§ 200-212 (applies to inventions made under Federal awards). (See Administrative Requirements—Management Systems and Procedures—Program Income).
Program Official/Program Officer/Project Officer	The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.
Progress report	Periodic, usually annual, report submitted by the recipient and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report. This report may also be called the non-competing continuation progress report.
Project period	The total time for which Federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions.
Project/performance site	Location(s) of where the work described in the research plan will be conducted.
Property	Real property or personal property.
Protected Personally Identifiable Information (Protected PII)	An individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. (See also Personally Identifiable Information (PII)).

Term	Definition
Questioned cost	A cost that is questioned by the auditor because of an audit finding: 1. Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a Federal award, including for funds used to match Federal funds; 2. Where the costs, at the time of the audit, are not supported by adequate documentation; or 3. Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.
Real property	Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.
Recipient	An entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency to carry out an activity under a Federal program. The term may also include an Individual. The term recipient does not include subrecipients, except as indicated below. See also Non-Federal entity.
Renewal application	An application requesting additional funding for a period subsequent to that provided by a current award. Renewal applications compete for funds with all other peer reviewed applications, and must be developed as fully as though the applicant is applying for the first time. The previous NIH term was “competing continuation.”
Research & Development (R&D)	All research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. ‘‘Research’’ is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. ‘‘Development’’ is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.
Research Administrator	The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. See also Roles and Responsibilities—Recipient Staff.
Research misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. 1. Fabrication is making up data or results and recording or reporting them. 2. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. 3. Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. 4. Research misconduct does not include honest error or honest differences of opinion.

Term	Definition
Research patient care costs	Costs of routine and ancillary services provided by hospitals to participants in research protocols.
Responsible party	Responsible party is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to refer to the entity or individual who is responsible under FDAAA for registering a clinical trial and submitting clinical trial information to ClinicalTrials.gov.
Resubmission application	An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. Applicants must make significant changes to the application and can only resubmit once the summary statement is available. Applicants must apply and undergo peer review. Additional policies on resubmissions can be found in the applicable Application Instruction Guide. The previous NIH term was "revision." A resubmission has a suffix in its application identification number, e.g., A1.
Revision application	As defined in the Federalwide SF424 (R&R): An application that proposes a change in 1) the Federal Government's financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. Note in general for NIH applicants, #2 would not require the submission of another application. NIH recipients use revision applications to request an increase in support in a current budget period for expansion of the project's approved scope or research protocol. Applicants must apply and undergo peer review. The previous NIH term was "competing supplemental." NOTE: The former NIH term "revision," is now "resubmission". A revision has a suffix in its application identification number; e.g., S1.
Scientific Review Group (SRG)	A peer review committee group of primarily non-government experts (peer reviewers), qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications. No more than one-fourth of the members of any SRG may be Federal employees, as noted in 42 CFR 52(h).
Scientific Review Officer (SRO)	The NIH official who serves as the designated Federal official having legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the SRG and the determinations and management of conflicts of interest, as noted in 42 CFR 52(h).
Scope of work	The aims, objectives, and purposes of a grant; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant's objectives. This includes the research or training plan included with the original grant application, along with any approved modifications.

Term	Definition
Senior/Key Personnel	The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel.
Significant rebudgeting	A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.
Simplified acquisition threshold	The dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items costing less than the simplified acquisition threshold. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1 and in accordance with 41 USC § 1908. (See also Micro-purchase.)
Small business concern	A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR 121.
Special purpose equipment	Equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers. See also Equipment and General purpose equipment.
State	Any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments.
State government	The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments generally are considered State governments. State institutions of higher education and State hospitals are not considered State governments for HHS's general administrative requirements for grants and the NIHGPS.

Term	Definition
Stipend	A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.
Subrecipient	A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants.
Successor-in-interest	Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
Supplies	All tangible personal property other than those described in Equipment. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or $5,000, regardless of the length of its useful life. See Computing devices and Equipment.
Suspension of award activities	An action by the NIH awarding IC requiring the recipient to cease all activities on the award pending corrective action by the recipient. It is a separate action from suspension under HHS regulations (2 CFR 376) implementing Executive Orders 12549 and 12689. (See Public Policy Requirements and Objectives—Debarment and Suspension and Administrative Requirements—Enforcement Actions).
Termination	The ending of a Federal award, in whole or in part at any time prior to the planned end of period of performance.
Terms and conditions of award	All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The NoA may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal government's interests.
Third-party in-kind contributions	The value of non-cash contributions (i.e., property or services) that: (1) Benefit a federally assisted project or program; and (2) Are contributed by non-Federal third parties, without charge, to a non- Federal entity under a Federal award.

Term	Definition
Total costs	The total allowable costs (both direct costs and F&A costs) incurred by the recipient to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the recipient to satisfy a matching or cost-sharing requirement.
United States	The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.
Unliquidated obligations	For financial reports prepared on a cash basis, obligations incurred by the non-Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-Federal entity for which an expenditure has not been recorded.
Unobligated balance	The amount of funds authorized under a Federal award that the non-Federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-Federal entity's unliquidated obligations and expenditures of funds under the Federal award from the cumulative amount of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate.
Withholding of support	A decision by NIH not to make a non-competing continuation award within the current competitive segment.

2 THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION

NIH is the steward of medical and behavioral research for the Nation. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH operates under the general policy guidance of the Department in carrying out its mission, which is accomplished through the conduct and support of biomedical and behavioral research, research training, research infrastructure, and communications. These efforts take place intramurally (primarily at NIH) and extramurally (through grants, cooperative agreements, and contracts awarded to institutions of higher education, governmental organizations, non-profit research organizations, for-profit organizations, and individuals). NIH also works closely with other HHS components and other Federal departments and agencies. HHS components include SAMHSA, FDA, CDC, IHS, AHRQ, HRSA, ACF, ACL, OASH, and CMS, among others.

HHS develops, issues, and maintains regulations that govern the Department's grants process. Among these are the regulations that implement the OMB Circular A-102 common rule, applicable to grants to State, local, and Indian tribes (or "federally recognized Indian tribes"), and OMB Circular A-110 (relocated to 2 CFR 215), applicable to grants to institutions of higher education, hospitals, and other non-profit organizations. These regulations are codified at 45 CFR 75 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards). Although the government-wide requirements do not cover grants to for-profit organizations, HHS has included them in the coverage of 45 CFR 75. The above regulations provide the framework for the terms and conditions of NIH awards as specified in Part II.

NIH is organized into ICs, which have their own mission and functions, separate appropriations, and statutory authorities. The ICs that award grants and their points of contact are listed in Part III. Although the ICs operate under the same general grant process and requirements, applicants and recipients need to be aware of differences that may exist. This information may be obtained from NIH IC staff. The policies and procedures generally applicable to NIH grants are set forth in the NIHGPS.

2.1 ROLES AND RESPONSIBILITIES

NIH, as a Federal grantor agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for recipient organizations.

The following subsections highlight the major functions and areas of responsibility of Federal and recipient staffs. NIH recognizes that additional staff members in a number of different organizations may be involved in grant-related activities; however, this section details only the major participants representing the Federal government and the recipient. The responsibilities of CSR staff members, who are involved only in the initial review phase of the peer review process, are described in The Peer Review Process—Initial Review—Responsibilities. The responsibilities of other offices, such as OHRP, are described in Part II as applicable.

2.1.1 NIH and HHS Staff

The roles and responsibilities of NIH and HHS participants are as follows:

- ***Grants Management Officer.*** The GMO whose name appears in the NoA is the NIH official responsible for the business management and other non-programmatic aspects of the award. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to applicants and recipients, including interpretation of grants administration policies and provisions; and administering and closing out grants. The GMO works closely with his or her counterparts in other NIH ICs and with the designated PO. The GMO is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of award. A Chief Grants Management Officer is the principal GMO who provides leadership to an organizational component that is responsible for the business and fiscal management of the ICs grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO.
- ***Grants Management Specialist.*** The GMS whose name appears in the NoA is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of grants.
- ***Program Official.*** The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC SROs; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the GMO. The PO and the GMO work as a team on many of these activities.
- ***Scientific Review Officer.*** SROs are health science administrators who manage the activities of SRGs, including CSR study sections. For the SRG for which he or she is responsible, the SRO reviews applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, and serves as the overall point of contact with applicants during the initial phase of the peer review process, i.e., until the conclusion of the SRG meeting.
- ***Other NIH, HHS and Federal Agency Staff.*** In addition to the GMO and PO, the recipient may be required to interact with other NIH or HHS staff members or offices with respect to its organization-wide systems and/or individual transactions. These include the office responsible for negotiating F&A costs and research patient care rates, typically the cognizant DCA office, ONR, or DFAS; OIG; OHRP; ORI; OLAW; and OPERA. Staff members in these offices generally coordinate with the GMO, but they are responsible for discrete areas of specialization and are not required to channel their communications with the recipient through the GMO. Part III includes a list of these organizations and their addresses and telephone numbers. ONR is the cognizant agency for negotiation of F&A costs for some NIH recipients.

2.1.2 Recipient Staff

Overall responsibility for successfully implementing an NIH grant is a shared responsibility of the PD/PI (s), the AOR, and the Research Administrator. As key members of the grant team, they respectively lead the scientific and administrative aspects of the grant. While communications can be conducted with Research Administrators and other institutional staff, NIH staff members conduct official business only with the designated PD/PI(s) and AORs. The roles and responsibilities of recipient participants are as follows:

- ***Authorized Organization Representative***. The AOR is the designated representative of the recipient organization in matters related to the award and administration of its NIH grants, including those that require NIH approval. The AOR should ascertain and assure that the materials the applicant organization are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used by other individuals in the preparation and submission of a similar grant application. In signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the grant application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application. (Also see Legal Implications of Applications.) This individual also is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards. For applications submitted electronically through Grants.gov, the signature of the AOR is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the Signing Official role. Although NIH requires that the recipient organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this official.
- ***Program Director/Principal Investigator.*** A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award. The applicant organization may designate multiple individuals as PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the recipient organization or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one identified PD/PI on an application diminishes neither the responsibility nor the accountability of any individual PD/PI.

  When a single PD/PI is designated, that individual is not required to be an employee of the applicant organization. However, because the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the PD/PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PD/PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

  When multiple PD/PIs are designated, NIH requires identification of one PD/PI who will be designated as the Contact PD/PI. This person is responsible for communication between the PD/PIs and the NIH. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. They are not required to be an employee of the applicant organization. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. This same principle applies to all PD/PIs at the applicant organization; e.g., they need not be employees; however the applicant organization must have a formal written agreement in place.

  When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but

need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role.

PD/PIs are members of the recipient team responsible for ensuring compliance with the financial and administrative aspects of the award. They work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. NIH encourages PD/PIs to maintain contact with the NIH PO with respect to the scientific aspects of the project and the GMO/GMS concerning the business and administrative aspects of the award. The NIH staff contacts list located at http://grants.nih.gov/grants/staff_list_grants_admin.htm#ics includes contact information for NIH grants management and program staff at each IC.

- ***Research Administrator***. The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. Depending on the structure of the organization, this individual can be located centrally or within an organizational component such as a Department.

2.2 ERA COMMONS

eRA Commons is an online interface where grant applicants, recipients and Federal staff at NIH and grantor agencies are able to conduct their research administration business electronically as well as access and share administrative information relating to research grants. While applicants use Grants.gov to find and apply for grants; the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and then makes it available to applicants and NIH staff for electronic research administration purposes.

Access to the eRA Commons is vital for all steps in the NIH grant administration process. Following application submission, the eRA Commons becomes the primary site for accessing grant information such as Institute/Center assignments, review outcomes, Summary Statements, and Notices of Award. The eRA Commons also provides electronic business processes such as Internet Assisted Review, submission of Just-In-Time material, submission of electronic SNAP progress reports (eSNAP), submission of Financial Reports (FSRs/FFRs), submission of notification of extensions without funds, and submission of Closeout documents. Appropriate user roles are assigned to registered individuals depending on the responsibilities assigned to them by the recipient organization.

2.2.1 eRA Commons Registration

An organization and PD/PI(s) must complete a **one-time** registration in the Commons. Institutional/organizational officials are responsible for registering PD/PI(s) in the eRA Commons. PD/PI(s) should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: Organizations registering in the eRA Commons for the first time should allow 2-4 weeks to complete the registration process.

2.2.1.1 eRA Commons Registration for the Organization

Prospective applicant organizations should also see Legal Implications of Applications before beginning the eRA Commons registration process.

Organizations may verify their current registration status by accessing the "List of Recipient Organizations Registered in eRA Commons" at https://public.era.nih.gov/chl/public/search/commonsRegisteredOrgs.era. This listing can be accessed without logging into the Commons. The list includes organization name and location, the NIH-assigned IPF Code, and any DUNS number that has been stored in the institutional profile for that organization.

To register an Organization in the eRA Commons an AOR should follow the procedures found on the eRA Commons homepage at https://commons.era.nih.gov/commons/ under the link "Register Grantee Organization."

Once an organization is registered, information in the Institutional Profile can be maintained through the Commons.

During this registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH may deny registration if an organization is determined ineligible. Note, acceptance of an organization's registration in the Commons does not mean an organization is an acceptable recipient for a particular program. That assessment will be made by the NIH awarding component prior as part of the pre-award process. See Determining Applicant Organization Eligibility for additional information.

Foundations that represent already existing recipient organizations, or a newly formed consortium where the consortium members are already individually recognized as NIH recipient organizations present unique and complex situations and should contact DGP, OPERA before attempting to separately register as a new applicant organization.

2.2.1.2 eRA Commons Registration for the PD/PI

The individual(s) designated as the PD/PI(s) on the application must also be registered in the Commons. The PD/PI(s) must hold a PD/PI eRA Commons role **and** be affiliated with the applicant organization. **The initial registration must be done by an AOR who has the SO role in the Commons or other authorized accounts administrators at the organization**. However, after the initial registration process is complete, it becomes the responsibility of each individual to maintain the information in his/her personal profile.

Designating the PD/PI role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., summary statements, scores, electronic submission status, etc.). The PD/PI role within the eRA Commons is necessary to complete the grant application process, to view the impact score and summary statement, and if an award is made, to complete required post-award actions such as submission of a progress report. The PD/PI may delegate certain authorities to other individuals.

Users should only have one PD/PI eRA Commons account. If the PD/PI has already been registered in eRA Commons by an organization other than the organization submitting an application, a separate eRA Commons registration with the submitting organization is not necessary. However, the submitting organization must take steps to affiliate the individual with that organization so that the individual can view and access data records for those applications.

For more information on the features of the eRA Commons, including links to resources such as user guides and frequently asked questions, see the eRA Commons webpage at: http://era.nih.gov/commons/index.cfm.

2.2.1.3 eRA Commons Registration for Other Individuals Participating in NIH Progress Reports

Any individual with an Undergraduate, Graduate Student, and/or Postdoctoral Role who participates in a NIH-funded project for at least one person month or more should also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. This is required regardless of whether salary is actually charged to the project. For graduate students supported on a particular research grant, this could include project roles of graduate research assistant or graduate student. For postdoctoral individuals supported on a particular research grant, this could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

When an individual is assigned the Undergraduate, Graduate Student, or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482. The Commons user name ID for those with an Undergraduate, Graduate Student, or Postdoctoral Role is not required at the time of application submission, but will be required as part of the Research Performance Progress Report (RPPR).

For individuals at the postdoctoral level, this requirement is already in effect and progress reports will not be accepted if the Commons ID is not provided. For individuals at the undergraduate and graduate student levels, a Commons ID is required with RPPRs. The Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

2.3 APPLICATION INFORMATION AND PROCESSES

This section provides an overview of NIH's grant support mechanisms, types of entities eligible to receive grants, types of applications, types of funding opportunities, legal implications of applications, policies affecting application preparation and submission, application forms, application receipt information and deadlines, fraud, waste and abuse of NIH grant funds, and availability and confidentiality of application information.

2.3.1 Support Mechanisms

NIH ICs award grants under multiple programs and subprogram initiatives and use a variety of support mechanisms. NIH grants may be distinguished by purpose, type of recipient, amount, or other characteristics. One method NIH uses to differentiate the various support mechanisms is activity coding that indicates the category and specific form of support (e.g., R01, F32, P01, R43). The applicability of requirements may vary for different activity codes. Some of the distinctions also are significant for purposes of applying Part II. NIH ICs may vary in the way they use specific activity codes; not all ICs accept applications for all types of grant programs and may apply specialized eligibility criteria. A comprehensive list of activity codes is available at http://grants.nih.gov/grants/funding/ac_search_results.htm.

2.3.2 Eligibility

In general, NIH grants may be awarded to organizations that are domestic or foreign, public or private, or non-profit or for-profit. Eligible organizations include governments, including Federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, in rare occasions, individuals (see Completing the Pre-Award Process—Determining Applicant Organization Eligibility). Any special criteria for applicant eligibility or requirements concerning the qualifications of the PD/PI or other staff or participants will be specified in the FOA, program guidelines, or other publicly available documents. Part IIB includes information on fellow and trainee eligibility.

2.3.3 Types of Award Instruments

NIH uses several different extramural award instruments in support of its mission. NIH grants and cooperative agreements are financial assistance instruments. Under a cooperative agreement, NIH expects to be substantially involved in carrying out the project. Grants are used both for investigator-initiated research and for more targeted research. Cooperative agreements generally do not result from investigator-initiated applications. The NIHGPS pertains to grants and cooperative agreements; however, NIH may apply terms and conditions that differ from those in the NIHGPS consistent with the nature of its involvement under cooperative agreements.

2.3.4 Types of Applications

In the NIH grants process, five types of applications are used most frequently. The first four application types described below are considered "competing" because, through the peer review process, the application must compete for available funding with other applications.

- ***New Application (Type 1).*** A request for financial assistance for a project or activity that is not currently receiving NIH support and must compete for support. A new application is being submitted for the first time.
- ***Renewal (Type 2).*** A request for additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be fully developed as though the applicant is applying for the first time.
- ***Revision (Type 3).*** A request for an increase in support in a current budget period for expansion of the project's approved scope or research protocol. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. Applications for revisions are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A revision application should not be submitted until after the original application has been awarded and may not extend beyond the term of the current award period. A revision application must have the same title as the currently funded grant. (A Type 3 prefix also refers to a request/award for a non-competing administrative supplement [see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Need for Additional NIH Funding without Extension of Budget and Project Period.]).
- ***Resubmission.*** An unfunded application that the applicant has modified following initial review and resubmitted for new consideration. Before a resubmission application can be submitted, the PD/PI must have received the summary statement from the previous review. A resubmission application may be submitted for any of the three preceding types of applications. See Application Information and Processes—Policies Affecting Applications for other policies affecting Resubmissions. NIH allows only one resubmission application.

- ***Non-Competing Continuation Progress Report (Type 5).*** A non-competing progress report is required to continue support of a PHS grant for the second or subsequent budget period within an approved competitive segment (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

In addition to the list above, NIH periodically uses a pre-application (also known as a "white paper" or "précis") to facilitate certain approaches or economies, such as reducing burden on the applicant community, for a funding opportunity. Pre-applications are generally used in combination with a competing application in a 2-phase process. Pre-applications do not result in an award; the end result is the opportunity to submit to the subsequent phase of a particular program. Successful applicants to the pre-application phase are notified of the opportunity to submit to the subsequent phase. In addition to the pre-application, NIH may use an application process for prospective applicants to request access to an NIH research resource. This process also does not result in an award; the end result is permission to access a resource. NIH uses the numbers shown in parentheses as prefixes to distinguish the application types and any resulting awards (e.g., 5R0198765-02 is a non-competing continuation progress report).

2.3.5 Types of Funding Opportunity Announcements (FOAs)

The majority of applications submitted to NIH under the categories of research and research training (including fellowships) are investigator-initiated. NIH accepts applications on the application due dates noted on the submission schedule. NIH generally reviews applications in three review cycles per year; however any variations in schedule will be noted in the FOA. Some ICs review applications for Institutional National Research Service Awards (T32) only once a year; such information is generally found in a particular FOA. The schedules for submission, review, and award of investigator-initiated applications are available at http://grants.nih.gov/grants/funding/submissionschedule.htm.

Funding Opportunity Announcement (FOA). A FOA is a publicly available document in which a Federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. FOAs may be program announcements, requests for applications, notices of funding availability, solicitations, or other identifiers depending upon the agency and type of program. All applications must be submitted in response to a FOA regardless if the submission is electronically or on paper. FOAs include information to allow prospective applicants to determine whether to apply.

NIH FOAs primarily fall into the categories of Program Announcements, Request for Applications and Parent Announcements. While individual announcements will continue to carry an announcement number reference to PA or RFA, all announcements are FOAs. This general term is used to reference any type of funding announcement. NIH uses the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

- ***Program Announcement (PA).*** A PA is a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time using standard peer review processes. NIH may also make funds available through PARs (PAs with special receipt, referral, and/or review considerations) and PASs (PAs with set-aside funds).

  PAs may be used for any support mechanism other than construction awards. Unless otherwise specified in the PA, new applications (and associated renewal and revision applications) submitted in response to PAs are treated as investigator-initiated. PAs also are used to annually soli-

cit applications for the SBIR and STTR programs. Those applications must be received by the dates specified in the PA.

- ***Request for Applications (RFA).*** An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and awardees as well as joint responsibilities and obligations. Applications submitted in response to an RFA are usually reviewed by an SRG specially convened by the awarding component that issued the RFA.
- ***Parent Announcements.*** Electronic submission of applications requires that applications must be associated with a specific FOA. Therefore, NIH omnibus parent announcements are provided for applicants to submit investigator-initiated (unsolicited) applications. Responding to such an omnibus or umbrella parent FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. This process in no way diminishes the interest of NIH ICs in investigator-initiated, unsolicited research grant applications. Parent announcements are NIH-wide, but some ICs may limit their participation; therefore prospective applicants should check the announcement to determine IC participation. For institute-specific opportunities in a particular area of science, search the *NIH Guide for Grants and Contracts*.

All applications involving one or more clinical trials must be submitted through a FOA specifically designed for clinical trials. NIH will no longer accept clinical trial applications through "parent" FOAs or through other FOAs that are not specifically designed to accept clinical trials. This policy will apply to all applications involving one or more clinical trials, including applications that involve a combination of studies that are clinical trials as well as studies that are not. These latter "hybrid" FOAs include applications that will involve a combination of trial and non-trial aims. These and other types of trial applications will also be submitted to clinical trial-specific FOAs if the combination of studies involve a NIH defined clinical trial.

All NIH FOAs are published in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/index.html) and on Grants.gov under Find Grant Opportunities (https://grants.nih.gov/funding/index.htm). NIH may develop areas of high priority or special research interest and use a special announcement to stimulate submission of applications in those areas. These announcements are also published as FOAs in the *NIH Guide for Grants and Contracts*.

2.3.6 Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates in order to be considered for support. The signature of an AOR on the application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application, including the F&A cost (indirect cost) rate. The AOR's signature further certifies that the applicant organization has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

Applicants for and recipients of NIH grant funds, whether such funds are received through a grant, indirectly under a contract or consortium agreement, or by a fiscal agent acting on another organization's behalf, or as student assistance under a training grant, are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulations to grant funds should be directed to the IRS. The applicant also is expected to be in compliance with applicable State and local laws and ordinances.

Applicants may be required to provide proof of organizational eligibility (such as proof of non-profit status), trainee or fellow eligibility and citizenship, or other eligibility information. Applications also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy requirements. The more significant of the public policy requirements for the purpose of peer review are those concerning research involving human subjects; inclusion of both genders, members of minority groups, and children in clinical research; and research involving live vertebrate animals. Part II details public policy requirements and cost and administrative policies.

There are times when an institution desires to use a Foundation or other similar organization to provide administrative services for NIH grants. These situations are often complex and each situation is unique when determining which organization is the appropriate applicant institution. Foundations, particularly those associated with institutions already recognized as NIH recipient organizations, should contact DGP, OPERA before attempting to separately register as an applicant organization.

Similarly, when new consortiums are formed where the consortium members are already separately recognized as NIH recipient organizations, DGP, OPERA should be contacted before attempting to separately register as a new applicant organization.

2.3.7 Policies Affecting Applications

Application information to be submitted typically includes a project description, budget and budget justification, biographical sketches of senior/key personnel, and other information specified in the application instructions, in the announcement, and/or in program guidelines, if any. Applicants should consult the cost principles and general administrative requirements for grants pertaining to their organizational type in order to prepare the budget and complete other parts of the application. This section describes NIH policies that affect application preparation and/or submission. Specific details on application content are addressed in application instructions and specific FOAs. Any significant change to the application post-submission must be reported immediately to the appropriate NIH official.

2.3.7.1 Applications That Include Consortium/Contractual F&A Costs

For FOAs that include a direct cost limit, NIH policy excludes consortium/contractual F&A when determining if an applicant is in compliance with the direct cost limitation. This policy extends to all solicited and investigator-initiated applications and to all active announcements (Request for Applications and Program Announcements), involving consortium/contractual F&A costs, regardless of budget amount or budget format (e.g., modular and non-modular). While consortium F&A costs may be requested and awarded, applicants should not consider these costs when determining if a budget exceeds a direct cost limit.

This policy impacts eligibility to submit a modular budget. The modular budget format is used for applications requesting $250,000 or less in direct costs per year. Consortium/contractual F&A costs are not factored into this direct cost limit; however, they may be requested in addition to the $250,000.

This policy also impacts applications requesting a budget of $500,000 direct costs or more for any year. These applications require prior approval from Institute/Center staff; however, the limit is exclusive of any consortium F&A costs. It does not affect any specific FOA that includes a total cost limit.

This policy does not affect the SBIR and STTR programs since the statutory budget guidelines are based on total costs, not direct costs. It also does not affect any specific Funding Opportunity Announcement that has a Total Cost limit.

2.3.7.2 Acceptance for Review of Unsolicited Applications Requesting $500,000 or More in Direct Costs

Any applicant requesting $500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period is required to contact the IC PO, in writing or by telephone, as early as possible during development of the application but no later than 6 weeks before submission for prior approval. This requirement applies to a single grant application, whether a new, renewal, revision, or resubmission application, under any NIH support mechanism; it also applies to a group of applications, such as those for clinical trial networks, meeting the $500,000 threshold in the aggregate even if no single application in the group requests that much.

This policy does not apply to applications submitted in response to RFAs or to other announcements that include specific budgetary limits. However, any such application must be responsive to budgetary limits specified or NIH will administratively withdraw the application and it will not be reviewed or considered for funding.

Applicants must seek agreement from IC staff at least six weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year (excluding consortium F&A costs). If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier.

The PD/PI must include a cover letter with the application identifying the PO contacted and the IC that has agreed to accept assignment of the application. CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits with its application a letter to that effect with the name of the authorizing program staff member and IC affiliation (see The Peer Review Process). An application subject to this policy that does not include the required information in the cover letter will be administratively withdrawn and will not be reviewed or considered for funding.

2.3.7.3 Resubmission of Unfunded RFA Applications

This policy applies to all activity codes that might be solicited via an RFA and to instances where there is a change in activity code. Unless a particular FOA states that resubmissions from an RFA may be submitted, unfunded applications should be submitted as **new** applications if the grant applications fall into the following categories:

1. Applications that were originally submitted in response to an RFA and now submitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently submitted in response to an RFA.
3. Applications that were originally submitted using one grant activity code and subsequently submitted using a different grant activity code (for example, an application that was originally an R01 and is now submitted as an R21).

The new application must be submitted on the scheduled due dates for new applications and follow all instructions that apply to new applications. Do not include an Introduction describing the changes and improvements made; do not mark text to indicate the changes; and do not explicitly address reviewers' comments. In these cases the reviewers will not be provided with the previous summary statement.

2.3.7.4 Submission of Resubmission Application

NIH will accept a new (A0) application following an unsuccessful resubmission (A1) application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review. NIH's policy for accepting overlapping applications remains in effect: NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not review:

1. a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping resubmission (A1) application.
2. a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
3. an application that has substantial overlap with another application pending appeal of initial peer review (see Section 2.3.9.4 below)

NIH policy allows a thirty-seven month window for one resubmission (A1) following the submission of a new, renewal, or revision application (A0 application). The initial submission of a new, renewal or revision application constitutes the starting point for the thirty-seven month policy. After thirty-seven months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the thirty-seven month time period.

Submission to a different FOA under review at the same time is not sufficient to make an application new. (There are exceptions for applications following an RFA or changing activity code. See Resubmission of Unfunded RFA Applications above). The new application must be submitted on the scheduled due dates for new applications (see http://grants.nih.gov/grants/funding/submissionschedule.htm). It must not include an Introduction describing the changes and improvements made; and the text must not be marked to indicate the changes.

2.3.7.5 New Investigators and Early Stage Investigators

The NIH is committed to identifying and attracting new biomedical researchers and will continue to explore novel ways to encourage early transition to independence. NIH has implemented a number of policies specific to New Investigators, and in particular the category of New Investigator called Early Stage Investigator.

New Investigator. In general, a PD/PI is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a substantial independent research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. See definitions section for additional information and references.

Early Stage Investigator (ESI). An ESI is a New Investigator who is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent). Extensions of the end of ESI eligibility date may be requested following the procedures documented on the New Investigator Web site.

The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new applications. ESIs should comprise a majority of the New Investigators supported. Where possible, New Investigator applications will be clustered during review. The applications will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.

NIH New Investigator policies are limited to applications for traditional research project grant (R01) support. Accordingly, the NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding. To determine New Investigator and Early Stage Investigator status, NIH relies on the data entered by the individual in their eRA Commons Profile, therefore it is important that PD/PIs verify the accuracy of their personal profiles. Particularly key for ESIs are the terminal research degree and end date of residency data fields. ESI status and end of eligibility date also appear in the Commons profile for the individual.

2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance

The applicant organization is required to secure and retain a unique signature and dated assurance from the PD/PI for each submitted application, prior to submitting an application to the NIH. This assurance must be available to the NIH or other authorized DHHS or Federal officials upon request. Such an assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; 2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and 3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. If multiple PIs are proposed in an application, this assurance must be retained for all named PIs.

For individual Fellowship applications, this assurance requirement applies to the individual fellow and the sponsor. Such an assurance must include at least the follow certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the Fellow's and Sponsor's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Fellow and Sponsor to criminal, civil, or administrative penalties; (3) that the Sponsor will provide appropriate training, adequate facilities, and supervision if a grant is awarded as a result of the application; (4) that the Fellow has read the Ruth L. Kirschstein National Research Service Award Payback and will abide by the Assurance if an award is made; and (5) that the award will not support residency training. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

2.3.7.7 Post-Submission Grant Application Materials

Post-submission of application materials is not required. Adding materials to reviewer workload may be counterproductive, so applicants should carefully consider the need to send post-submission materials. For materials that are submitted after the initial grant application submission but prior to initial peer review, NIH will only accept such materials resulting from unforeseen administrative issues. This policy does not modify the Just-in-Time requirements or any other requests for additional information after the initial peer review.

For all research and research-related applications, individual fellowship, and individual career development awards, acceptable materials include:

- Revised budget page(s) (e.g., change in budget request due to a new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator)

- Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (e.g., PD/PI moved to another university)
- News of an article accepted for publication (a copy of the article should not be sent; submit only the following: authors, institutional affiliations, title of the article, the journal that accepted it, and the expected time of publication)
- News of a professional promotion or positive tenure decision for any PD/PI and Senior/Key Personnel
- News of a trainee's or former trainee's graduation, employment, promotion, funding, publication or other professional achievement since the training grant was submitted
- News of a faculty members promotion, funding, publication, or other professional achievement since the training grant was submitted
- News of an additional faculty member who will be involved in the training activity.

All post-submission materials must conform to NIH policy on font size, margins, and paper size as referenced in the applicable application instructions. Any material using established forms/format pages (e.g. budget pages, biographical sketches) must follow standards for those pages. If post-submission material is not on a required form/format page, each explanation or letter is limited to one page. If the application has subprojects or cores, each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page. See Non-traditional Application Materials below for further information on video.

Unacceptable post-submission materials include:

- Updated Specific Aims or Research Strategy pages
- Late-breaking research findings
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator

Exceptions to this policy include:

- Applications submitted in response to an RFA that has only one due date or the last due date when multiple due dates are available. Updated Specific Aims or Research Strategy pages, late-breaking research findings and new letters of support or collaboration will be allowed. If additional material is not required on a form/format page, post-submission materials for these applications are dependent on the number of pages of the Research Strategy section:
    - When the Research Strategy is fewer than 12 pages, additional materials are limited to one printed page.
    - When the Research Strategy is limited to 12 pages, additional materials are limited to two printed pages.
    - When the Research Strategy is greater than 12 pages, additional materials are limited to three printed pages.
    - When the application has subprojects or cores, additional materials follow the page limit of the Research Strategy of each subproject or core as indicated above.
- Certain FOAs may allow specific other types of post-submission materials to facilitate the goals of the program. Such stipulations will be explained in the FOA.

For institutional training and training-related applications, including institutional Career Development Awards, up to three pages of post-submission materials will be allowed to present new information or data that was not available at the time of the application submission. Acceptable material includes:

- Updated information and data on the applicant pool, admissions, enrollment, appointments and/or achievements
- Updated faculty research support
- For training-related programs (e.g., R25) acceptable post-submission materials will be detailed in the FOA

For Kirschstein-NRSA Fellowship and non-NRSA International Fellowship applications, update to the Sponsor(s)' funding information in the originally submitted application is allowed as post-submission material.

Non-traditional Application Materials

NIH will accept only videos as non-traditional application materials. No devices or other media will be accepted unless specified in the Funding Opportunity Announcement (FOA). However, videos may include demonstrations of devices and other items as listed below. These guidelines may be superseded by instructions in specific FOAs.

The only acceptable content for videos is demonstrations of devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change.

- Examples of acceptable content include unusual interventions or surgical procedures, prototype model use, visualization of 3-D structures or structural changes in molecules or cells, software or database demonstrations, educational materials or video games.
- Examples of unacceptable content include virtual tours of laboratories, equipment in place, platform presentations, advertisements, commercials, or PowerPoint presentations [unless requested by the Scientific Review Officer (SRO) in lieu of a site visit].

Application requirements. The application must be structured at the time of submission to indicate that a video will be submitted subsequently. The cover letter submitted with the application must include information about the intent to submit a video; if this is not done, a video will not be accepted. Key images/"stills" and a brief description of each video must be included within the page limits of the research strategy. Sufficient descriptive information must be provided within the research strategy to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints.

When human subjects or personally identifiable information is represented in a video, the applicant organization is responsible for ensuring that human subjects have been consented and protected appropriately. Submission through the Authorized Organizational Representative (AOR) certifies acceptance of this responsibility.

Video formats. Multiple videos may be submitted per application but their aggregate length must not exceed 2 minutes for single-project applications and 5 minutes for multi-component applications.

Post-submission videos must be embedded in .pdf files with a maximum file size of 25 MB. This material can be submitted on CD/DVD or via e-mail and it will be uploaded to the grant folder by the SRO. Currently popular, cross-platform, video formats include mp4, mov, avi, flv, and wmv.

Closed captioning is not required when narration is present. However, captioning is recommended as an optional component of the video to assist reviewers evaluating the application.

Limitations. Video files containing unacceptable content or exceeding the time or size limits will not be accepted. Applications submitted with hyperlinks to videos or with videos embedded in the research strategy will be considered in violation of page limits and the application will be withdrawn before review.

Note: Due to technological constraints, the NIH cannot guarantee that reviewers will be able to view videos.

Video submission. If the submission requirements have been met (see above), videos will be accepted by the SRO managing the review. After the assignment of the application to a review group is visible in the eRA Commons, the applicant should contact the SRO for that review group to discuss logistics for submission of any videos.

As with all other post-submission materials, videos must be received by the SRO one month (30 calendar days) prior to the peer review meeting. Videos will not be accepted if fewer than 30 calendar days remain before the peer review meeting.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the video may originate from the Program Director/Principal Investigator (PD/PI), Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send his/her concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

The opportunity to submit additional materials should not be a means of circumventing submission deadlines, page limitations, or content requirements and should not substantially enhance, alter or add to the originally submitted application.

After the initial peer review phase is completed, the Chief GMO of the IC is the NIH official responsible for accepting additional materials. Most of the material submitted after peer review can be submitted as part of the Just-in-Time process.

Effective for applications submitted for the January 25, 2017 due date and thereafter, NIH is consolidating the policy concerning post-submission materials. The text above in subsection 2.3.7.7 is rescinded and replaced by the following:

Post-submission of application materials is not required. Adding materials to reviewer workload may be counterproductive, so applicants should carefully consider the need to send post-submission materials. For materials that are submitted after the initial grant application submission but prior to initial peer review, NIH will only accept such materials resulting from unforeseen administrative issues. This policy does not modify the Just-in-Time requirements or any other requests for additional information after the initial peer review.

Allowable Post-Submission Materials for All Applications

For all research and research-related applications, individual fellowship, and individual career development awards, acceptable materials include:

- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)

- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application (see NOT-OD-12-111)
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Applicants must follow the directions in NOT-OD-12-141 for submitting videos to accompany grant applications
- Other post-submission materials specified in the FOA for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application, which must include only:**
    - List of authors and institutional affiliations
    - Title of the article
    - Journal or citation (if available)

Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Funding Opportunity Announcement (FOA) for which the application was submitted or a special Guide Notice.

Additional Materials for Certain Applications

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news—since the training grant application was submitted—of:

- a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- a faculty member's promotion, funding, or publications; and
- the addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).

Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications: in addition to the materials for All Applications listed above:

- New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- News of change in Mentor(s) or other Senior/Key Persons specified in the original application.

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference Grant Applications (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Any other types of post-submission materials are not likely to be accepted.

Requirements for Submitting Post-Submission Materials

All post-submission materials must conform to NIH policies on font size, margins, and paper size as referenced in the applicable application instructions.

- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.
- If post-submission material is not required on a specific format page and does not have a specified page limit, each explanation or letter is limited to one page.
- If the application has multiple components (subprojects or cores), each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Post-submission materials must be received by the NIH Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted if fewer than 30 calendar days remain before the peer review meeting, unless specifically stated otherwise in the FOA for which the application was submitted or in a special Guide Notice.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or organizational officials, the AOR must send the materials directly to the SRO or must send his/her concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

Post-submission materials **can only** be submitted as a PDF attachment. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check his/her application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

2.3.7.8 DUNS Number and SAM Registration Requirements

All applicant organizations **must have** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual PD/PIs do not need to register for a DUNS.

Additionally, all applicant organizations must register in the System for Award Management (SAM) and maintain the registration with current information at all times during which it has an application under consideration for funding by NIH and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/portal/public/SAM/.

If an award is granted, the recipient organization must notify potential subrecipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

2.3.7.9 Graduate Student Compensation

The maximum amount NIH will award for the support of a graduate student on a research grant or a cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend in effect at the time the grant award is issued on the Federal award date. The schedule for NRSA stipends can be found at http://researchtraining.nih.gov. Consistent with cost principles for Institutions of Higher Education (IHEs) described in 45 CFR 75.431(j) and 75.466, the compensation of graduate students supported by research grants must be reasonable. These operating principles associated with the compensation of students performing necessary work on NIH funded research projects are described in detail in the *NIH Grants Policy Statement* at http://grants.nih.gov/grants/policy. The amount provided for compensation includes salary or wages, fringe benefits, and tuition remission.

These guidelines apply to graduate students at the recipient institution who are supported by NIH research grants and cooperative agreements and not to individuals supported by NRSA training grants and fellowships. NIH has separate appropriations to support research training under the NRSA authorization at Section 487 of the Public Health Service Act.

The stipends provided to recipients of NRSA support offset the cost-of-living during the period of training and are not considered equivalent to salaries or other forms of compensation provided to individuals supported on research grants. Nevertheless, the entry-level postdoctoral NRSA stipend provides a useful benchmark for an award amount that approximates a reasonable rate of compensation for graduate students. Expected future increases in NRSA stipends, to adjust for inflation, should permit annual increases in the maximum award for such individuals.

For all new and competing grant and cooperative agreement awards, the NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level. NIH staff will review the compensation requested for graduate students on competing and cooperative agreement applications for which a detailed budget is submitted. NIH will neither request nor accept budgets for those applications using a modular budget format solely for the purpose of reviewing graduate student compensation. However, applicants should use this policy when estimating the number of modules.

When submitting detailed budgets that request support for a graduate student, recipients are reminded to request actual institutional-based compensation and to provide information justifying the requested compensation level. If this information is not provided, NIH staff will obtain this information from the institution's business office for any request that appears excessive.

NIH Institutes and Centers will review the requested compensation level and, if considered reasonable, will award the actual amount requested, up to a maximum equal to the NRSA zero level postdoctoral stipend. Revised budgets submitted solely to adjust requested levels for graduate students will not be accepted.

Institutions may continue to rebudget funds to charge more than the awarded amount provided that OMB cost principles requiring reasonable compensation are observed. In general, graduate student compensation will not be considered reasonable if in excess of the amount paid to a first-year postdoctoral scientist at the same institution performing comparable work.

2.3.7.10 NIH Genomic Data Sharing

NIH Genomic Data Sharing (GDS) Policy expects that applicants preparing grant applications state in the cover letter when the studies proposed will generate large-scale human and/or non-human genomic data. Applications proposing such research are expected to include a genomic data sharing plan. Guidance on developing data sharing plans may be found here: http://gds.nih.gov/pdf/NIH_guidance_developing_GDS_plans.pdf.

Applicants who wish to use controlled-access human genomic data from NIH-designated data repositories as a secondary user, to achieve the specific aim(s) of the research proposed in the Research Plan of the application, should briefly address their plans for requesting access to the data, and state their intention to abide by the NIH Genomic Data User Code of Conduct. NIH acknowledges that data sharing is not always possible. Exceptions to the data sharing expectation may be requested in cases where the criteria in the Institutional Certification cannot be met.

2.3.8 Application Forms

Exhibit 3 lists the required application forms for competing applications, which vary by support mechanism. These forms and associated instructions are available on the OER forms page (http://grants.nih.gov/grants/forms.htm).

Exhibit 3. Required Forms for Competing Applications

Application Title	Form Number	Use
SF424 (R&R) Application Guide for NIH and Other PHS Agencies	SF424 (R&R)	The SF424 (R&R) form set, combined with PHS 398 components, is used for electronic submission.
SF424 (R&R) Individual Fellowship Application Guide for NIH and AHRQ	SF424 (R&R) and PHS 416-1	The SF424 (R&R) form set, combined with a PHS Fellowship Supplemental form component, is used for electronic submission of individual fellowship applications. The Fellowship Supplemental form component is from the PHS 416-1.
Application for a Public Health Service Grant	PHS 398	Form PHS 398 is used for paper submission for those programs that have not yet transitioned to electronic submission.

The majority of NIH competing applications now require electronic application submission. The FOA will identify whether the application requires electronic or paper submission. Paper submissions require use of the PHS 398 application form. An electronic submission requires the use of a unique set of application forms that combine SF424 (R&R) forms with agency-specific forms (e.g., 398 component forms, Fellowship supplemental component form). For electronically submitted applications, the applicable forms package and instructions is attached to a specific FOA. Questions about application forms and instructions may be directed to GrantsInfo, OER, NIH; see Part III for contact information.

2.3.9 Application Receipt Information and Deadlines

Applicants should carefully read instructions in the FOA and the application guide to determine submission requirements. The FOA will either provide unique application deadlines or refer to NIH's standard receipt dates.

NIH expects all applications (paper and electronic) to be submitted on time. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a cover letter explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Only DRR, CSR has the authority to accept a late application; however, contacting DRR in advance will not influence the acceptance of a late application. The NIH

policy on late applications is stated in the applicable application instructions. Also see 2.3.9.2 - Electronically Submitted Applications, below.

2.3.9.1 Paper Applications

Paper application submission dates fall under two different categories: 1) Standard Postmark/Submission Dates (also known as "send by" dates) and 2) Special Receipt Dates (also known as "arrive by" dates) which are specified in RFAs and PAs.

Applications submitted for the standard submission dates are considered on time if they are sent on or before the appropriate date listed and a proof of mailing is provided. The critical determination is when the application is sent, not when it arrives at NIH. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark, or a dated receipt from a commercial carrier or the USPS. Private metered postmarks are not acceptable.

All paper applications must be submitted via either courier delivery or the USPS. The number of copies specified in the application instructions or announcement must be submitted to the central NIH receipt point for CSR noted in Part III.

Preaddressed mailing address labels are available on the applicable forms page on the OER Web site.

Do not hand deliver your application to CSR. Applications delivered by individuals will not be accepted.

If the submission date falls on a weekend or a Federal holiday, the date for receipt/mailing is extended to the next business day. The application will be on time if it is sent on or before the following business day. The ten Federal holidays are: New Years Day, Birthday of Martin Luther King, Jr., Presidents Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

A paper application submitted in response to an FOA with a unique receipt date (if one is specified in the FOA) must be received at NIH by the specified date. However, an application received after the deadline may be accepted if it carries a legible proof-of-mailing date assigned by the carrier not later than 1 week prior to the deadline date. This applies only to FOAs with specific, published receipt dates, i.e., dates other than the standard ones used for investigator-initiated applications. For FOAs using the standard submission dates, the policies described above for "send by" dates apply.

2.3.9.2 Electronically Submitted Applications

For applications submitted electronically for the Standard Submission Dates, on time submission means the electronic grant application must be successfully submitted to Grants.gov on or before 5:00 p.m. local time (of the applicant institution/organization) on the appropriate date listed.

Applications submitted to FOAs with a single submission date are considered on time if they are submitted to Grants.gov on or before 5:00 p.m. local time (of the applicant institution/organization) on the appropriate date listed. Applications submitted for Special Receipt Dates are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the Grants.gov Closing Date. RFAs and PARs with special receipt dates always must be received by Grants.gov on the dates designated in the announcement.

If a submission date falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday (see list of Federal holidays in Paper Applications above), the submission date will be extended to the following business day. The application will be on time if it is submitted on or before the following business day.

There is a two week window of consideration after the application due date, during which time NIH might consider accepting a late application (see details below). When the application due date falls on a

weekend or Federal holiday, and is extended to the next business day, the window of consideration for late submission of applications will be calculated from that business day. Acceptance of late applications will be made on a case-by-case basis, dependent upon the explanation provided in a cover letter submitted with the application.

NIH will not consider accepting late applications under the following circumstances:

- RFAs that must be reviewed on a compressed timeline and that have declared, in the Application Due Date field, "No late applications will be accepted for this Funding Opportunity Announcement".
- New Investigator R01 applications resubmitted on special due dates (April 10, August 10, and December 10) as part of the New Investigator Initiative (http://-grants.nih.gov/grants/guide/notice-files/NOT-OD-12-001.html) because the submission deadline for these applications has already been extended by several weeks.
- Additional circumstances as outlined below:

Funding Opportunity Announcement Type		
PA*	PAR	RFA
2 week	2 week	2 week
		None if Application Due Dates Field States: "No late applications will be accepted for this Funding Opportunity Announcement".
*Includes PAS: Program Announcement with Set-Aside Funds		

NIH does not expect to accept any applications received beyond the window of consideration or for RFAs that specify no late applications will be accepted.

Please be aware that any reasons for late submission must be in relation to the individual(s) with the PD/PI role on the application. For multiple PD/PI (MPI) applications, the reasons may apply to any or all of the PD/PIs. This accommodation does not apply to co-Investigators, project leaders in a multi-component application, or other Key Persons listed in an application (unless they also have MPI status).

The windows of time for consideration of late applications have been carefully chosen so that the late applications can be processed with the cohort of on-time applications. Note that the late window always ends in a receipt (not submission) date.

Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH in advance will not influence the acceptance of a late application. Additional information on submission of electronic applications can be found in the applicable SF424 (R&R) Application Guide.

2.3.9.3 Modified Submission Policy for Appointed Members of NIH Review and Advisory Group and Reviewers with Recent Substantial Service

An alternative submission policy is available for certain applications submitted listing as PD/PI individuals serving as appointed members of NIH chartered standing study sections, NIH Boards of Scientific Counselors, NIH Advisory Boards or Councils, NIH Program Advisory Committees, and/or peer reviewers who have served as regular or temporary members six times in 18 months. This policy

applies to R01, R21, and R34 applications that would normally be received on standard application submission dates (not special receipt dates); and allows for applications to be submitted as soon as they are fully developed. The applications will be reviewed no later than 120 days after receipt. Applications using the multiple PD/PI model, are eligible if one or more of the PD/PIs are eligible for continuous submission. Continuous submission does not apply to applications for which the eligible members have roles other than PD/PI, including eligible members as sponsors for fellowships and mentors for career award applications.

See frequently asked questions at http://grants.nih.gov/grants/peer/faq_continuous_submission.doc.

2.3.9.4 Similar, Essentially Identical, or Identical Applications

Simultaneous submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization for the same receipt date. This includes derivative or multiple applications that propose to develop a single product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted for the same receipt date. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigator are the original work of the principal investigator and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may not be reviewed.

Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application; 3) submissions of applications previously submitted to an RFA that were not paid or resubmissions of investigator-initiated applications originally submitted to an RFA (see Grants Policy Statement section 2.3.7.3); and 4) resubmissions of applications with a changed grant activity code.

2.3.9.5 Application Non-conformity

Applicants are reminded that non-conformity with application requirements can have serious consequences. NIH may withdraw any application identified during the receipt, referral and review process that does not conform with the instructions in the SF424 (R&R) Application Guide, the Funding Opportunity Announcement, and relevant NIH Guide Notices.

Some **examples** of how this policy is applied to NIH applications *include but are not limited to*:

- Applications containing one or more biosketches that do not conform to the required format may be withdrawn.
- Applications that do not conform to the page limit requirements because inappropriate materials have been included in other parts of the application may be withdrawn.
- Applications submitted as new but containing elements of a resubmission or renewal application that do not conform with the resubmission policy and may be withdrawn.
- Applications submitted after 5 PM local (applicant organization) time on the application due date may be withdrawn.

It is important to remember that these are just examples, and that all requirements specified in the SF424 (R&R) Application Guide, the Funding Opportunity Announcement, and relevant NIH Guide Notices are to be followed. Questions about application requirements can be directed to NIH "Grants Info" or the Division of Receipt and Referral.

If an application is withdrawn because it does not conform to the application preparation and submission instructions, a letter will be placed in the eRA Commons Status page for that application.

2.3.10 Fraud, Waste and Abuse of NIH Grant Funds

Any individual who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds should consider contacting:

- Your institution's Office of Sponsored Research, Compliance Office, or other responsible office,
- The NIH CGMO listed in the NoA for the IC that funded the grant,
- The DGCO/OPERA/OER.

In addition, allegations of criminal offenses should be reported to the Department of Health and Human Services, OIG Hotline.

The OIG has authority within HHS to conduct criminal investigations. The HHS OIG maintains a post office box and a toll-free hotline for receiving information from individuals concerning fraud, waste, or abuse under HHS grants and cooperative agreements. The identity of the caller is kept confidential, and callers are not required to give their names. The address and telephone number of the OIG and the OIG hotline are included in Part III.

Further allegations of non-criminal misuse of grant funds, and recipient conflict of interest should be reported to the NIH OMA.

OMA provides a centralized management survey and review capability to promote program integrity, conducts appraisals of alleged incidents of waste, fraud, and abuse and has lead responsibility for cases received through the Office of Inspector General (OIG) Hotline that are referred to NIH for action. OMA has no authority to undertake criminal investigations. OMA refers all allegations of criminal offenses to the OIG for investigation. The address and telephone number for the OMA, DPI are included in Part III.

False statements involving false, fabricated, or plagiarized information identified during research misconduct proceedings should be reported to the NIH Extramural Research Integrity Officer.

Examples of fraud, waste, and abuse that should be reported include, but are not limited to, embezzlement, misuse, or misappropriation of grant funds or property, and false statements, whether by organizations or individuals. Other examples include theft of grant funds for personal use; using funds for non-grant-related purposes; theft of federally owned property or property acquired or leased under a grant; charging the Federal government for the services of "ghost" individuals; charging inflated building rental fees for a building owned by the recipient; submitting false financial reports; and submitting false financial data in bids submitted to the recipient (for eventual payment under the grant).

The Federal government may pursue administrative, civil, or criminal action under a variety of statutes relating to fraud and making false statement or claims. Part II includes administrative and other remedies the Federal government may use if a recipient deliberately withholds information or submits fraudulent information or does not comply with applicable requirements. Even if a grant is not awarded, the applic-

ant may be subject to penalties if the information contained in or submitted as part of an application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.

The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 et seq., provides for the administrative imposition by HHS of civil penalties and assessments against any person who knowingly makes false, fictitious, or fraudulent claims to the Federal government for money, including money representing grants, loans, or benefits. A civil penalty of not more than $5,500 may be assessed for each such claim. If a grant is awarded and payment is made on a false or fraudulent claim, an assessment of not more than twice the amount of the claim, up to $150,000, may be made in lieu of damages. Regulations established by HHS at 45 CFR 79 specify the review process for imposing civil penalties and assessments, including hearing and appeal rights.

The Criminal False Claims Act, 18 U.S.C. 287, and 18 U.S.C. 1001, provides for criminal prosecution of a person who knowingly makes or presents any false, fictitious, or fraudulent statements or representations or claims against the United States. Violations of these statutes carry a maximum sentence of 5 and 8 years imprisonment, respectively.

The Civil False Claims Act, 31 U.S.C. 3729(a), provides for imposition of penalties and damages by the United States, through civil litigation, against any person who knowingly makes a false or fraudulent claim for payment, makes or uses a false record or false statement to get a false claim paid or approved, or conspires to defraud the Federal government to get a false claim paid. A “claim” includes any request or demand for money or property made to the United States or to a contractor, recipient, or other recipient, if the Federal government provides or will reimburse any portion of the funds claimed. Civil penalties of $5,500 to $11,000 may be imposed for each false claim, plus damages of up to three times the amount of the damages the government sustains because of the violation, and the costs of any civil action brought to recover such penalties and damages.

NIH also may administratively recover misspent grant funds pursuant to the authorities contained in 45 CFR 75.

2.3.11 Availability and Confidentiality of Information

2.3.11.1 Availability of Information

Except for certain types of information that may be considered proprietary or private information that cannot be released, most grant-related information submitted to NIH by the applicant or recipient in the application or in the post-award phase is considered public information and, once an award is made, is subject to possible release to individuals or organizations outside NIH. The statutes and policies that require this information to be made public are intended to foster an open system of government and accountability for governmental programs and expenditures and, in the case of research, to provide information about federally funded activities.

NIH routinely places information about awarded grants, including project title, the name of the PD/PI, and the project description, on the RePORT Web site (see http://report.nih.gov). For funded research grant applications, NIH also sends the project description provided by an applicant to the DoC’s NTIS. NTIS disseminates scientific information for classification and program analysis. The public may obtain the project descriptions from RePORT or request them from NTIS. Other information may be released case by case as described in this subsection.

Several policies require acknowledgment of support and a disclaimer for publications, inventions, and other research products, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources and elsewhere in the NIHGPS.

2.3.11.2 Confidentiality of Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets, information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified as specified in the application instructions.

When such information is included in the application, it is furnished to the Federal government in confidence, with the understanding that the information will be used or disclosed only for evaluation of the application. The information contained in an application will be protected by NIH from unauthorized disclosure, consistent with the need for peer review of the application (including the agreement by peer reviewers and Advisory Council members to the NIH confidentiality and nondisclosure rules); and the requirements of the FOIA and Privacy Act (5 U.S.C. 552 as discussed below). However, if a grant is awarded as a result of or in connection with an application, the Federal government has the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Federal government's right to use the information if it is obtained without restriction from another source.

2.3.11.2.1 Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a (as amended), and its implementing regulations (45 CFR 5b) provide certain safeguards for information about individuals maintained in a system of records (i.e., information may be retrieved by the individual's name or other identifying information). These safeguards include the rights of individuals to know what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used, how they may obtain access to their records, and how to correct, amend, or request deletion of information in their records that is factually incorrect.

The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0225 (https://era.nih.gov/privacy-act-and-era.htm)

This system of record provides guidance on requirements for the management of applicable grant records in NIH's possession and include appropriate routine uses of such information. It also includes requirements for safeguarding the records and for record retention and disposal.

Parties other than PD/PIs may request the release of Privacy Act grant records. Such requests are processed under FOIA. For example, information requested by co-investigators in grant applications is released to them only when required under FOIA because they have no right of access under the Privacy Act. When releasing information about an individual to a party other than the subject of the file, NIH will balance the individual's right to privacy with the public's right to know as provided by the FOIA.

Records maintained by recipients ordinarily are not subject to the requirements of 45 CFR 5b.

2.3.11.2.2 The Freedom of Information Act

The Freedom of Information Act, 5 U.S.C. 552, and implementing HHS regulations (45 CFR 5) require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information. These policies and regulations apply to information in the possession of NIH. Generally NIH cannot require recipients or contractors under grants to permit public access to their records. An exception related to certain research data is described in this subsection.

NIH generally will release the following types of records pursuant to a FOIA request:

- Funded applications and funded progress reports, including award data.
- Final reports that have been transmitted to the recipient organization of any audit, survey, review, or evaluation of recipient performance.

NIH generally will withhold the following types of records or information in response to a FOIA request:

- Pending competing grant applications
- Unfunded new, renewal, and revision applications
- Financial information pertaining to project personnel, such as institutional base salary information
- Information pertaining to an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
- Predecisional opinions in interagency or intraagency memorandums or letters expressed by Federal government officers, employees, or consultants
- Evaluative portions of site visit reports and peer review summary statements, including impact scores
- Trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from a person or organization and are privileged or confidential
- Information which, if released, would adversely affect the competitive position of the person or organization
- Patent or other valuable commercial rights of the person or organization.

Applicants are instructed to identify proprietary information at the time of submission of an application. If, after receiving a FOIA request, NIH has substantial reason to believe that information in its records could reasonably be considered exempt from release, the appropriate NIH FOI office will notify the applicant or recipient, through the PD/PI, before the information is released. In the case of multiple PD/PI's the Contact PD/PI will be notified and is responsible for coordinating any response to the notice. Multiple responses to the notice will not be accepted. If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA. The PD/PI will be given five (5) working days to identify potentially patentable or commercially valuable information that the PD/PI believes should not be disclosed. Any such submission must be specific as to the nature and type of commercial harm that will result if the requested information is released. Submissions that merely state in general terms that the grant application or portions should not be released will not be honored. If the PD/PI does not respond within that time period, the grant will be prepared for release in accordance with applicable FOIA policies and released to the requester. If the PD/PI does identify commercial or proprietary information an NIH official will review that response. After NIH consideration of the response, the PD/PI and recipient will be informed if NIH does not agree with the PD/PI's position. If a document contains both disclosable and non-disclosable information, the non-disclosable information will be redacted and the balance of the document will be disclosed.

The HHS regulations implementing FOIA provide that only the NIH FOI Officer may deny requests for information. Requests for information, the release of which is believed to be exempt under FOIA, are referred to the NIH FOI Officer along with written documentation of the rationale for nondisclosure. If the NIH FOI Officer determines that the requested information is exempt from release under FOIA, the requester may appeal that determination to the Deputy Assistant Secretary for Public Affairs (Media),

HHS. Additional information on the FOIA process is available at the NIH FOI Office Web site (http://www.nih.gov/icd/od/foia).

2.3.11.2.3 Access to Research Data

NIH handles requests for the release of research data by certain types of recipients as FOIA requests. The term "research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

As required by 45 CFR 75.322, recipients that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, NIH directs the requester to the public source. Otherwise, the IC FOI coordinator handles the request, consulting with the affected recipient and the PD/PI. This requirement also provides for assessment of a reasonable fee to cover recipient costs and (separately) the NIH costs of responding.

This requirement to release research data does not apply to commercial organizations or to research data produced by State or local governments. However, if a State or local governmental recipient contracts with an IHE, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Additional information is available on the NIH Web site at http://grants.nih.gov/grants/policy/data_sharing/index.htm. (Also see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.)

2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds are reminded of their vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also Public Policy Requirements and Objectives—Federal Information Security Management Act.

2.4 THE PEER REVIEW PROCESS

Competing applications for NIH grants and cooperative agreements, including renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006. NIH policy is intended to ensure that applications for funding submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that

strives to eliminate bias. The peer review system used by NIH, often referred to as the "dual review system," is based on two sequential levels of review for each application—initial review by an IRG or SRG, and a second level of review by the IC National Advisory Council/Board.

The NIH peer review process has evolved over the years to accommodate increasingly collaborative and multi-disciplinary research, changes in workload, resource constraints, and recommendations of various groups that have studied it. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at http://grants.nih.gov/grants/peer/peer.htm. Information also is available from GrantsInfo, or from OEP (see Part III).

2.4.1 Initial Review

2.4.1.1 Responsibilities

The DRR in the CSR is the receipt point for all competing grant applications submitted to NIH, whether the peer review will be conducted by CSR or by an IC. The primary determining factors in whether CSR or an IC will be responsible for the peer review are the announcement type, the support mechanism, and/or the program. In general, CSR is responsible for the initial review of research project grant applications (including AREA applications), Kirschstein-NRSA individual fellowship applications, and SBIR/STTR applications, while the ICs handle the initial review of conference grant applications, applications resulting from RFAs, and program project and center grant applications.

CSR also may review other types of applications at IC request. When the IC is responsible for the initial review, CSR reviews the application for completeness and staff in the soliciting IC review the application for responsiveness to the RFA, and the scientific review office in that IC coordinates the initial technical review, and prepares the summary statements.

CSR Referral Officers, who are senior health science administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to an IRG or SRG for initial review of the scientific merit of the application. These determinations are made on the basis of the application's contents, the referral guidelines, and any written request by the applicant organization (accompanying the application) for a specific study section or IC assignment.

SRGs, including CSR study sections, are organized by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc SEPs are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that the application has been received and that they may have access to the SRO, SRG, and IC assignments for the application in the eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO is the primary contact for communication with the applicant until the conclusion of the SRG meeting. An applicant organization may

withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least three reviewers to write a critique of the application and to be prepared to discuss the application in detail.

Following the initial review, the SRO prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of strengths and weaknesses, other summary highlights of the discussion, and an impact score. Summary statements are then provided to the IC's program staff and the PD(s)/PI(s).

2.4.1.2 Overall Impact

The SRG assesses overall impact in the determination of scientific and technical merit; overall impact is defined differently for different types of applications. When considering applications for research grants and cooperative agreements, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the project proposed). All of the criteria, weighted as appropriate for each application or as described in the FOA, will be considered when assigning the overall impact score.

2.4.1.3 Scored Review Criteria

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, and enhance health. For research grant applications, and most other types of applications, reviewers judge the overall impact to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, taking into account, among other pertinent factors: Significance, Investigator(s), Innovation, Approach, and Environment. These scored review criteria may not be applicable for some types of applications. When these criteria are not applicable, the FOA will include the specific review criteria.

Reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

The FOA should be consulted for additional information describing each of the scored review criteria.

2.4.1.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children

- Vertebrate Animals
- Resubmission Applications
- Renewal Applications
- Revision Applications
- Biohazards

The FOA should be consulted for additional information describing each of the relevant additional review criteria.

2.4.1.5 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Provision of Family Care Facilities (for Conference Grant Applications)
- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period Support

The FOA should be consulted for additional information describing each of the relevant additional review considerations.

Although the review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R01 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and non-research activities. However, for some activities (e.g., construction grants), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in FOAs.

2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. The NIH policy for appeals of initial peer review does not apply to appeals of the technical evaluation of Research and Development contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT awards. In addition, NIH will not review a resubmission application when an appeal of initial peer review is pending on the original application. Appeals of initial peer review outcome will not be accepted for applications in response to an RFA.

An appeal is a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence from the Authorized Organization Representative (AOR).

An applicant who is concerned about procedural aspects related to the completed initial peer review of his or her application first should consider the comments in the summary statement, and then should contact the appropriate NIH Program Official (PO). Following discussion of concerns with the PO, if the PD/PI and/or an official of the applicant organization wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send his/her concurrence to the PD/PI who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than the AOR) only or with a "cc" to the AOR will not be accepted. The PO will send the PD/PI and/or institutional official, and AOR, an acknowledgement letter within 10 days of receipt of the appeal letter.

An appeal letter will be accepted only if the letter 1) describes the flaws in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest, as specified in regulation at 42 CFR 52h.5 "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-Federal peer reviewers.
- Lack of appropriate expertise within the SRG.
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

If review staff and program staff do not support the appeal, or do not agree on its merit, the PD/PI and/or an institutional official (not necessarily the AOR) may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the request directly to the PO, or must send his/her concurrence to the PD/PI who will forward the materials and his/her concurrence to the PO. A communication from the PD/PI or institutional official (other than the AOR) only or with a "cc" to the AOR will not be accepted.

If review staff and program staff do not support the appeal, or do not agree on its merit, and the appeal letter is not withdrawn, the appeal letter will be made available to Council. The IC may not deny the PD/PI or applicant organization the opportunity to have an appeal letter made available to Council. Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal, and recommend that the application be re-reviewed.
- The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. No action by the Council is equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know. If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting. If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation of the IC's plan for making the appeal available to Council.

If the Council recommended that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same or a different SRG, depending on the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions will be announced in NIH Guide Notices and/or the relevant Funding Opportunity Announcements when they are issued in the NIH Guide for Grants and Contracts.

2.4.3 National Advisory Council or Board Review

Summary statements for those applications recommended for further consideration are presented to the assigned IC National Advisory Council or Board (hereafter "Council") for use in the second level of review. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission. The Council reviews applications not only for scientific and technical merit, as judged by the SRG, but also for relevance to the IC's programs and priorities. The Council may concur with the SRG's recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review.

In addition, Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the threshold for Special Council Review. These are investigators who currently receive $1 million or more in direct costs of NIH funding to support Research Project Grants. Council members will be asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This does not represent a cap to NIH funding.

With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

2.4.4 Disposition of Applications

All incomplete applications, non-compliant modular applications, and applications determined to be non-responsive to FOA requirements will not be reviewed. If the FOA remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle. One resubmission application may be submitted for an appropriate due date up to 37 months after the application due date of the initial application. Any application on the same topic proposed as a resubmission more than 37 months from the initial receipt date will not be accepted; it must be formatted and submitted as a new application.

Following the initial review, the summary statement will be available to the PD/PI in the eRA Commons. If an application does not result in funding, there may be an opportunity to respond to the reviewers' comments and resubmit the application. Applicants just receiving their summary statements should consult the NIH Next Steps page for detailed guidance. Applicants seeking advice beyond that available online may want to contact the NIH Program Officer listed at the top of the summary statement.

The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application for review in a future cycle.

Some of the ICs publish paylines as part of their funding strategies to guide applicants on their likelihood of receiving funding. Application scores can only be compared against the payline for the fiscal year when the application will be considered for funding, which is not necessarily the year when it was submitted. At the beginning of fiscal years when the agency awaits an actual budget, there may be a delay of several months to determine paylines. If the application is assigned to an IC that does not announce a payline, the Program Officer listed at the top of the summary statement may be able to provide guidance on the likelihood of funding.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in Completing the Pre-Award Process below. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC approval) or to undertake certain activities (such as negotiation of an F&A cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each FOA will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of

IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

Applicants will be notified (primarily by e-mail) when Just-in-Time information is needed. This notification is not a Notice of Award nor should it be construed to be an indicator of possible funding. Applicants should only submit this information when requested. Information must be submitted electronically using the Just-in-Time feature in the eRA Commons. In some circumstances the GMO may ask for information in addition to the descriptions below, e.g., if the application involves hESCs and the applicant did not identify a hESC from the NIH Registry in the application.

The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through the Just-in-Time process. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award. This includes items such as Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel; or any changes in the use or approval of vertebrate animals or human subjects. Similar to the NIH public policy requirements, applicants are responsible for establishing and maintaining the necessary processes to monitor its compliance and informing NIH of any problems or concerns. Failure to address changes to Just-in-Time submissions prior to award does not diminish the applicant's responsibility to address changes post-award by submitting a prior approval request to NIH in accord with Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award.

Other Support. Information on other active and pending support will be requested as part of the Just-in-Time procedures. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are not included. Other support is requested for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Information on Other Support is not specifically requested for Program Directors, training faculty, and other individuals involved in the oversight of training grants since applicable information is collected in other sections of a training grant application. It is also not requested for individuals categorized as Other Significant Contributors.

IC scientific program and grants management staff will review this information before award to ensure the following:

- Sufficient levels of effort are committed to the project.
- There is no scientific, budgetary, or commitment overlap.
    - Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
    - Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.
    - Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.
    - Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the IC with the applicant and the PD/PI at the time of award.
- Only funds necessary to the approved project are included in the award.

Certification of IRB Approval. If the proposed project involves human subjects research, the certification date of IRB review and approval must be submitted. Pending or out-of-date approvals are not acceptable. See Public Policy Requirements/Human Subjects for additional information.

Verification of IACUC Approval. If the proposed project involves research with live vertebrate animals, verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable. See Public Policy Requirements/Animal Welfare for additional information.

Human Subjects Education Requirement. If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted. See Public Policy Requirements/Human Subjects/Education in the Protection of Human Research Participants for additional information.

Human Embryonic Stem Cells (hESCs). If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line (s) should be included in the Just-in-Time submission.

Genomic Data Sharing Institutional Certification. If the proposed project involves a Genomic Data Sharing plan. The certification form and directions for completing it are available on the GDS Data Sharing website: http://gds.nih.gov/Institutional_Certifications.html. This certification should be submitted as an "other Upload" in the eRA Commons Just-in-Time module.

SBIR Funding Agreement Certification. For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

STTR Funding Agreement Certification. For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at:

https://grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

My Bibliography Report of Publications. For renewal applicants to research training programs, a My Bibliography report of publications arising from work conducted by trainees while supported by the training grant will be requested as Just-in-Time information prior to award. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

Other Information Requested by the Awarding IC. NIH IC's may also request additional Just-in-Time information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animal sections of the application. These changes should be submitted as an "Other Upload" file in the eRA Commons Just-In-Time module.

2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement

When requested by NIH as part of the pre-award process, PD/PIs and the AOR should discuss potential changes in scope with NIH PO and revise the Project Summary/Abstract, Specific Aims, and/or Public Health Relevance sections of their application as appropriate. Once all issues are resolved, applicants should e-mail a document with final versions of the revised sections to the IC-designated e-mail address (normally a Program Official, Grants Management Official, or centralized e-mail box) as a single Microsoft Word or PDF file. Be reminded that all revised application information submitted to the NIH must be approved by an AOR. Applicants should use the template found at: http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_ModifiedScopeTemplate.doc. The template includes specific headings that must be used for each section. All three headings must be included in the document that is submitted even if a particular section had no changes from the previous submission. If there are no changes for a section include the header but leave the text area blank to ensure appropriate processing of this information by NIH's electronic systems.

2.5.3 Determining Applicant Organization Eligibility

All applicant organizations must complete the one-time eRA Commons registration process prior to submitting any application (paper or electronic) to the NIH. During the registration process, NIH may make a preliminary assessment of applicant organization eligibility. In an effort to streamline the registration requirements and reduce the administrative burden (i.e., time between registration submission and NIH's final determination), NIH urges potential applicants to consider the following eligibility considerations:

- What is the nature of the research and business that your organization performs and how does that fit within the NIH mission?
- Is your organization professionally responsible for the research?
- How many people are in your organization?
- Are the researchers employed by your organization?
- Where physically is the proposed research to be conducted?
- Can you identify a Funding Opportunity Announcement that you would apply for?
- Has your organization applied to and/or been directly funded by any Federal agency?

Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH reserves the right to deny registration if an organization is determined not to be an appropriate applicant for a particular FOA. NIH will not accept forms or other documentation bearing

generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

NIH awards may be made only to eligible applicants. Continued funding is dependent on the recipient's continued eligibility. In general, domestic or foreign, public or private, non-profit or for-profit organizations and individuals are eligible to receive NIH grants. However, on the basis of statutory, regulatory, or published policy limitations, under certain programs or types of awards, NIH may limit eligibility to, or exclude from eligibility, classes or types of entities. Examples are limitations on the participation of foreign entities, and programs under which only small businesses are eligible applicants. The determination of eligibility includes verification of the applicant's status. The applicant may be required to provide proof of its status by submitting documentation; otherwise the AOR's signature on the application certifies that the applicant is eligible to apply for and receive an award (e.g., a small business applying under the SBIR or STTR programs).

In addition to reviewing organizational eligibility, NIH may consider other factors relating to the applicant's ability to responsibly handle and account for Federal funds and to carry out the project. These factors include the applicant's intended role in the project, the location where the project will be performed, the role of the PD/PI in the project, and the PD/PI's employment and citizenship status. Although some of these same considerations are reviewed as part of the peer review, NIH's concern at this stage in the process is making an award to a legal entity that will be accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. NIH will not make an award to an applicant that does not have a substantive role in the project and would simply serve as a conduit for another entity.

2.5.4 Determining Eligibility of Individuals

It is the responsibility of the applicant organization to select the individuals who have the appropriate expertise to manage the scientific and administrative aspects of the project. The eligibility of these individuals to complete the project will be evaluated during peer review and at the IC level by grants management and program staff.

The GMO will verify whether the proposed PD/PI or other senior/key personnel are debarred or suspended from participation in Federal assistance programs (see Public Policy Requirements and Objectives—Debarment and Suspension for certification requirements).

Generally, PD/PIs and other personnel supported by NIH research grants are not required to hold any particular education degree, and are not required to be U.S. citizens. However, some NIH programs/mechanisms have a citizenship requirement. Any citizenship requirement will be stated in the FOA. In these cases, individuals are required to have the appropriate citizenship status when the award is made rather than when the application is submitted. For example, under most career development awards or Kirschstein-NRSA individual fellowships, the individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of award.

NIH requires the applicant to determine that individuals' visas will allow them to remain in this country long enough for them to be productive on the research project, but NIH does not provide guidance on or assess the different types of visas. NIH expects recipient organizations to have policies, consistently applied regardless of the source of funds, to address this area. If a grant is awarded and an individual's visa will not allow a long enough stay to be productive on the project, NIH may terminate the grant (see Administrative Requirements—Changes in Project and Budget and Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

The eligibility requirements for trainees and additional eligibility requirements for fellows are addressed in Ruth L. Kirschstein National Research Service Awards chapter in IIB.

In the post-award phase, NIH monitors changes in recipient and project status to ensure they meet legal and programmatic requirements and takes actions necessary to protect the Federal government's interests.

2.5.5 Cost Analysis and Assessment of Management Systems

The GMO will ensure that a cost analysis is performed on any application that requires a detailed budget. Cost analysis involves obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and allowability of, the costs included in the application budget. The extent of cost analysis will depend on the type of funding instrument and award mechanism, the complexity of the project, prior experience with the applicant, and other factors. Information on the applicable cost principles and on allowable and unallowable costs under NIH grants is provided in the Cost Considerations chapter.

The amount of NIH funding is based on reasonable and allowable costs consistent with the principles of sound cost management, considering IC priorities (e.g., program relevance), constraints on the growth of average grant costs, and available funds.

In addition to considering the specific information provided in the application, the GMO determines the adequacy of the applicant's financial and business management systems that will support the expenditure of and accountability for NIH funds. When an applicant has had no prior Federal grants or cost-reimbursement contracts, the GMO may review the applicant's financial management and other management systems before award, or within a reasonable time after award, to determine their adequacy and acceptability. For an applicant with prior NIH or other Federal cost-reimbursement awards, the GMO may review recent audit reports and other available information to determine whether the applicant's management systems meet the standards established in 45 CFR 75. The GMO will advise the applicant if additional information is required. On the basis of the review results, the GMO will determine the need for any corrective action and may impose special conditions on the award.

PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

Subpart A: General

3 OVERVIEW OF TERMS AND CONDITIONS

Part II includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards. Subpart A (IIA) includes those terms and conditions that apply, in general, to NIH awards. Subpart B (IIB) either expands on IIA coverage or specifies additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

NIH grants awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in the NoA.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts. This also includes any recent legislation.
- 45 CFR 75.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIHGPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

This NIHGPS is an aid to the interpretation of statutory and regulatory requirements. These terms and conditions are intended to be compliant with governing statutes and the requirements of 45 CFR 75, as modified by previously approved waivers and deviations. However, in the case of a conflict, the statutes and regulations govern.

If there is a perceived conflict between or among these three categories of requirements—statutory and regulatory requirements, the terms and conditions in the NIHGPS, and award-specific terms and conditions—or if the recipient has other questions concerning award terms and conditions, the recipient

should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the recipient not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the recipient agrees to the terms and conditions of the award.

3.1 FEDERALWIDE STANDARD TERMS AND CONDITIONS FOR RESEARCH GRANTS

In order to create greater consistency in the administration of Federal research awards, all Federal research agencies now utilize a standard core set of administrative terms and conditions on research and research-related awards that are subject to 45 CFR Part 75, to the extent practicable. The core set of administrative requirements for participating Federal research agencies and other pertinent documents are posted at: http://www.nsf.gov/bfa/dias/policy/rtc/index.jsp. Recipients are encouraged to review the companion documents which include a Prior Approval Matrix, National Policy Requirement Matrix, Subaward Requirement Matrix, and Agency-Specific Requirements. NIH implementation of these Federalwide research terms and conditions has no significant change in the requirements or terms and conditions for NIH awardees.

3.2 NIH STANDARD TERMS OF AWARD

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approval; these are known as expanded authorities. In 2001, NIH extended these authorities to all NIH awards except for the provision to automatically carry over unobligated balances; therefore the term “expanded authorities” has been replaced with “NIH Standard Terms of Award”. See Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award for more details.

4 PUBLIC POLICY REQUIREMENTS, OBJECTIVES AND OTHER APPROPRIATION MANDATES

NIH grants are subject to requirements intended to ensure that recipient organizations handle their Federal awards responsibly. Recipients are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, its employees, and organizations and individuals whom they may collaborate, and that limit the potential for research results to be tainted by possible financial or other gain. In addition, NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

This chapter addresses public policy requirements, objectives, and other appropriation mandates applicable to NIH awards. The term "public policy" indicates that the requirement is based on social, economic, or other objectives or considerations that may be attached to the expenditure of Federal funds by recipients, consortium participants, and contractors, in general, or may relate to the expenditure of Federal funds for research or other specified activities.

In addition to cross-cutting requirements that some or all Federal agencies must apply to their grant programs, NIH recipients are subject to requirements contained in the HHS annual appropriations act that apply to the use of NIH grant funds, applicable provisions in other Federal agencies' appropriations acts, including Treasury, and other Federal statutes. Some of those requirements are included here in a separate section titled Appropriation Mandates since they have been included in the appropriations acts for several years with little or no change. Those requirements may be changed or other requirements may be added in the future.

The public policy requirements, objectives, and appropriation mandates listed in Exhibit 4 apply to all NIH awards with exceptions as noted.

4.1 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The public policy requirements specified in this section set many of those standards. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information. The signature of the AOR on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions. The policies, certifications and assurances listed in this section may or may not be applicable to the project, program, or type of applicant organization. Requirements/objectives are listed in alphabetical order.

As noted in this section, some requirements may necessitate the submission of a separate document (e.g., human subjects assurance, certification of IRB approval or institutional exemption, civil rights assurance). Applicants and recipients should take particular note of these requirements (for example, see specific sections on Human Subjects Protections and Civil Rights Protections), the absence or inadequacy of which may delay an award or render an applicant ineligible for award.

The recipient is responsible for: 1) establishing and maintaining the necessary processes to monitor its compliance and that of its employees, consortium participants, and contractors with these requirements; 2) taking appropriate action to meet the stated objectives; and, 3) informing NIH of any problems or concerns.

If a grant is awarded on the basis of false or misrepresented information, or if a recipient does not comply with these public policy requirements, NIH may take any necessary and appropriate action, including using any of the remedies described in Administrative Requirements—Enforcement Actions or other available legal remedies.

Exhibit 4 contains information to help the recipient determine what public policy requirements, objectives and appropriations mandates apply to its activities and whether a requirement should be included in a consortium agreement or a contract for routine goods or services under the grant (see Glossary in Part I for definitions). The exhibit distinguishes between these types of transactions under a grant and indicates (by "Y" for Yes or "NA" for Not Applicable) whether a given requirement normally would apply. However, even if the exhibit indicates that a requirement is not applicable that requirement potentially could be applicable in a specific situation, e.g., if a contract under a grant involves research activity. Therefore, this exhibit should be used as general guidance only. The recipient should consult the terms and conditions of its award and should contact the GMO if it has any question concerning the applicability of a particular public policy requirement or objective.

Exhibit 4 also indicates where, in the NIHGPS, the individual public policy requirements, objectives and appropriation mandates are covered in more detail. The recipient should also consult its attorney, as appropriate, regarding particular questions about the governing statute or regulation as applied to its specific circumstances. Other cited policies or documents may provide additional information.

In addition to the requirements addressed in this section, there are applicable NIH administrative requirements outlined in the Administrative Requirements chapter.

Some programs may have special requirements and are covered in IIB.

Exhibit 4. Public Policy Requirements, Objectives and Appropriation Mandates *

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Consortium Participant	Contractor under Grant (routine goods/services)
Military Recruiting and ROTC Program Access to Institutions of Higher Education 4.1.19	Y	N	N
Seat Belt Use 4.1.28	Y	NA	NA
Labor Standards under Federally Assisted Construction 10.5.3	Y (Construction Grants and major A&R Contracts Exceeding $100,000)	NA	Y
Smoke-Free Workplace 4.1.29	Y	NA	NA
Drug-Free Workplace 4.1.7	Y	NA	NA

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Consortium Participant	Contractor under Grant (routine goods/services)
Flood Disaster Protection Act of 1973 — Flood Insurance 10.10.1	Y (Construction grants only)	NA	NA
National Environmental Policy Act of 1969 (including Public Disclosure) 4.1.20 and 10.10.1	Y	NA	NA
Intergovernmental Review of Federal Programs under EO 12372 10.10.1	Y (Construction grants only)	NA	NA
Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 10.10.1	Y	NA	NA
Standards of Conduct 4.1.30	Y	NA	NA
Federal Funding Accountability and Transparency Act (FFATA) 4.1.8 and 8.4.1.5.5	Y	NA If under $25,000	NA If under $15,000
President's Emergency Plan for AIDS Relief (PEPFAR Program 4.1.22	Y	Y	Y
Nondelinquency on Federal Debt 4.1.21	Y	Y	NA
National Historic Preservation Act of 1966 - Archaeological and Historic Preservation Act of 1974 10.10.1	Y (Construction Grants; any award involving major or minor A&R, or any work resulting in physical changes to real property)	Y	Y
Lead-Based Paint Poisoning Prevention Act 10.10.1	Y (Construction grants only)	Y	Y
Investigational New Drug Applications/Investigational Device Exceptions 4.1.16	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Consortium Participant	Contractor under Grant (routine goods/services)
Inclusion of Women/Minorities as Subjects in Clinical Research 4.1.15.8	Y	Y	NA
Metric System 4.1.18 and 10.10	Y	Y	Y
Lobbying (Appropriation Mandate) 4.2.6	Y	Y	Y
Limited English Proficiency 4.1.2.5	Y	Y	NA
Pro-Children Act of 1994 4.1.23	Y	Y	Y
Safe Drinking Water Act 10.10.1	Y (Construction grants only)	Y	Y
Salary Limitation/Cap (Appropriation Mandate) 4.2.10	Y	Y	NA
Restriction on Distribution of Sterile Needles (Appropriation Mandate) 4.2.9	Y	Y	Y
Select Agents (see Public Health Security & Bioterrorism Preparedness and Response Act) 4.1.24.1.1	Y	Y	Y
USA Patriot Act 4.1.33	Y	Y	Y
U.S. Flag Air Carriers 7.9.1	Y	Y	Y
Text Messaging While Driving 4.1.31	Y	Y	Y
Restriction on Abortions & Exceptions (Appropriation Mandates) 4.2.8 & 4.2.8.1	Y	Y	Y
Wild and Scenic Rivers Act of 1968 10.10.1	Y (Construction grants only)	Y	Y
Protection of Wetlands (EO 11990) 10.10.1	Y (Construction grants only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Consortium Participant	Contractor under Grant (routine goods/services)
Promotion or Legalization of Controlled Substances (Appropriation Mandate) 4.2.7	Y	Y	Y
Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents) 4.1.24.1.1	Y	Y	Y
Research Misconduct 4.1.27	Y	Y	NA
Research Involving Recombinant or Synthetic Nucleic Acid Molecules (including Human Gene Transfer Research) 4.1.26	Y	Y	Y
Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees 4.1.25	Y	Y	NA
Inclusion of Individuals Across the Lifespan as Participants in Research 4.1.15.7	Y	Y	NA
Copeland Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y
Controlled Substances 4.1.5	Y	Y	Y
Conservation of Petroleum and Natural Gas (EO 12185) 10.10.1	Y (Construction grants only)	Y	Y
Data and Safety Monitoring 4.1.15.6	Y	Y	Y
Dual Use Research of Concern 4.1.24.2	Y	Y	Y
Dissemination of False or Deliberately Misleading Information (Appropriation Mandate) 4.2.3	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Consortium Participant	Contractor under Grant (routine goods/services)
Davis-Bacon Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y
Confidentiality of Alcohol and Drug Abuse Patient/Client Records 4.1.4.2	Y	Y	Y
Architectural Barriers Act of 1968 10.10	Y (Construction grants and any grant involving major A&R)	Y	Y
Animal Welfare 4.1.1	Y	Y	Y
Acknowledgment of Federal Funding (Appropriation Mandate) 4.2.1	Y	Y	NA
Certificates of Confidentiality 4.1.4.1	Y	Y	Y
Coastal Zone Management Act of 1972 10.10	Y (Construction grants only)	Y	Y
Clinical Trials.gov 4.1.3	Y	Y	NA
Clean Air and Clean Water Act 10.10.1	Y (Construction grants only); for contracts exceeding $100,000	Y	Y
Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (EO 12699) 10.10	Y (Construction grants only)	Y	NA
Human Subjects Protections 4.1.15	Y	Y	Y
Gun Control 4.2.4	Y	Y	Y
Fly America Act 4.1.11	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Consortium Participant	Contractor under Grant (routine goods/services)
Hotel and Motel Fire Safety Act of 1990 14.6.1	Y (Conference Grants Only)	Y	Y
Human Fetal Tissue Research (Including Transplantation Research) 4.1.14	Y	Y	Y
Human Stem Cell Research 4.1.13	Y	Y	Y
Human Embryo Research and Cloning Ban (Appropriation Mandate) 4.2.5	Y	Y	Y
Health and Safety Regulations and Guidelines 4.1.12	Y	Y	Y
Endangered Species Act of 1973 10.10.1	Y (Construction grants only)	Y	Y
Equal Employment Opportunity 10.5	Y (Construction grants and any grant involving major A&R)	Y	NA If under $10,000
Financial Conflict of Interest 4.1.10	Y (NA to Phase I of the SBIR/STTR programs and to Federal institutions)	Y	NA
Federal Information System Security Management Act 4.1.9	Y	Y	Y
Age Discrimination Act of 1975 4.1.2.4	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Civil Rights Act of 1964 (Title VI) 4.1.2.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Consortium Participant	Contractor under Grant (routine goods/services)
Health Insurance Portability and Accountability Act (HIPAA) 4.1.4.3	Y (if a covered entity)	Y (if a covered entity)	Y (if a covered entity)
Debarment and Suspension 4.1.6	Y (NA to certain foreign organizations)	Y (NA to certain foreign organizations)	Y If contract equals or exceeds $25,000 (NA to certain foreign organizations)
Education Amendments of 1972 (Title IX) 4.1.2.2	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Rehabilitation Act of 1973 (section 504) 4.1.2.3 and 10.10.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Lobbying (Federalwide Certification) 4.1.17	Y Certification required if total costs expected to exceed $100,000	Y Certification required if greater than $100,000 only	Y Certification required on contracts greater than $100,000 only
Trafficking in Persons 4.1.32	Y Private entities	Y Private entities	NA

* NA: A designation of NA in this table indicates that a particular requirement does not apply to an otherwise eligible recipient, consortium participant, or contractor or may not apply because the type of activity covered is one not normally performed by such an entity.

Please note that the core set of National Policy Requirements for participating Federal research agencies is maintained by the National Science Foundation and is posted at: http://www.nsf.gov/bfa/dias/policy/rtc/index.jsp.

4.1.1 Animal Welfare Requirements

The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all recipient organizations receiving PHS support for research or related activities using live vertebrate animals. Recipient organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495).

The PHS Policy defines “animal” as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or related purposes.

Applications from organizations proposing the use of animals are incomplete if they do not thoroughly address the use of vertebrate animals required in the Research Plan of the application. If the involvement of animals is indefinite at the time of application, the applicant should provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to conducting any animal activities the recipient must submit to the NIH awarding IC for prior approval the detailed information about the use of animals as required in the Research Plan of the application, and meet the Assurance and IACUC approval requirements of the PHS Policy.

Noncompeting and competing awards are prohibited from using NIH funds to procure cats from USDA Class B dealers. The procurement of cats may only be from USDA Class A dealers or other approved legal sources.

NIH funds may not be used to procure or support the use of dogs from Class B dealers. Dogs used in NIH-supported research may only be from USDA Class A dealers or other approved legal sources. Any costs incurred in violation of this policy are unallowable and will be subject to a cost disallowance.

No costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and IACUC approval of the activity.

The PHS Policy does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research. All recipient organizations are required to comply, as applicable, with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture under the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

4.1.1.1 Animal Welfare Assurance Requirements

An Animal Welfare Assurance is the document submitted by an institution assuring institutional compliance with the PHS Policy. OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances.

When an applicant institution does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in accordance with the PHS Policy, and the authorized IACUC shall review those components of the application related to the care and use of animals. Except in certain circumstances, the Assurance must be submitted to and approved by OLAW in order for the IC to award the grant. No costs for activities with live vertebrate animals may be charged to NIH grants in the absence of a valid Assurance on file with OLAW.

If the prime recipient does not have an Assurance and the animal activities will be conducted at an Assured institution named as a performance site, the recipient must obtain an Inter-institutional Assurance from OLAW. Under the Inter-institutional Assurance, the recipient and performance site agree that

the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance.

4.1.1.2 Verification of IACUC Approval

NIH will delay an award for research involving live vertebrate animals until the recipient organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the recipient has provided verification of IACUC approval of those sections of the application that involve use of vertebrate animals. IACUC approval must have been granted within three years of the budget period start date to be valid; however, IACUCs may determine that continuing review on a more frequent basis is appropriate.

Verification of IACUC approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with approved Assurances may wish to proceed with IACUC review for those applications that have not yet received IACUC approval and that appear to be in a fundable range.

It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.

No costs for activities with live vertebrate animals may be charged to NIH grants if there is not a valid IACUC approval.

4.1.1.3 Consortiums

Under consortium (subaward) agreements in which the recipient collaborates with one or more other organizations, the recipient, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the recipient as specified in the NIHGPS (see Consortium Agreements chapter in IIB). The animal welfare requirements that apply to recipients also apply to consortium participants and subprojects.

The primary recipient is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the recipient and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted.

The recipient is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).

The list of organizations with approved assurances is available at the OLAW Web site (domestic institutions: http://grants.nih.gov/grants/olaw/assurance/300index.htm, and foreign organizations: http://grants.nih.gov/grants/olaw/assurance/500index.htm).

4.1.1.4 Foreign Recipients and Foreign Performance Sites

Foreign recipients must provide OLAW with an Animal Welfare Assurance for Foreign Institutions. This constitutes institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the International Guiding Principles for Biomedical Research Involving Animals. IACUC

approval is not required of foreign recipients; however, OLAW encourages foreign recipients to use the standards in the *Guide for the Care and Use of Laboratory Animals*.

When the recipient is a domestic institution and performance sites are foreign (i.e., domestic grant with a foreign component), PHS Policy requirements are applicable. Accordingly, the recipient remains responsible for animal activities conducted at the foreign site and must provide verification of IACUC approval (i.e., certification that the activities as conducted at the foreign performance site are acceptable to the recipient). The recipient IACUC may accept, as its own, the approval of a foreign organization's IACUC; however, the recipient IACUC remains responsible for the review. Additionally, the foreign site must obtain an Animal Welfare Assurance for Foreign Institutions as described in the preceding paragraph.

4.1.1.5 Reporting to OLAW

Reporting requirements under the PHS Policy include an annual report to OLAW describing any change in the institution's program for animal care and use as described in the Assurance, changes in IACUC membership, and the dates the IACUC conducted its semiannual evaluations of the institution's program and facilities. The IACUC, through the institutional official signing the Assurance, must promptly report any serious or continuing noncompliance with the PHS Policy, serious deviations from the Guide for the Care and Use of Laboratory Animals, and any IACUC suspensions.

Charges to NIH grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the grant award are not upheld are not allowable. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.
2. The conduct of animal activities in the absence of a valid IACUC approval of the activities. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

Instances of serious noncompliance with section IV.F.3. of the PHS Policy, such as those mentioned above, are to be reported to OLAW and the IC supporting the grant award. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. NIH requires that reports contain a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance. If such a certification cannot be made, a detailed accounting of unallowable charges made to each affected grant should be included with the report. If a detailed accounting has not been completed at the time of reporting, a date when it will be provided should be included.

NIH expects recipients to continue to maintain and care for animals during periods when animal activities are conducted in the absence of a valid Animal Welfare Assurance and/or IACUC approval. ICs may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis. Consultation with the IC is encouraged regarding questions concerning allowable costs.

Information about the PHS Policy, Animal Welfare Assurances, and other relevant topics is available from OLAW (see http://grants.nih.gov/grants/olaw/olaw.htm).

4.1.2 Civil Rights Protections

Before NIH may make an award to a domestic organization, the AOR must certify, by means of the signature on the application, that the organization has on file with the HHS OCR a one-time Assurance of Compliance with the statutes described in this subsection. The Assurance, Form HHS 690, is filed for

the organization and is not required for each application. If the application has been recommended for funding and the applicant organization does not have an Assurance of Compliance on file, it will receive the required form and instructions for completion and submission from the awarding IC. The HHS 690 also is available from GrantsInfo@nih.gov or by telephone at 301-435-0714.

Domestic organizations that receive funding from recipients (including consortium participants and contractors under grants) rather than directly from NIH, also are required to file an HHS 690. The applicant/recipient is responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR.

4.1.2.1 Civil Rights Act of 1964

Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR 80.

4.1.2.2 Educational Amendments of 1972

Title IX of the Education Amendments of 1972 provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR 86.

4.1.2.3 Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act of 1973, as amended, provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the physical or mental impairment, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. These requirements pertain to the provision of benefits or services as well as to employment. The HHS implementing regulations are codified at 45 CFR Parts 84 and 85.

4.1.2.4 Age Discrimination Act of 1975

The Age Discrimination Act of 1975 prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR 91.

4.1.2.5 Limited English Proficiency

EO 13166, August 11, 2000, requires recipients receiving Federal financial assistance to take steps to ensure that people with limited English proficiency can meaningfully access health and social services. A program of language assistance should provide for effective communication between the service provider and the person with limited English proficiency to facilitate participation in, and meaningful access to, services. The obligations of recipients are explained on the OCR Web site at http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/.

4.1.3 Clinical Trials Registration and Reporting in ClinicalTrials.gov Requirement

4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

Effective for grant applications submitted on or after January 18, 2017, that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date, the NIH Policy on

Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by the NIH, will ensure that their clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting. The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Disseminating this information supports the NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11, hereinafter referred to as the regulation.

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov according to the timelines described in the regulation.

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Applicants seeking NIH funding for clinical trials will be required to submit a plan that will address how the expectations of this policy will be met. Recipients and investigators conducting clinical trials funded in whole or in part by the NIH are required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.

The signature of the AOR on the grant or progress report form certifies that, for any clinical trials funded under the NIH award, the recipient and all investigators are in compliance with the recipient's clinical trial information dissemination plan.

Responsibilities of recipients and investigators will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the recipient is the responsible party, the recipient will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the recipient is not the responsible party, the recipient will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the recipient will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

In addition, informed consent documents for clinical trials within all three categories are to include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. Recipients need not and should not create a separate record of the applicable clinical trial to comply with this policy.

4.1.3.2 Food and Drug Administration Amendments Act (FDAAA)

Applicants and recipients should familiarize themselves with the requirements of 42 U.S.C. 282(j), also known as Sec. 801 of Public Law 110-85 (the FDA Amendments Act of 2007 or FDAAA), as

implemented in regulation by 42 CFR Part 11, with respect to registration and results reporting requirements that apply to certain clinical trials. Of particular note is that, in general, results of applicable clinical trials are due not later than 12 months after the primary completion date. If this date occurs after the period of performance has ended, results reporting is still required in accordance with FDAAA and the terms and conditions of grant award.

The signature of the AOR on the grant or progress report form certifies that, for applicable clinical trials funded in whole or part by the award, the responsible party has made all registration and results submissions required by 42 CFR Part 11.

4.1.4 Confidentiality

4.1.4.1 Certificates of Confidentiality

Section 301(d) of the PHS Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255, states that the Secretary shall issue Certificates of Confidentiality (Certificates) to NIH funded investigators or institutions engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected.

All recipients who conduct biomedical, behavioral, clinical, or other research that collects or uses identifiable, sensitive information, are covered by a new NIH Policy (NOT-OD-17-109), and are deemed to be issued a Certificate. Recipients are therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. Institutions and their investigators are responsible for determining whether research they conduct is subject to the new Policy. Certificates issued in this manner will not be issued as a separate document.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

Recipient Responsibilities

To determine if the Policy applies to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

- Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

- Does the research involve Human Subjects as defined by 45 CFR Part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
- Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is yes, then the Policy will apply to the research and therefore, in accordance with subsection 301(d) of the Public Health Service Act, the recipient of the Certificate shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH supported research applicable to the Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award.

Recipients of Certificates are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate issued by the Policy, understand they are also subject to the requirements of subsection 301(d) of the Public Health Service Act. In accordance with NIHGPS Chapter 15.2.1, recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sens-

itive information protected by a Certificate issued by the Policy understand they are also subject to subsection 301(d) of the Public Health Service Act.

For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by the Policy.

Information on CoCs is available on the NIH Web site at http://grants.nih.gov/grants/policy/coc/index.htm.

4.1.4.2 Confidentiality of Alcohol and Drug Abuse Patient Records

Section 543 of the PHS Act, as implemented in 42 CFR 2, requires that records of substance abuse patients be kept confidential except under specific circumstances and purposes. These protections differ from those available to patients under HIPAA and are intended to ensure that a patient in a drug or alcohol abuse program is not made more vulnerable than a similar patient who does not seek treatment. The covered records are any information, written or not, of a patient who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program. This includes records of the identity, diagnosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, training, treatment, rehabilitation, or research, which is conducted under an NIH grant. Except as authorized under a court order, no patient record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient. The regulations also describe procedures to allow for nonvoluntary disclosure of certain information by persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs.

4.1.4.3 Confidentiality of Patient Records: Health Insurance Portability and Accountability Act

HHS issued the final version of the "Standards for Privacy of Individually Identifiable Health Information"—the Privacy Rule—on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. It is administered and enforced by OCR, HHS. Those entities required to comply with the Privacy Rule (classified under the rule as "covered entities") had until April 14, 2003 to do so (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and the recipient organization. The OCR Web site (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including the complete text of the regulation and a set of decision tools for determining whether a particular entity is subject to the rule. An educational booklet, Protecting Heath Information in Research: Understanding the HIPAA Privacy Rule, is available through OCR's Web site and also at http://privacyruleandresearch.nih.gov/. That Web site also includes other educational materials including information specific to grants.

4.1.5 Controlled Substances

If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the drugs themselves, applicants/recipient must ensure that the DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 301-443-6300.

4.1.6 Debarment and Suspension

HHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for HHS' non-procurement programs and activities. "Non-procurement transactions" include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH grants ("primary covered transactions"), including sponsoring institutions for Kirschstein-NRSA individual fellowships, are required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in a covered transaction (i.e., grant or cooperative agreement) prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the grant award. Recipients may decide the method and frequency by which this determination is made and may check excluded parties in SAM, although checking SAM is not required.

Prior to the drawdown of funds for each grant award, recipients must report to the funding IC if the recipient or any of its principals:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 CFR 180.800(a) or had a civil judgment for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

Disclosure of unfavorable information by recipients under this requirement will not necessarily cause NIH to deny participation in the grant. NIH will consider the information when determining whether to enter into the covered transaction. NIH will also consider any additional information or explanation that recipients elect to submit with the disclosed information. However, if it is later determined that a recipient failed to disclose information that it knew at the time it accepted the NIH grant award, NIH may (a) terminate the transaction for material failure to comply with the terms and conditions of the award or (b) pursue any other available remedies, including suspension and debarment.

Recipients must immediately report to the NIH funding IC if at any time during the project period, including periods of no-cost extension, they discover that they (a) failed to disclose information prior to the drawdown of funds or (b) due to changed circumstances the recipient or any of its principals for the grant now meet the reporting criteria.

"Lower tier" transactions (e.g., consortiums, subcontracts, consultants, collaborators, and contractors that require the provision of goods or services that will equal or exceed $25,000) also are subject to the HHS regulations. Prior to entering into a lower tier covered transaction with a participant (as defined in 2 CFR 180.980), recipients must verify that the person (as defined in 2 CFR 180.985) is not excluded or disqualified. Recipients may not enter into any transaction with a person who is disqualified from that transaction unless an exception under the disqualifying statue, Executive Order, or regulation has been obtained from HHS.

Recipients must require participants at the next lower tier to (a) comply with the HHS Debarment and Suspension regulations as a condition of participation in the transaction and (b) pass the requirement to comply with the HHS Debarment and Suspension regulations to each person involved in the covered transaction at the next lower tier. Likewise, before entering into such a transaction lower tier participants and contractors under grants (where the contract requires the provision of goods or services that

will equal or exceed $25,000) must report to the recipient if it or any participants are presently excluded or disqualified.

Recipients also are required to assure compliance for each trainee under a Kirschstein-NRSA institutional research training grant, or other similar NIH-supported institutional training grant, before their appointment.

Organizations or individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants, be paid from NIH grant funds, whether under a primary or lower-tier transaction (including trainees on NIH-supported training grants), or otherwise participate during the period of suspension, debarment, or exclusion. Because individuals who have been debarred, suspended, declared ineligible, or voluntarily excluded from covered transactions may not receive Federal funds for a specified period of time, charges made to the NIH grants for such individuals (e.g., salary) are unallowable.

4.1.7 Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. § 701 et seq.) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the AOR agrees that the recipient will provide a drug-free workplace and will comply with the requirement to notify NIH if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. Government wide requirements for Drug-Free Workplace for Financial Assistance are found in 2 CFR 182; HHS implementing regulations are set forth in 2 CFR 382.400. All recipients of NIH grant funds must comply with the requirements in Subpart B (or Subpart C if the recipient is an individual) of Part 382. Foreign applicants and recipients may be exempted from the drug-free workplace requirements of 2 CFR 182 based on a documented finding by the NIH awarding IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

4.1.8 Federal Funding Accountability and Transparency Act (FFATA)

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, USASpending.gov. The Web site includes information on each Federal financial assistance award and contract over $25,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including FAIN, transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all subawards/subcontracts/consortiums over $25,000. Information on the recipient reporting requirement for this law can be found in Monitoring—Reporting—Financial Reports—Recipient Reporting of Subrecipient Data for FFATA.

This requirement is being implemented in accordance with OMB Interim Final Guidance, Federal Register Volume 75, Number 177, September 14, 2010. Full text of the award term is available at 2 CFR 170.

4.1.9 Federal Information Security Management Act

All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access. This also applies to information associated with NIH grants and contracts. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), 44 U.S.C. 3541 et seq. The applicability of FISMA to NIH recipients applies only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. The recipient retains the original data and intellectual property, and is responsible for the security of this data, subject to all applicable laws protecting security, privacy, and research. If and when information collected by a recipient is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA.

4.1.10 Financial Conflict of Interest

NIH requires recipients and investigators (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A Final Rule amending the 1995 PHS regulation (and the companion regulation at 45 CFR 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

The requirements under the 2011 revised regulation promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. These requirements do not apply to Federal employees or Federal agencies. Federal agencies have their own set of rules governing financial conflicts of interest for employees. When submitting a grant application, the signature of the AOR certifies the applicant Institution's compliance with the requirements of 42 CFR 50, Subpart F, including that:

1. There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;
2. The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests;
3. The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;

4. When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;
5. The Institution shall fully comply with the requirements of the regulation.

When the Institution determines that an FCOI exists (see #3 above), the Institution must report to the NIH awarding IC through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. The initial FCOI report will include the following information:

- Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;
- Name of Investigator (if different from the PD/PI) with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- Value of the financial interest $0-4,999; $5,000-9,999; $10,000-19,999; amounts between $20,000-100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000 or a statement that a value cannot be readily determined;
- A description how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan, including:
    1. Role and principal duties of the conflicted Investigator in the research project;
    2. Conditions of the management plan;
    3. How the management plan is designed to safeguard objectivity in the research project;
    4. Confirmation of the Investigator's agreement to the management plan;
    5. How the management plan will be monitored to ensure Investigator compliance; and
    6. Other information as needed.

The annual FCOI report must be submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until the Institution reports that the FCOI no longer exists. The annual FCOI report will include the following information:

- Status of the FCOI
- Changes to the management plan, if applicable

The Institution will incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified Financial Conflicts of Interest to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the NIH to meet its reporting obligations. (See Consortium Agreements, 15.2.1 Written Agreement.)

The Institution will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.

The Institution will require each Investigator (including subrecipient Investigators, if applicable) to complete training prior to engaging in NIH-supported research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

As described in the regulation, examples of how FCOIs might be addressed include but are not limited to, the following:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of research by independent reviewer(s);
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of Significant Financial Interests (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts.

The information above is only a sample of the regulatory requirements found in 42 CFR 50, Subpart F. Applicants and recipients must review the regulation in its entirety to ensure compliance with all of the requirements. Resources applicable to FCOI, including Frequently Asked Questions, etc. can be found on OER's Conflict of Interest Web site at http://grants.nih.gov/grants/policy/coi/index.htm.

4.1.11 Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:

1. ***Airline "Open Skies" Agreement.*** A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States.

   The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued Guidance October 6, 2010. Pursuant to the amendment, federal contractors and recipients (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and recipients must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the European Union. For additional information, please see the text of the Amendment and GSA Bulletin FTR 11-02. For information on other "open skies" agreements in which the United States has entered, refer to GSA's Web site: http://www.gsa.gov/portal/content/103191.

2. ***Involuntary Rerouting.*** Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.
3. ***Travel To and From the U.S.*** Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
4. ***Travel Between Points Outside the U.S.*** Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
5. ***Short Distance Travel.*** For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

4.1.12 Health and Safety Regulations and Guidelines

Recipients are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR 1910.1030, Blood borne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR 1910. These regulations are available at http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910.
- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at https://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf.
- Prudent Practices for Safety in Laboratories (2011), National Research Council, National Academies Press, 500 Fifth Street, NW, Lockbox 285, Washington, DC 20055 (ISBN 978-0-309-13864-2). This publication is available at https://www.nap.edu/catalog/12654/prudent-practices-in-the-laboratory-handling-and-management-of-chemical.

Recipient organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding IC, recipients should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.

4.1.13 Human Stem Cell Research

Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, effective July 7, 2009, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

For the purpose of the NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos.

NIH recipients may use hESCs that have been approved by NIH in accord with the NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry, or may establish eligibility of specific cell lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and recipients must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/recipient must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used.

DHHS regulations for Protection of Human Subjects, 45 CFR 46, Subpart A, establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 CFR 46, Subpart A.

In addition, 45 CFR 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 CFR 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidance at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html.

4.1.13.1 Human Pluripotent Stem Cell Research Prohibited with NIH Funding

The following uses of hESCs, even if derived from embryos donated in accordance with the NIH Guidelines and listed on the NIH Registry, or human induced pluripotent stem cells, are prohibited:

- Research in which hESCs or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- Research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line.

In addition, the derivation of stem cells from human embryos is prohibited in NIH funded research by the annual appropriations ban on funding of human embryo research known as the Dickey Wicker Amendment. NIH funding for research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is also prohibited.

Effective September 23, 2015, NIH will not fund any new or competing grant applications or contract proposals for research in which human pluripotent cells are introduced into non-human vertebrate animal pre-gastrulation stage embryos while the NIH considers a possible policy revision in this area. This policy will be in place until NIH issues a subsequent policy notification.

- *Current research funding*: NIH will not consider requests for administrative supplements or revisions to any grants or modification to R&D contracts that include costs for or involve research introducing human pluripotent cells into non-human vertebrate animal pre-gastrulation stage embryos. Ongoing NIH awards will be addressed with the awardees on a case-by-case basis.
- *Peer reviewed competing applications*: Any grant applications previously submitted to the NIH and already reviewed (through both the initial and Council levels of review) which propose to introduce human pluripotent cells into non-human vertebrate animal pre-gastrulation stage embryos will be held for funding decisions until NIH has issued a policy notification. At that time, highly ranked applications can be modified, as necessary, to comply with the policy notification to receive full consideration for funding.
- *Competing applications/contract proposals pending submission and/or peer review*: NIH will not review applications or contract proposals for research proposing to introduce human pluripotent cells into non-human vertebrate animal pre-gastrulation stage embryos until NIH has issued a policy notification.
- Once the policy notification is released, applicants for grants that have not completed initial peer review will have the opportunity to submit additional post-submission material to comply with the policy notification. Provided that the additional material can be sent 30 days before the initial peer review meeting, those grant applications will be reviewed and considered for funding. See NOT-OD-10-115 for instructions and details.
- Once the policy notification is released, offerors for R&D contract proposals shall not submit additional material or information addressing the issue related to this notice after the cutoff date for receipt of proposals, unless directed to do so by the Contracting Officer.
- Applications that completed initial peer review before issuance of this Notice will not proceed to Council review at this time. R&D contracts that have completed peer review and have been determined to be in the competitive range before issuance of this Notice may proceed to negotiations.
- Alternatively, applicants may withdraw the application and submit again at the next available due date.

4.1.14 Human Fetal Tissue Research

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects. 45 C.F.R. 46.204 and 46.206 may be specifically relevant.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements, particularly section 498B. When an application involving human fetal tissue research is submitted to NIH, the AOR's signature certifies that researchers using these tissues are in compliance with section 498B of the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

Current federal laws and regulations require informed consent for research involving the transplantation of human fetal tissue and for research with human fetal material associated with information that can identify a living individual. Most states require informed consent for the use of fetal tissue in research. Accordingly, NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.

When obtaining primary human fetal tissue for research purposes, NIH expects grantees and contractors to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

4.1.14.1 Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:
  - for therapeutic transplantation research,
  - without any restriction regarding the identity of individuals who may receive the transplantation, and
  - without the donor knowing the identity of the recipient.
- The attending physician must sign a statement that he/she has:
  - obtained the tissue in accordance with the donor's signed statement and
  - fully disclosed to the donor his or her intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.

- In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that he/she:
  - obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
  - did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
  - performed the abortion in accordance with applicable State and local laws.
- The PD/PI must sign a statement certifying that he/she is aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The PD/PI must certify in writing that he/she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the AOR that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA has jurisdiction over fetal cells and tissues intended for use in humans and requests that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm105857.htm.

4.1.15 Human Subjects Protections

The HHS regulations for the protection of human subjects, in 45 CFR 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the NIH or other HHS components.

The HHS regulations stipulate that the recipient organization(s), whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in HHS-supported activities (46.101(a) and 46.103(a)). Recipient institutions "engaged" in human subjects research must obtain a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects. An institution is engaged in human subjects research if:

1. the institution's employees or agents intervene or interact with human subjects for research purposes;
2. the institution's employees or agents obtain individually identifiable private information about human subjects for research purposes; or
3. the institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

The OHRP's document entitled Guidance on Engagement of Institutions in Human Subjects Research provides additional guidance on "engagement".

The HHS regulations at Subparts B, C, and D include additional protections for specific populations as follows:

1. human fetuses, pregnant women, and neonates (45 CFR 46, Subpart B);
2. prisoners (45 CFR 46, Subpart C); and
3. children (45 CFR 46, Subpart D).

Certain research activities are exempt from regulatory requirements for an FWA and IRB oversight (45 CFR 46.101(b)). OHRP guidance states that institutions must adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations. NIH will make a final determination as to whether proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan.

Unless all research activities meet the criteria for one or more exemptions from 45 CFR 46, research involving human subjects may only be conducted under an HHS award if the organization has a current OHRP approved FWA and provides certification that an Institutional Review Board (IRB) registered under the specific Assurance has reviewed and approved the proposed activity in accordance with the HHS regulations.

In accepting an award that supports human subjects research, the recipient institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites, and for ensuring that an FWA and certification of IRB review and approval exists for each site before human subjects research may begin. When consultants are performing research involving human subjects on NIH-funded projects, the consultant's institution must establish an approved FWA.

The NIH Office of Extramural Research Human Subjects Web site contains additional information and Frequently Asked Questions that are available to help investigators understand how these Federal requirements apply to their research. See http://grants.nih.gov/grants/policy/hs/index.htm.

Applications will be considered incomplete if they do not address the involvement of human subjects in the Research Plan of the application. If human subjects research is anticipated within the period of the award but definite plans for involvement of human subjects cannot be described in the application (referred to as "delayed onset human subjects research" in the NIH grant application instructions), applicants must provide a detailed explanation of why it is not possible to develop definite plans. Prior to the involvement of human subjects the recipient must submit to the NIH awarding IC for prior approval either (1) detailed information as required in the Research Plan of the application, and meet the FWA and IRB certification requirements, or (2) if all of the research meets the criteria for one or more exemptions, identification of which exemptions(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate. Typically, recipients that are part of large clinical research networks or consortia that plan to add new protocols after the award must follow the awarding IC's procedures for approval of new protocols. Institutions with award mechanisms that allow them to select new projects, typically small future research projects (e.g., pilot projects), for support by their NIH award are responsible for ensuring that the selected projects follow all relevant regulations and policies including those governing the involvement of human subjects in research, including prior approval from the institutional IRB if applicable. They must follow the awarding IC's procedures for prior approval of

new protocols and updating the IC on the status of funded projects in annual progress reports which are typically described in the FOA and/or NoA.

Recipients may not draw funds from the payment system, request funds from the paying office, or make obligations against Federal funds for research involving human subjects at any site engaged in nonexempt research for any period not covered by both an FWA and IRB approval consistent with 45 CFR 46. Costs associated with IRB review of human research protocols are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.

The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR 46.

4.1.15.1 Federalwide Assurance Requirements

The Federalwide Assurance (FWA) commits the institution to compliance with the requirements set forth in 45 CFR 46, and the Terms of Assurance. Each institution that is "engaged" in HHS supported human subjects research must be covered by an FWA approved by OHRP. (See http://www.hhs.gov/ohrp/assurances/assurances/index.html.)

When an applicant organization proposes non-exempt human subjects research and does not have a FWA, the AOR signature on the application constitutes declaration that the organization will comply with 45 CFR 46 and proceed to obtain a FWA. The NIH awarding component will place a restriction in the NoA so that no human subjects research may be conducted under the award until the FWA and certification of IRB review and approval (or certification of institutional determination of exemption, if applicable) have been obtained and accepted by NIH.

Each recipient institution must file its own FWA even if the organization does not operate its own IRB and designates another IRB for that purpose. IRBs must be registered with OHRP before the IRB may be designated on an FWA as reviewing proposed research for the FWA-holding institution.

Organizations that will serve as additional performance sites that are conducting non-exempt human subjects research under the award must obtain an FWA, or, under specified circumstance, may be covered by the recipient's FWA in accordance with the OHRP's Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement.

It is the recipient organization's responsibility to ensure that all sites engaged in research involving human subjects are covered by an appropriate FWA and have IRB approval consistent with 45 CFR 46. It also is the recipient's responsibility to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements). A list of organizations with approved assurances is available at the OHRP Web site (http://www.hhs.gov/ohrp).

No individual may receive NIH grant funds for nonexempt research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an FWA or the individual makes other arrangements with OHRP.

Detailed information concerning FWAs, including the OHRP Assurance Training Module, is available on the OHRP Web site (http://www.hhs.gov/ohrp/).

4.1.15.2 Certification of IRB Approval

Recipients must provide a certification to NIH that the research application has been approved by an appropriate IRB, consistent with 45 CFR 46 and OHRP guidance. IRB approval must have been granted within 12 months before the budget period start date to be valid. Note that NIH requires the date of final IRB approval; conditional IRB approval is not sufficient. According to OHRP, in the case of IRB

approval with conditions, IRB approval only becomes effective when the IRB has approved all information submitted in response to their conditions.

Certification of IRB approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with OHRP FWAs may wish to proceed with IRB review for those applications that have not yet received IRB approval and that appear to be in a fundable range.

The HHS regulations require that the IRB review the actual application or proposal for HHS support (45 CFR 46.103(f)). OHRP's 5/31/2000 memo *IRB Review of Applications for HHS Support* (http://www.hhs.gov/ohrp/policy/aplrev.html) recommends that IRBs ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB.

4.1.15.3 Reporting to Funding Agency and OHRP

Under the HHS regulations, recipient institutions must have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the NIH of any unanticipated problem involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR 46 or IRB requirements (45 CFR 46.103(b)(5)). Any IRB suspension or termination of approval must include a statement of the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and NIH (45 CFR 46.113). Recipient institutions must also file incident reports with OHRP of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR 46 or with the requirements or determinations of the IRB, and suspension or termination of IRB approval. See OHRP 6/20/2011 *Guidance on Reporting Incidents to OHRP* (http://www.hhs.gov/ohrp/compliance/reports/index.html).

4.1.15.4 OHRP Oversight

OHRP has regulatory responsibility for oversight of recipient compliance with the HHS human subjects regulations. In carrying out this responsibility, OHRP evaluates all written allegations or indications of non-compliance with the HHS regulations it receives from any source. All compliance oversight evaluations are predicated on the HHS regulations and the organization's assurance of compliance. Any corrective actions imposed as a result of a compliance oversight evaluation are intended to remedy identified non-compliance and prevent reoccurrence. Because each case is different, OHRP tailors corrective actions to foster the best interest of human research subjects and, to the extent possible, of the organization, research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OHRP level. However, OHRP may recommend actions to be taken by other HHS officials.

Information about the FWA submission process and about OHRP activities related to oversight and compliance, as well as copies of the human subjects regulations, may be obtained from OHRP at the address shown in Part III or from its home page at http://www.hhs.gov/ohrp/.

4.1.15.5 Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, applicants must submit documentation that all senior/key personnel involved in human subjects research have received training in the protection of human subjects. Senior/key personnel include all individuals responsible for the design or conduct of the study, including senior/key personnel of consortium participants or alternate performance sites if they are participating in research that involves human subjects. This documentation should be included in the cover letter signed by the AOR that accompanies the description of other support, IRB and IACUC approval, and other information submitted prior to funding in accordance with Just-in-Time procedures. For non-competing continuation awards, the description of education for new senior/key personnel should be part of the progress report submitted as a prerequisite to award.

Additional information about this education requirement is available on the NIH Web site at: http://-grants.nih.gov/grants/policy/hs_educ_faq.htm.

4.1.15.6 Data and Safety Monitoring

The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. The NIH policies on data and safety monitoring specify that the level and frequency of monitoring should be commensurate with the risks, nature, and complexity of the clinical trial, and are in addition to any monitoring requirements imposed by FDA or the *NIH Guidelines for Research Involving Recombinant DNA Molecules ("NIH Guidelines")*. There are a number of options for monitoring clinical trials including, but not limited to, monitoring by a/an:

- PD/PI (required),
- IRB (required),
- Independent individual/safety officer,
- Designated medical monitor,
- Internal committee or board with explicit guidelines,
- DSMB (required for multi-site trials).

Applications that include clinical trials must include a general description of the data and safety monitoring plan. The description of the data and safety monitoring plan in competing applications will be reviewed by the SRG. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It must describe the entity that will be responsible for monitoring how adverse events will be reported to the IRB and the NIH and, when appropriate, how the NIH Guidelines and FDA regulations for INDs and IDEs will be satisfied.

A detailed monitoring plan must be included as part of the research protocol, be submitted to the local IRB, and be reviewed and approved by the NIH awarding IC prior to the accrual of human subjects. The awarding IC may specify the reporting requirements for adverse events, which are in addition to the annual report to the IRB. The clinical trial monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by clinical trial monitoring entities and the monitor must provide periodic reports to investigators for transmittal to the local IRB.

NIH specifically requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials also may use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.

For multi-site Phase I and II trials, investigators should organize a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and the IRBs of participating sites. The frequency of summary reports will depend on the nature of the trial. Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and II clinical trials. However, such plans always should be evaluated for appropriateness for the particular investigation.

All multi-site trials with DSMBs are expected to forward summary reports of adverse events to individual IRBs so they can address reports related to the site for which they have responsibility. Recipients should address questions on this subject to the NIH PO.

Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

4.1.15.7 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

For all competing grant applications for due dates on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. Applications/proposals must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the recipient/offeror must provide an acceptable justification for the exclusion.

Scientific review groups at the NIH will assess each application/proposal as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions. NIH staff will monitor implementation of this policy during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.

NIH recipients must submit data on participant age at enrollment in progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided to NIH in progress reports.

Ongoing, non-competing awards and competing applications submitted prior to January 25, 2019, will not be expected to comply with this policy until the grantee submits a competing renewal application. For these projects, the previous policy on the inclusion of children (NOT-98-024) continues to apply.

4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation

NIH-conducted and supported Clinical research must conform to the *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* in accord with Public Health Service Act sec. 492B, 42 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations be included in NIH-conducted or supported clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the NIH IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification.

Cost is not an acceptable reason for exclusion except when the research would duplicate existing data. Women of childbearing potential should not be routinely excluded from participation in clinical research. The policy applies to research subjects of all ages in NIH-supported clinical research studies (see definition of clinical research). The inclusion of individuals on the basis of sex/gender, race, and ethnicity must be addressed in developing a research design appropriate to the scientific objectives of the study. A proposed outreach program for recruiting should also be included. When an NIH-defined Phase III

clinical trial is proposed, investigators must consider whether clinically important sex/gender, racial, and/or ethnic differences in the intervention effect are to be expected and plan the research accordingly. When registering in Clincialtrials.gov, applicable clinical trials as defined in 42 C.F.R. Part 11, that are also NIH-defined Phase III clinical trials must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. For applicable clinical trials that are also NIH-defined Phase III clinical trials, submissions of results to Clinicaltrials.gov must include results of valid analyses by sex/gender and race/ethnicity, as required based on prior evidence.

Investigators must also collect and annually report information on sex/gender, race, and ethnicity in clinical research studies. The OMB minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant projects are described in OMB Directive No. 15. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards include five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: “Hispanic or Latino,” and “Not Hispanic or Latino.”

For more information on policies and procedures related to inclusion: Inclusion Procedures

4.1.15.9 Informed Consent for Research on Dried Blood Spots Obtained Through Newborn Screening

NIH funded research using newborn dried blood spots collected on or after March 18, 2015, will be considered to be non-exempt human subjects research, and therefore, must follow the HHS protection of human subjects regulations at 45 CFR part 46.

Grant applications and R&D contract proposals submitted to NIH that will use such materials in research should be designated as non-exempt human subjects research and include a complete human subjects section per relevant NIH instructions including plans for inclusion on the basis of sex/gender, race, ethnicity, and age per the NIH Policies on the Inclusion of Women, Minorities, and Children.

Such applications and proposals that are funded by NIH must comply with all the relevant federal regulatory and NIH policy requirements for human subjects research including the requirement that the awardee institution (and all engaged institutions) have a Federalwide Assurance (FWA) from OHRP and certification of IRB approval of the proposed research.

Parental permission must have been obtained in order to use newborn dried blood spots collected on or after March 18, 2015, in NIH-funded research. Waiver of parental permission for such research is not permitted under this legislation.

Continuing NIH awards that are conducting research with newborn dried blood spots collected on or after March 18, 2015, will also have to comply with these new requirements. Awardee institutions will need to meet all NIH requirements for human subjects research, including IRB approval, prior to starting such research.

Non-identifiable newborn dried blood spots collected prior to March 18, 2015, may continue to be used in NIH-funded research without parental permission, and this activity would continue to be considered research that does not involve human subjects under the current human subjects regulations.

NIH recognizes that there is no universal agreement on the optimal timing for collection of parental permission for research purposes. Obtaining permission at the time the dried blood spots are collected may be one option. Ideally, an educational process could take place prior to the process of obtaining permission, and may be provided prenatally or after the birth of the child.

Section 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014 applies to use of newborn dried blood spots in HHS funded research, as "research" is defined in 45 CFR 46.102 (d). Research funded solely by state or private entities does not constitute "Federally funded research" and is not subject to Section 12 of the new law.

4.1.15.10 Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2). (See https://www.fda.gov/downloads/drugs/guidances/ucm073122.pdf).

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials.

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

GCP training complements other required training on protections for human research participants. Since June 2000, the NIH Extramural Research Program has required training on protections for human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of a research involving human subjects.

This policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials. GCP training includes the Principles of ICH GCP found in Section 2 of ICH E6. GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. Acceptable GCP courses include the NIAID GCP Learning Center website (http://gcplearningcenter.niaid.nih.gov) and National Drug Abuse Treatment Clinical Trials Network (https://gcp.nidatraining.org/). Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training, and make it available to NIH upon request.

For purposes of Good Clinical Practice training the following definitions apply:

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

4.1.15.11 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Effective for all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018, NIH expects that all sites participating in multi-site studies involving non-exempt human subjects research funded by NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protection of Human Subjects at 45 CFR Part 46. Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.

This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. It does not apply to career development, research training or fellowship awards. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.

Applicants are expected to submit a plan describing the use of an sIRB that will be selected to serve as the IRB of record for all study sites. The plan should include a statement confirming that participating sites will adhere to the sIRB Policy and describe how communications between sites and sIRB will be handled. If, in delayed-onset research, an sIRB has not yet been identified, applications/proposals should include a statement that awardees will follow this Policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site study. The applicant/offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, as described in Chapter 7 (Cost Consideration) and the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs). The NIH's acceptance of the submitted plan will be incorporated as a term and condition in the Notice of Award.

Recipients are responsible for ensuring that authorization agreements are in place; copies of authorization agreements and other necessary documentation should be maintained in order to document compliance with this policy, as needed. As appropriate, recipients are responsible for ensuring that a mechanism for communication between the sIRB and participating sites is established.

All sites participating in a multi-site study are expected to rely on an sIRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46. Participating sites are responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB. Participating sites must communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations. Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review. Although IRB ethical review at a participating site would be counter to the intent and goal of this policy, the policy does not prohibit any participating site from duplicating the sIRB. However, if this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review.

Exceptions

Exceptions to the policy will be made where the proposed sIRB would be prohibited by a federal, state, or tribal law, regulation or policy (policy-based exceptions). Policy-based exceptions are automatically granted when identified in the sIRB plan.

The NIH sIRB policy allows the consideration of requests for other exceptions not based on a legal, regulatory, or policy requirement, if there is a compelling justification for the exception. These other exceptions must be reviewed and approved by NIH.

NIH funds many awards that are ancillary to other ongoing studies, or parent studies. During this transitional time, new multi-site non-exempt human subjects ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy. This is a standing exception until the associated parent study is submitted for competitive renewal after the effective date of the sIRB policy.

The need for this time limited exception for these ancillary studies should be documented in the sIRB plan by identifying the associated parent study and will not require review and approval of the NIH Exceptions Review Committee.

4.1.16 Investigational New Drug Applications/Investigational Device Exceptions

To be eligible for NIH funding, all clinical research involving investigational drugs and devices, or other products regulated by the FDA, must comply with all applicable FDA requirements, including those for INDs, IDEs, and human subjects protections. Among other provisions, FDA regulations for human subjects protections are published in 21 CFR Parts 50 and 56 with additional standards found in Parts 312 and 812.

When applicable, the sponsor of the IND/IDE, whether NIH, a recipient, or a third party, is legally responsible for meeting the FDA requirements for sponsors. If the sponsor is also the PI, then the sponsor will need to satisfy FDA's requirements for sponsor-investigators. If the IND/IDE sponsor is a third party, such as a pharmaceutical company or research organization under contract to a recipient or to a pharmaceutical company, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the recipient. This generally will be the case for larger, multi-site clinical trials. If the recipient is the IND/IDE holder, commonly referred to as an "investigator-initiated IND/IDE," the recipient or the investigator serves as the sponsor and assumes the legal responsibility. In any case, the recipient is ultimately responsible to NIH for ensuring compliance with the applicable requirements for protection of human subjects, including compliance with FDA's requirements.

Following the filing of an IND, FDA has a 30-day period in which to review it. FDA may allow the IND to proceed or may defer approval of the IND until changes it deems acceptable are made. FDA also may order a clinical trial to be suspended or terminated, at any time, based on information it receives about that clinical trial.

When NIH funds any part of a clinical study involving an IND or an IDE, NIH must be knowledgeable about any significant communications with FDA concerning the study. The recipient organization must report certain types of FDA communications to the NIH awarding IC within 72 hours of receiving a copy of, or upon being informed of, the FDA communication (through the PD/PI or another person acting on behalf of the recipient), whichever occurs first. This notification requirement applies to any of the following communications from FDA with the sponsor of the IND or IDE:

- Warning letters (whether sent to the recipient or to the commercial sponsor)
- Notices of Initiation of Disqualification Proceedings and Opportunity to Explain
- Notice of Opportunity for Hearing
- Notice of Disqualification
- Consent Agreements
- Clinical hold letters that pertain to breaches of good manufacturing practices, good clinical practices, or other major issue requiring significant changes in the protocol.

The notification should be made in writing, but also may be done by telephone if a written notice would delay the notification. It should include a statement of the action taken or contemplated and the assistance needed to resolve the situation. These requirements apply to the recipient even if the recipient or the NIH-funded PD/PI is the sponsor. Failure to comply with this requirement may result in NIH imposing a corrective and/or enforcement action (see Administrative Requirements—Enforcement Actions). FDA communications are considered grant-related records for purposes of retention and access (see Administrative Requirements—Monitoring—Record Retention and Access).

4.1.17 Lobbying Prohibition

Recipients of Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR 93, which also describes types of activities, such as legislative liaison activities and professional and technical services, which are not subject to this prohibition under certain circumstances.

Applicants for NIH awards are required to certify and disclose that they:

- have not made, and will not make, such a prohibited payment;
- used or will use non-appropriated funds if they have made or agreed to make such payment; and
- will include these requirements in consortium agreements and contracts under grants that will exceed $100,000 and obtain necessary certifications from those consortium participants and contractors.

Certifications and disclosures must be filed at the times prescribed in the regulations based on the expected total costs.

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in Administrative Requirements—Monitoring—Reporting.

See also Appropriation Public Policy Requirements Mandates Lobbying—Appropriation Prohibition for additional restrictions.

4.1.18 Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and recipient-prepared reports, publications, and other grant-related doc-

uments should be in metric. See Construction Grants chapter in IIB for requirements for metric usage in construction activities.

4.1.19 Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education

Section 588 of the National Defense Authorization Act of 1995, amended (10 U.S.C. §983), precludes NIH grant awards to institutions of higher education that DoD determines have an anti-Reserve Officer Training Corps (ROTC) policy or practice (regardless of when implemented) that either prohibits or, in effect, prevents the Secretary of Defense from gaining entry to campuses or access to students or information for military recruiting. DoD publishes each determination of ineligibility in the Federal Register as well as publishing, once every 6 months, a list of all currently ineligible schools. If DoD determines that an institution is ineligible during an ongoing project period, NIH will suspend support of current and future grant awards as provided in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. Funding eligibility may be restored on the basis of new information provided by DoD.

4.1.20 National Environmental Policy Act

All NIH grants, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires Federal agencies to consider the reasonably foreseeable environmental consequences of all grant-supported activities. As part of NIH's implementation of this Act, recipients are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from grant-supported activities, or certify that no such impacts will arise upon receipt of a grant award. In addition, NIH has determined that most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

This requirement is in addition to other public policy requirements for grants for construction and alteration and renovation activities discussed more fully in the Construction chapter - Construction,

Modernization, or Major Alteration and Renovation of Research Facilities—Public Policy Requirements.

4.1.21 Nondelinquency on Federal Debt

The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the AOR of the applicant organization (or individual in the case of a Kirschstein-NRSA individual fellowship) certifies, by means of his/her signature on the application, that the organization (or individual) is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, NIH will take that delinquency into account when determining whether the applicant would be a responsible NIH grant recipient.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against him or her should not be listed as a participant in an application for an NIH grant until the judgment is paid in full or is otherwise satisfied. No funds may be used for or rebudgeted following an award to pay such an individual. NIH will disallow costs charged to awards that provide funds to individuals in violation of this Act.

These requirements apply to all types of organizations and awards, including foreign grants.

4.1.22 President's Emergency Plan for AIDS Relief (PEPFAR) Program

4.1.22.1 PEPFAR Agreements

Special terms and conditions concerning prostitution and sex trafficking apply to all grants awarded under the U.S. President's Emergency Plan for AIDs Relief (PEPFAR) program. These are:

A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

B. The following definitions apply for purposes of this provision:
   1. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.
   2. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.
   3. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.

C. The Recipient must insert this provision, which is a standard provision, in all subawards or subcontracts.

D. This provision includes express terms and conditions of the award and any violation of it is grounds for unilateral termination of the award by NIH prior to the end of its term.

4.1.22.2 PEPFAR Agreements Between the U.S. Government and Foreign Non-Governmental Organizations (NGOs)

Additional requirements regarding the opposition to prostitution and sex trafficking may be applied to grants awarded under PEPFAR and issued to foreign Non-Governmental Organizations (NGOs). Subject to the United States Supreme Court's decision in Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al., 133 S. Ct. 2321 (2013) and subsequent proceedings, the terms and conditions for such agreements with foreign NGOs may include the following:

A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

B.
1. Except as provided in (B)(2) and (B)(3), by accepting this award or any subaward, a non-governmental organization or public international organization awardee/subawardee agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children. Any enforcement of this clause is subject to *Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al.*, 133 S. Ct. 2321 (2013) and subsequent proceedings.
2. The following organizations are exempt from (B)(1): the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.
3. Contractors and subcontractors are exempt from (B)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.
4. Notwithstanding section (B)(3), not exempt from (B)(1) are recipients, subrecipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any subaward, or procurement contract or subcontract by:
   i. Providing supplies or services directly to the final populations receiving such supplies or services in host countries;
   ii. Providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or
   iii. Providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

C. The following definitions apply for purposes of this provision:
1. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.

2. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.
3. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

D. The recipient shall insert this provision, which is a standard provision, in all subawards, procurement contracts or subcontracts.

E. This provision includes express terms and conditions of the award and any violation of it shall be grounds for unilateral termination of the award by NIH prior to the end of its term.

4.1.23 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH grant should be directed to the GMO.

4.1.24 Public Health Security

4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201, is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the U.S. homeland or other criminal acts. The Act was implemented, in part, through regulations published by HHS and USDA at 42 CFR 73, 9 CFR 121 and 7 CFR 331 or commonly referred to as "Select Agent Regulations." Copies of these regulations are available at http://www.selectagents.gov/Regulations.html, or can be obtained from CDC, 1600 Clifton Road, MS A-46, Atlanta, GA 30333; telephone: 404-718-2000.

Research involving select agents and recombinant or synthetic nucleic acid molecules also is subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. The *NIH Guidelines* apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organ-

ization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the *NIH Guidelines* are available at https://osp.od.nih.gov/biotechnology/nih-guidelines/.

4.1.24.1.1 Select Agents

4.1.24.1.1.1 Select Agent Awards to U.S. Institutions

Domestic recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR 73 and 9 CFR 121 and Section 3 of 7 CFR 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

4.1.24.1.1.2 Select Agent Awards to Foreign Organizations and International Organizations

Foreign Organizations and International Organizations who conduct research involving select agents (see 42 CFR 73 for the select agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens) must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by NIH funds before using these funds for any work directly involving select agents. Recipients must be willing to address the following key elements appropriate for their institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to the NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.1.1.3 Select Agent Awards to U.S. Institutions with Foreign Subcomponents

Recipients who conduct research involving select agents (see 42 CFR 73 for the select agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens) must complete registration with CDC (or USDA, depending on the agent) before using NIH funds for any work directly involving the select agent at the U.S. institution. No funds can be used for research involving select agents if the final registration certificate is denied. Before using NIH funds for any work directly involving the select agents at a foreign subrecipient, the U.S. recipient must provide information from the foreign organization satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by these funds. Recipients must be willing to address the following key elements appropriate for the foreign organization: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73 are followed. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to the NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.2 Dual Use Research of Concern

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC). This policy applies to all New and Renewal awards issued on applications submitted on or after January 25, 2015, and to all non-competing continuation awards issued on or after January 25, 2015. Institutions must then implement the Policy by September 24, 2015. DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a

significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Despite its value and benefits, some research may be misused for harmful purposes. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The DURC policy applies to recipients in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy and to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Institutions must establish an Institutional Review Entity (IRE) which must review research involving these agents or toxins to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR), as required by the U.S. Government's DURC Policy, and explain the ICDUR's role. The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

For research that may be considered DURC, NIH will work collaboratively with the institution and investigators to develop a risk mitigation plan, which may be implemented through a term of award and that the NIH must approve. For example, NIH may request that institutions periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal.

4.1.24.3 Agents Regulated Under the Chemical Weapons Convention

The United States is one of 175 States Parties to the Chemical Weapons Convention (CWC), which prohibits the development, production, stockpiling, and use of chemical weapons (CW). The CWC does not prohibit production, processing, consumption, or trade of related chemicals for peaceful purposes, but it does establish a verification regime to ensure such activities are consistent with the object and purpose of the treaty.

NIH researchers engaged in activities involving these chemicals, especially Schedule 1 chemicals, may be required to submit declarations and/or reports to the Bureau of Industry and Security (BIS) and may be subject to inspection by the Organization for the Prohibition of Chemical Weapons, which administers the CWC. In addition, trade in certain chemicals with States not Party to the CWC may be prohibited or subject to an export license and or end-use certificate.

Schedule 1 chemicals include, but are not limited to, the toxic chemicals sarin, soman, tabun, VX, sulfur mustards, Lewisites, saxitoxin, ricin, and nitrogen mustards. More information about the U.S. CWC, including complete lists of Schedule 1, 2, and 3 chemicals under the CWC may be found at http://www.cwc.gov/index.html. Federal regulations that apply to the CWC are 15 CFR CHAPTER VII, SUBCHAPTER B, PARTS 710-722, SUBCHAPTER C, PARTS 730-774; 22 CFR CHAPTER I, PART 103, PARTS 120-130. These CRFs and other applicable safety standards issued by the Department of Commerce and Department of State are available at http://www.cwc.gov/regulations_cwc_regulations.html.

4.1.25 Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees

As required by Section 403C of the Public Health Service Act, each institution receiving an NIH award for the training of graduate students for doctoral degrees must provide information on completion rates

and time to degree to all applicants to doctoral programs supported by NIH training awards. Specifically, institutions must provide applicants with the following information for the programs to which they apply:

- The percentage of students admitted for study who successfully attain a doctoral degree, and
- The average time (not including any leaves of absence) between the beginning of graduate study and the receipt of a doctoral degree.

Institutions **affected** by this Assurance and information disclosure requirement are doctoral degree granting institutions that receive any of the following institutional training grant awards or cooperative agreements from the NIH for the doctoral training of graduate students:

- D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1

Institutions are **not affected** by this requirement if they:

- Receive only individual NIH fellowship awards.
- Provide training only to undergraduate or master's level students supported through one of the activity codes listed above.
- Provide only short-term training to doctoral-level health professional students through one of the activity codes listed above.
- Receive an award for one or more of the activity codes for doctoral training of graduate students, but do not confer doctoral degrees themselves (e.g., teaching hospitals).
- Receive an institutional training grant award for doctoral training of graduate students from a Public Health Service Agency other than the NIH.

In complying with this Assurance and information disclosure requirement, institutions may decide how best to present the required information to applicants and may wish to consider consolidating data by department or broad program to which candidates apply, or providing additional information in order to provide context.

Recipients with awards for any of the activity codes listed above are also required to provide corresponding information on trainees supported by each of their awards when submitting a renewal application or RPPR.

4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules (including Human Gene Transfer Research)

4.1.26.1 Scope and Availability

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (April 2016 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the *NIH Guidelines* is available at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

According to the *NIH Guidelines*, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3)molecules that result from

the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. Two specific requirements of the *NIH Guidelines* are discussed below, but the recipient should carefully review the *NIH Guidelines* in their entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Recombinant or synthetic nucleic acid research involving select agents also is subject to pertinent CDC and USDA regulations, 42 CFR 73, Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins.

4.1.26.2 Institutional Biosafety Committee

Each organization that conducts research involving recombinant or synthetic nucleic acid molecules, including contractors under grants, must have policies and procedures to ensure compliance with the *NIH Guidelines* and must establish a standing IBC. The IBC is required to review each proposed project for recombinant or synthetic nucleic acid molecule experiments to ensure that the procedures, project, personnel, and facilities are adequate and in compliance with the *NIH Guidelines*. Section IV of the *NIH Guidelines* specifies the composition of IBCs. A roster of the IBC members and biosketches for each member must be submitted to the NIH. At a minimum, the roster should indicate the name of each IBC member, as well as which IBC members are serving as the chairperson, contact person, and, as applicable, experts in biosafety or plant, animal, or human experimentation. Biosketches should include a description of the occupation and professional qualifications of each member. Organizations can register their IBC with NIH on-line by utilizing the IBC Registration Management System (RMS). IBC-RMS can be accessed at: http://ibc-rms.od.nih.gov

4.1.26.3 Investigators and Institutional Staff

Section IV of the *NIH Guidelines* also specifies the roles and responsibilities of PIs, biological safety officers (BSOs) and recipient institutions with respect to the safe conduct and oversight of recombinant or synthetic nucleic acid research. Investigators, laboratory staff, BSOs, and institutional officials should read and be aware of their duties and expected biosafety practices, as described by the *NIH Guidelines*.

4.1.26.4 Safety and Annual Reporting

Appendix M-I-C-4 of the *NIH Guidelines* requires PIs to report serious adverse events (SAEs) that are both unexpected and possibly associated with the human gene transfer product to the NIH Office of Science Policy - Biosafety, Biosecurity, and Emerging Biotechnology Policy Division and the IBC as soon as possible but no later than 15 calendar days after the sponsor's initial receipt of the information (i.e., at the same time the event must be reported to the FDA). SAEs that are also fatal or life-threatening must be reported no later than seven calendar days. In addition, investigators must submit to OBA annual reports covering certain information about the protocol. Further information about the content of these reports can be found in Appendix M-I-C-3 of the *NIH Guidelines*. Investigators may use the GeMCRIS database (http://www.gemcris.od.nih.gov/) as an electronic tool to report adverse events or annual reports on human gene transfer trials to NIH OBA.

4.1.27 Research Misconduct

Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" specifies recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity, and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities (http://www.ori.dhhs.gov).

To be eligible for PHS funding an institution must have an assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of research misconduct in PHS-supported research that complies with 42 CFR 93. An institution establishes an assurance when an official signs the face-page (SF 424 (R&R) or PHS 398) of the grant application form or when the institution files a separate assurance form. Once established, institutions maintain their assurance by filing the Annual Report on Possible Research Misconduct (between January 1 and March 1 each year), submitting their policy for responding to allegations of research misconduct for review when requested by ORI, revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and complying with the PHS regulation.

As stated throughout the NIHGPS, the recipient has primary responsibility for ensuring that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award. The recipient must carry out its responsibilities with extra care where research misconduct has been found or where a research misconduct investigation has been initiated, as specified in 42 CFR 93, Subpart C. The recipient must report promptly to ORI any decision to initiate an investigation of research misconduct.

The regulations specify the timing of an institutional investigation, related reporting to ORI, notice to the respondent, custody of records, documentation, opportunity for respondent to comment on the report, and the components on a final institutional investigative report.

If a misconduct investigation is initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and live vertebrate animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to help recipients with investigating and reporting on research misconduct, and IC staff members are available to provide technical assistance and to work with recipients to protect funded projects from the adverse effects of research misconduct.

The recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. When the recipient finds research misconduct by anyone working on an NIH grant-supported project, whether at the recipient organization or at a third-party organization, the recipient must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and must promptly obtain NIH approval of any intended change of PD/PI or other senior/key personnel or change of scope. A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more enforcement actions including disallowance of costs, withholding of further awards, suspension, or termination. These actions are described in Administrative Requirements—Enforcement Actions.

Where research misconduct has affected data validity or reliability, ORI or NIH may require the recipient and its employee/collaborator authors to submit a correction or retraction of the data to a journal,

publish the corrected data, or both. If the recipient does not comply with this requirement, NIH may invoke its rights, under 45 CFR 75, to access the data (including copyrightable material developed under the award), have the data reviewed, and submit the correction.

4.1.28 Seat Belt Use

Pursuant to EO 13043 (April 16, 1997), Increasing the Use of Seat Belts in the United States, NIH encourages recipients to adopt and enforce on-the-job seat belt policies and programs for their employees when operating vehicles, whether organizationally owned or rented or personally owned.

4.1.29 Smoke-Free Workplace

NIH strongly encourages recipients to provide smoke-free workplaces and to promote the nonuse of tobacco products. NIH defines the term "workplace" to mean office space (including private offices and other workspace), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public spaces.

4.1.30 Standards of Conduct

NIH requires recipients to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, NIH does not require a recipient to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas as political participation and bribery. The standards also must do the following:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper.
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official.
- Include a process for notification and review by the responsible official of potential or actual violations of the standards.
- Specify the nature of penalties that the recipient may impose. These penalties would be in addition to any penalties that NIH or a cognizant Federal agency may impose for infractions that also violate the terms or conditions of award.

The recipient is not required to submit its general standards of conduct to NIH for review or approval. However, a copy must be made available to each of its officers, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH. The recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the IC CGMO if the infraction is related to an NIH award. (A listing of the NIH GMOs is available at http://grants.nih.gov/grants/stafflist_gmos.htm.) If a suspension or separation action is taken by a recipient against a PD/PI or other senior/key personnel under an NIH grant, the recipient must request prior approval of the proposed replacement as specified in Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements.

The recipient must promptly report issues involving potential criminal violations, such as misappropriation of Federal funds, to the HHS OIG .

4.1.31 Text Messaging While Driving

Executive Order 13513 (E.O. 13513) requires each Federal agency to encourage contractors, subcontractors, and grant and cooperative agreement recipients and subrecipients to adopt and enforce policies that ban text messaging while driving company-owned or -rented vehicles or Government Owned Vehicles, or while driving Personally Owned Vehicles when on official Government business or when performing any work for or on behalf of the Government.

To further the requirement of encouraging such policies, the NIH encourages recipients to consider new rules and programs, reevaluate existing programs to prohibit text messaging while driving, and conduct education, awareness, and other outreach for employees about the risks associated with texting while driving. These initiatives should encourage voluntary compliance with the recipient agency's text messaging policy while off duty.

For the purposes of this policy and pursuant to E.O. 13513, the following definitions apply:

a. ''Texting'' or ''Text Messaging'' means reading from or entering data into any handheld or other electronic device, including for the purpose of SMS texting, e-mailing, instant messaging, obtaining navigational information, or engaging in any other form of electronic data retrieval or electronic data communication.

b. ''Driving'' means operating a motor vehicle on an active roadway with the motor running, including while temporarily stationary because of traffic, a traffic light or stop sign, or otherwise. It does not include operating a motor vehicle with or without the motor running when one has pulled over to the side of, or off, an active roadway and has halted in a location where one can safely remain stationary.

4.1.32 Trafficking in Persons

This government-wide award term implements Section 106 (g) of the Trafficking Victims Protection Act (TVPA) of 2000, as amended (22 U.S.C. 7104), located at 2 CFR 175. This is implemented in accordance with OMB Interim Final Guidance, Federal Register Volume 72, No. 218, November 13, 2007. A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance.

In accordance with the statutory requirement, in each agency award under which funding is provided to a private entity, section 106(g) of the TVPA, as amended, requires the agency to include a condition that authorizes the agency to terminate the award, without penalty, if the recipient or a subrecipient —

a. Engages in severe forms of trafficking in persons during the period of time that the award is in effect;

b. Procures a commercial sex act during the period of time that the award is in effect; or

c. Uses forced labor in the performance of the award or subawards under the award.

Full text of the award term is provided at 2 CFR 175.15.

4.1.33 USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. 10 and provides criminal

penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. “Restricted persons,” as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent (see Public Health Security and Bioterrorism Preparedness and Response Act in this section).

4.1.34 Federal Awardee Performance and Integrity Information System (FAPIIS)

NIH award recipients are subject to the reporting requirements provided in Appendix XII to 45 CFR Part 75. NIH recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semi-annual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75.

The FAPIIS Public Access - Search Page is provided at https://www.fapiis.gov/fapiis/index.action.

4.1.35 Mandatory Disclosures

Consistent with 45 CFR 75.113, NIH applicants and recipients must disclose, in a timely manner, in writing to the NIH awarding IC and the HHS Office of Inspector General (OIG) all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially impacting the federal award. Subrecipients must disclose, in a timely manner, in writing to the prime recipient (pass-through entity) and the HHS OIG all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the NIH awarding IC and to the HHS OIG at the following address:

NIH CGMO listed on the NoA for the IC that funded the grant (See Part III: Points of Contact 20 INSTITUTES AND CENTERS)

AND

U.S. Department of Health and Human Services

Office of Inspector General

ATTN: Mandatory Grant Disclosures, Intake Coordinator

330 Independence Avenue, SW, Cohen Building

Room 5527

Washington, DC 20201

URL: https://oig.hhs.gov/fraud/report-fraud/index.asp

(Include "Mandatory Grant Disclosures" in the subject line")

Fax: (202) 205-0604 (Include "Mandatory Grant Discolsures" in subject line) or

Email: MandatoryGranteeDisclosures@oig.hhs.gov

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance and Administrative Requirements – Enforcement Actions, including suspension or debarment (See 2 CFR parts 180 and 376, 31 U.S.C.3321 and Public Policy Requirements and Objectives— Debarment and Suspension), as necessary and appropriate.

4.2 APPROPRIATION MANDATES

The following statutory provisions limit the use of funds on NIH grants, cooperative agreements, and contract awards. These are provided separately in this section since they are subject to change annually based on specific appropriation language that restricts the use of grant funds. References to "Act" in these sections refer to the governing HHS annual appropriation Act. A list of Appropriation Mandates applicable to each fiscal year can be found on the OER Web site.

4.2.1 Acknowledgment of Federal Funding

All HHS recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Recipients are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

See also Availability of Research Results—Rights In Data (Publication and Copyrighting) for additional information on acknowledging NIH grant support for each publication that results from NIH grant-supported research.

4.2.3 Dissemination of False or Deliberately Misleading Information

None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

4.2.4 Gun Control

NIH funds may not be used, in whole or in part, to advocate or promote gun control.

4.2.5 Human Embryo Research and Cloning Ban

NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204 (b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism not protected as a human subject under 45 CFR 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Furthermore, per the NIH Director's Statement of April 28, 2015, NIH will not fund any use of gene-editing technologies in human embryos.

In addition to the statutory restrictions on human fetal research under subsection 498((b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

4.2.6 Lobbying—Appropriation Prohibition

NIH appropriated funds may not be used, other than for normal and recognized executive-legislative relationships for publicity or propaganda purposes, for the preparation, distribution, or use of a kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State legislature or local legislature itself or designed to support or defeat any proposed or pending regulation administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. No part of any governing appropriation act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government. No part of any governing appropriation Act shall be used for any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control, except as described above. Also see Public Policy Requirements and Objectives—Lobbying Prohibition, Appropriation Mandates—Gun Control and Cost Considerations—Allowability of Costs and Activities.

4.2.7 Promotion or Legalization of Controlled Substances

Recipients are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the recipient notifies the GMO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage (see also Public Policy Requirements/Controlled Substances).

4.2.8 Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term ‘‘health benefits coverage’’ means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

4.2.8.1 Exceptions to Restrictions on Abortions

A. The limitations established in the preceding section shall not apply to an abortion —
   1. If the pregnancy is the result of an act of rape or incest; or
   2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

B. Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds).

C. Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).

D.
1. None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.
2. In this subsection, the term ''health care entity'' includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

4.2.9 Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

4.2.10 Salary Cap/Salary Limitation

None of the funds appropriated in the governing appropriation Act for the NIH (the Act), shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is on the OER Salary Cap Summary webpage.

4.2.11 Restriction of Pornography on Computer Networks

NIH appropriations since FY2014 have included the following restriction:

"(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities."

4.2.12 Compliance with Guidance on the Spread of the Ebola Virus for Applicable Grants

A grant awarded by the Department of Health and Human Services with funds made available by this title is made conditional on agreement by the awardee to comply with existing and future guidance from the Secretary regarding control of the spread of the Ebola virus.

This provision is applicable to NIH grants funded under Division G, Title VI of P.L. 113-235, Ebola Response and Preparedness.

5 THE NOTICE OF AWARD

The Notice of Award (NoA) is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. A revised NoA may be issued during a budget period to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect a recipient's post-award rebudgeting. Until an IC has issued the NoA for the initial award, any costs incurred by the applicant for the project are incurred at its own risk (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs for NIH policy on the allowability of pre-award costs).

The NoA sets forth pertinent information about the grant, including, but not limited to, the following:

- Federal award date
- Application/grant identification number (grant number)
- Federal award identification number (FAIN)
- Name of recipient organization
- Name(s) of the PD/PI(s)
- Name(s) of Senior/key personnel that are subject to NIH prior approval requirements if a significant change in level of effort occurs
- Approved period of performance start and end dates
- Budget approved by the NIH awarding IC
- Total amount of Federal funds obligated (federal share)
- Total approved cost sharing or matching, where application (Non-Federal share)
- Total amount of the Federal award
- Amount of anticipated future-year commitments (if applicable)
- Federal award project description (Project title)
- Names of the cognizant IC PO, GMO, and GMS
- CFDA Name and Program Name
- Indirect cost rate for the Federal award (including if the de minimis rate is charged per 45 CFR 75.414)
- Applicable terms and conditions of award, either by reference or inclusion
- Federal award performance goals (as required by the periodic report in the RPPR or in the final RPPR when applicable)
- Any restriction on the use of funds

Note: If applicable, section III of the NoA will also reference an institution's participation in the current phase of the Federal Demonstration Partnership (FDP).

As specified in the NoA, all awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should

test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

A recipient indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. If the recipient cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. NIH's determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal (post-award appeal rights are discussed in Administrative Requirements—Grant Appeals Procedures). Once the award is accepted by the recipient, the contents of the NoA are binding on the recipient unless and until modified by a revised NoA signed by the GMO.

5.1 NOTICE OF AWARD NOTIFICATION

NIH notifies the recipient organization via e-mail when an award has been issued-i.e., on the Federal award date. In order to allow for the e-mail notification of the NoA, recipient organizations must register a valid e-mail address in the NoA E-mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique e-mail address that is not specific to an individual in order to avoid communication problems when personnel change. It is the responsibility of the recipient organization to maintain a current and accurate e-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated e-mail notification process. Recipients that do not maintain a current NoA notification e-mail address will be responsible for accessing NoAs via the eRA Common.

On the Federal award date, the NoA is made available to recipient officials and corresponding PD/PIs in the eRA Commons through the Status module. The eRA Commons is the official repository for the NoA document.

In addition to e-mail notifications, there is a public query *Issued Notice of (Grant) Award* (http://era.nih.gov/commons/quick_queries/NIH_issued-NGAs.cfm) available on the eRA Web site to generate a list of awards issued to an organization over a selected period. The organization's Institution Profile File (IPF) Number is required in order to use the query.

5.2 ASSOCIATED APPLICATIONS AND/OR AWARDS

For some special initiatives a project or program may be funded by multiple awards that are associated with the others through special terms and conditions. These terms include any reporting requirements that would need to be coordinated in future years. When multiple awards are issued for a particular project/program at different institutions, the coordination required among the recipient institutions administering the awards will be documented in the special terms and conditions.

5.3 FUNDING

For most grants, NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH awarding IC on the basis of:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project, and
- NIH funding principles.

The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. NIH policy limits each competitive segment to a maximum of 5 years (exclusive of non-competing extensions). A single award covering the entire period of support generally is used only if the project is solely for construction or modernization of real property, if the total planned period of support will be less than 18 months, or if the project is awarded under a special support mechanism.

The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Report). A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. A recipient may appeal this decision only if the withholding was for the recipient's failure to comply with the terms and conditions of a previous award (see Administrative Requirements—Grant Appeals Procedures).

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. This provision may limit the availability of funds for carryover. It may also limit or eliminate the authority to extend the final budget period when an entire project period is funded by a single award.

5.4 BUDGET

Each NoA sets forth the amount of funds awarded. The amount may be shown either as a categorical (line item) budget or as an amount for total direct costs (not broken down by category) and an amount for F&A costs, if applicable. Modular awards represent a type of award made without a categorical budget (see Modular Applications and Awards chapter in IIB). The recipient has certain rebudgeting flexibility

within the overall amount awarded (see Administrative Requirements—Changes in Project and Budget). The recipient may be required to provide matching funds under construction awards as specified in Construction Grants—Matching in IIB as well as under other NIH programs or awards if specified in the funding opportunity announcement.

5.5 ADDITIONAL TERMS AND CONDITIONS

In addition to, or in lieu of, the standard terms and conditions of award specified in the NIHGPS, NIH may use terms and conditions for program-specific or award-specific reasons. For example, if, on the basis of a recipient's application or other available information, the GMO finds—at the time of award or at any time subsequent to award—that the recipient's management systems and practices are not adequate to ensure the appropriate stewardship of NIH funds or to achieve the objectives of the award, the GMO may impose special, more restrictive terms and conditions on the award in accordance with 42 CFR 52.9 and 45 CFR 75.371. For example, NIH could require a recipient to obtain prior approval for expenditures that ordinarily do not require such approval or to provide more frequent reports. In addition to closer monitoring, NIH may assist the recipient in taking any necessary corrective action.

6 PAYMENT

The PMS is a centralized grants payment and cash management system, operated by HHS PSC, PMS. HHS grant payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in the NoA and as described in this chapter. Payments under NIH grants generally are made as advance payments. NIH grant payments are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements, as implemented by 45 CFR75.305. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a recipient. Therefore, although the grant may be financed by advance payments, the intent is that recipients draw funds on an as-needed basis—specifically, no more than 3 business days before the funds are needed.

All Federal funds deposited by PMS in a recipient's bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds. The potential for excessive Federal cash on hand exists each time a recipient does not disburse Federal funds in this manner. The recipient is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next workday after they are received, and immediately returning all undisbursed Federal funds to PMS.

The Treasury and OMB policies also establish accountability for interest earned on advances of grant funds and provide for use of the reimbursement method if cash management requirements are not met. Advances made by recipients to consortium participants and contractors under grants must conform to substantially the same standards of timing and amount that govern advances to the recipient.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (SF 425) should be directed to PSC/PMS (see Part III).

6.1 SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a recipient's bank account and requires recipients to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the Federal Reserve Bank's (Richmond, Virginia) ACH process.

6.2 CASH REQUEST

Recipients not eligible for an unrestricted advance of funds by SMARTLINK II/ACH must submit a cash request, usually monthly. The cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding IC. Cash requests are used when a recipient's cash management must be closely monitored (for example, recipients whose financial management systems do not meet the standards specified in 45 CFR75.302) or under programs where reimbursement financing is appropriate. A recipient also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the GMO determines that a recipient is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Enforcement Actions—Modification of the Terms of Award).

If the cash request is for an advance payment, the recipient may request grant funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of Federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, a recipient must submit the request through the awarding IC early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the recipient electronically through the ACH process upon receipt of the approved payment request from the awarding IC.

6.3 INTEREST EARNED ON ADVANCES OF GRANT FUNDS

Except as provided in 45 CFR 75.302(b)(8), any NIH recipient subject to the requirements of 45 CFR 75 that receives advance payments must maintain those advances in an interest-bearing account.

Recipients are expected to promptly return any funds not spent within three business days. As provided in 45 CFR 75.305(b)(9) subject to the requirements of 45 CFR 75 and to the extent required by law, interest earned on Federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to $500 per year may be retained by the non-Federal entity for administrative expense.

6.4 IMPROPER PAYMENTS ELIMINATION AND RECOVERY IMPROVEMENT ACT

The Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (PL 112-248), signed into law on January 10, 2013, established the Do Not Pay Initiative to reduce improper payments or awards. Improper payments occur when funds go to the wrong recipient, the recipient receives the incorrect amount of funds (including overpayments and underpayments), documentation is not available to support a payment, or the recipient uses funds in an improper manner. HHS has implemented provisions of IPERIA through integrating use of the Do Not Pay system into the current payment processes managed by the PMS, HHS.

7 COST CONSIDERATION

7.1 GENERAL

Cost considerations are critical throughout the life cycle of a grant. An applicant's budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the recipient may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for recipients to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval. Prior approval requirements and authorities are discussed in Administrative Requirements—Changes in Project and Budget.

During post-award administration, the GMO, or a GMO designee, monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments (see Administrative Requirements—Closeout).

This chapter addresses the general principles underlying the allowability of costs, differentiates direct costs from F&A costs, and highlights a number of specific costs and categories of cost for NIH applicants and recipients. It is not intended to be all-inclusive and should be used as a supplement to the applicable cost principles.

7.2 THE COST PRINCIPLES

In general, NIH grant awards provide for reimbursement of actual, allowable costs incurred and are subject to Federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization (regardless whether domestic or foreign) making the expenditure. For example, a for-profit organization collaborating with a university recipient would be subject to the cost principles for commercial organizations, while the university would be subject to the cost principles for Institutions of Higher Educations (IHEs).

The cost principles are set forth in HHS regulations at in 45 CFR 75, Subpart E and Appendix IX (hospitals) to Part 75. Commercial organizations are subject to the cost principles located at 48 CFR 31.2 Federal Acquisition Regulation.

The cost principles apply to all NIH award instruments, award mechanisms, and special programs and authorities, including modular awards and awards under SNAP with one exception: they do not apply to Kirschstein-NRSA individual fellowship awards. The allowable use of funds under those awards is included in Ruth L. Kirschstein National Research Service Awards in IIB.

Recipients may use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as they meet the standards prescribed in 45 CFR 75.302 for financial management systems.

The cost principles address four tests to determine the allowability of costs. The tests are as follows:

- ***Reasonableness (Including Necessity).*** A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large as well as to the organization.
- ***Allocability.*** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the institution, including other grant-supported projects; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant. A cost is allocable as a direct cost to a grant if it is incurred solely in order to advance work under the grant or meets the criteria for closely related projects determination (see Cost Considerations—Allocation of Costs and Closely Related Work).
- ***Consistency.*** Recipients must be consistent in assigning costs to cost objectives. Costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.
- ***Conformance.*** This test of allowability—conformance with limitations and exclusions as contained in the terms and conditions of award, including those in the cost principles—varies by the type of activity, the type of recipient, and other characteristics of individual awards. Cost Considerations—Allowability of Costs/Activities provides information common to most NIH grants and, where appropriate, specifies some of the distinctions if there is a different treatment based on the type of grant or recipient. IIB contains additional information on allowability of costs for particular types of grants, recipients, and activities.

These four tests apply regardless of whether the particular category of costs is one specified in the cost principles or one governed by other terms and conditions of an award. These tests also apply regardless of treatment as a direct cost or an F&A cost. The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability.

7.3 DIRECT COSTS AND FACILITIES AND ADMINISTRATIVE COSTS

A direct cost is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the grant-supported project or activity. Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project or program. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for the management and accounting of costs consistently and must not include costs associated with its F&A rate as direct costs.

Note, the term facilities and administrative costs and the term indirect costs may be used interchangeably to determine applicable policies. For NIH purposes, including the NIHGPS, these costs will

be referred to as F&A costs; however, other documents or non-NIH entities may refer to them as indirect costs.

Project costs consist of the allowable direct costs directly related to the performance of the grant plus the allocable portion of the allowable F&A costs of the organization, less applicable credits (as described below and in the cost principles).

The amount NIH awards for each budget period will reflect the total approved budget for the grant, including direct costs and, if applicable, F&A costs. (SBIR and STTR awards also may include a fee as specified in Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs in IIB.) If a recipient waives reimbursement of full F&A costs, NIH will either not award F&A costs or will award only partial F&A costs, as appropriate. The NIH award amount shown in the NoA constitutes NIH's maximum financial obligation to the recipient under that award.

7.4 REIMBURSEMENT OF FACILITIES AND ADMINISTRATIVE COSTS

For grant programs that can provide F&A cost reimbursement, NIH will generally not provide F&A costs unless the recipient has established an F&A cost rate covering the applicable activities and period of time, except for awards under which F&A costs are reimbursed at a fixed rate.

In addition, NIH will not require a recipient to establish an F&A rate if the organization's total operations consist of a single grant-supported project or if the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project. This includes being able to identify and segregate costs on the basis of a process that assigns costs commensurate with the benefits provided to individual projects (see Administrative Requirements—Management Systems and Procedures—Financial Management System Standards).

F&A rates are negotiated by DCA, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating F&A cost rates for for-profit entities receiving awards from HHS), or other agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation. If an applicant is advised by the GMO of the need to establish a rate, the GMO will indicate the responsible office to be contacted.

F&A cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency for indirect costs, and must conform to cost policies in the NIHGPS. Further information concerning the establishment of F&A rates and the reimbursement of F&A costs may be obtained from DCA or DFAS (see Part III). DCA should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of 45 CFR 75, Subpart E-Cost Principles.

Consistent with 45 CFR 75.414(f), any institution of higher education (IHE), nonprofit organization, or state or local government that has never received a negotiated indirect cost rate, except for those non-Federal entities described in 45 CFR 75, Appendix VII, Section (D)(1)(b), may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in 45 CFR 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.

If a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used. It is not permissible for pass-through entities to force or entice a proposed subrecipient without a negotiated rate to accept less than the de minimis rate. The cost principles are designed to provide that Federal awards bear their fair share of costs recognized under these principles. (See 45 CFR 75.100(c)). Pass-through entities may, but are not required, to negotiate a rate with a proposed subrecipient that asks to do so. If the consortium is with a for-profit entity, such as a small business, the organization must have an established F&A cost rate before they can charge F&A costs. The default small business rate of 40 percent is only applicable to SBIR and STTR applications.

Regardless of the type of recipient, the rate(s) in effect at the beginning of the competitive segment will be used to determine the amount budgeted for F&A costs for each year of the competitive segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years. NIH generally will not award additional F&A costs beyond those calculated in the approved budget.

F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated and recipient type. Generally, recipients may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in the scope of the approved project. F&A cost reimbursement on grants formerly subject to OMB Circular A-21 (IHEs) is based on the rates used in the award, which are not subject to adjustment in reimbursement except for the establishment of permanent rates when a provisional rate was used for funding. Therefore, per 45 CFR 75 Appendix III C.7., recipients formerly subject to OMB Circular A-21 (IHEs) may not rebudget from direct costs to accommodate a rate increase if the F&A costs provided for a period were based on negotiated (final, fixed or predetermined) rates rather than provisional rates (defined as not “negotiated” for the application of the OMB Circular A-21 requirement). However, for recipients that were not formerly subject to OMB Circular A-21 (e.g., SBIR/STTR awardees), F&A cost reimbursement is based on the negotiated F&A rate agreement consistent with the time period when the cost is incurred, except if F&A costs were limited or not provided. F&A costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

Some grants require negotiation of project costs annually, e.g., clinical trials. For these awards, the policies pertain to each year of support rather than to a multiyear competitive segment.

Once NIH awards a grant, it is not obligated to make any supplemental or other award for additional F&A costs or for any other purpose. There are limited circumstances under which the GMO may award F&A costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for F&A costs because the applicant or recipient did not submit a timely F&A cost proposal and the recipient subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for F&A costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the F&A costs applicable to the period after the date of the recipient’s F&A cost proposal submission. This provision does not affect local governmental agencies that are not required to submit their F&A (indirect) cost proposals to the Federal government. They may charge F&A costs to NIH grants based on the rate computations they prepare and keep on file for subsequent Federal review.

If funds are available, a GMO may amend an award to provide additional funds for F&A costs, but only under the following circumstances:

- NIH made an error in computing the award. This includes situations in which a higher rate than the rate used in the grant award is negotiated and the date of the rate agreement for the higher rate is before 1 calendar month prior to the beginning date of the grant budget period.
- NIH restores funds previously recaptured as part of a recipient’s unobligated balance.

- The recipient is eligible for additional F&A costs associated with additional direct costs awarded for the supplementation or extension of a project.

NIH does not reimburse indirect costs under the following classes of awards:

- ***Fellowships.*** F&A costs will not be provided on Kirschstein-NRSA individual fellowships or similar awards for which NIH funding is in the form of fixed amounts or is determined by the normal published tuition rates of an institution and for which the recipient is not required to account on an actual cost basis.
- ***Construction and Modernization.*** F&A costs will not be provided on construction or modernization grants.
- ***Grants to Individuals.*** F&A costs will not be provided on awards to individuals.
- ***Grants to Federal Institutions.*** F&A costs will not be provided on grants to Federal institutions.
- ***Grants in Support of Scientific Meetings (Conference Grants).*** F&A costs will not be provided under grants in support of scientific meetings.
- ***Endowment Grants.*** F&A costs will not be provided for endowment grants.

NIH limits the amounts included in the F&A base for the following type of costs:

- ***Genomic Arrays (GA)*** are a high-throughput genetic analysis technology which enables the study of genetic variation and gene expression at high resolution. Approaches such as genome-wide association and gene expression profiling often depend upon manufactured products known as microarrays or bead arrays. These tools are exceptional among laboratory supplies in that they are almost always procured from a commercial source; have a relatively high unit cost and are often utilized in large numbers. The treatment of the costs for purchase of GA as “supplies” in these specialized award budgets at high levels of usage would result in the application of F&A cost recovery that is disproportionate to the actual administrative burden associated with the relatively high cost of the procurement of these GA. Accordingly, for purposes of budgeting for and award of high volume purchases of GA in excess of $50,000 per year, the standard treatment of these resources as supplies in determining the F&A base of an award will be non-applicable. Instead the requested and reimbursed costs for GA will utilize as a surrogate the concept of subcontracts (consortium/contractual cost). Therefore for each budget year, the first $50,000 of GA will be treated as “supplies”, and any GA in excess of $50,000 (for high volume requirements) will use as a surrogate the budgeting and reimbursement concept utilized for subcontracts (consortium/contractual cost), providing consistent budgeting, accounting and reimbursement of these costs.

NIH provides F&A costs without the need for a negotiated rate under the following classes of awards:

- ***Research Training and Education Grants (e.g., R25), and K Awards.*** F&A costs under Kirschstein-NRSA institutional research training grants, educational and K awards will be budgeted and reimbursed at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, expenditures for equipment, and consortiums in excess of $25,000. State, local, and Indian tribes (or "federally recognized Indian tribes") may receive full F&A cost reimbursement under NIH Kirschstein-NRSA institutional research training grants and K awards. For this policy, State universities or hospitals are not considered governmental agencies.

- ***Grants to Foreign Organizations and International Organizations.*** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. Some examples of NIH compliance requirements are the protection of human subjects (including the required education in the protection of human research participants), animal welfare, invention reporting, other post-award reporting requirements, financial conflict of interest and research misconduct. Note, these are just a few representative examples of compliance requirement; this list is not all inclusive. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Therefore, these expenses may not be requested as a direct cost; however, equipment is an allowable direct cost. *Other items normally treated as F&A costs (e.g., rent) may be requested as direct costs and will be evaluated by NIH for allowability.*

7.5 COST TRANSFERS, OVERRUNS, AND ACCELERATED AND DELAYED EXPENDITURES

Cost transfers to NIH grants by recipients, consortium participants, or contractors under grants that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the recipient, consortium participant, or contractor. An explanation merely stating that the transfer was made “to correct error” or “to transfer to correct project” is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.

Recipients must maintain documentation of cost transfers, pursuant to 45 CFR 75.364, and must make it available for audit or other review (see Administrative Requirements—Monitoring—Record Retention and Access). The recipient should have systems in place to detect such errors within a reasonable time frame; untimely discovery of errors could be an indication of poor internal controls. Frequent errors in recording costs may indicate the need for accounting system improvements, enhanced internal controls, or both. If such errors occur, recipients are encouraged to evaluate the need for improvements and to make whatever improvements are deemed necessary to prevent reoccurrence. NIH also may require a recipient to take corrective action by imposing additional terms and conditions on an award(s).

The GMO monitors recipient expenditure rates under individual grants within each budget period and within the overall project period. The funding that NIH provides for each budget period is based on an assessment of the effort to be performed during that period and the recipient’s associated budget, including the availability of unobligated balances. Although NIH allows recipients certain flexibilities with respect to rebudgeting (see Administrative Requirements—Changes in Project and Budget), NIH expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations.

The GMO may review recipient cash drawdowns to determine whether they indicate any pattern of accelerated or delayed expenditures. Expenditure patterns are of particular concern because they may

indicate a deficiency in the recipient's financial management system or internal controls. Accelerated or delayed expenditures may result in a recipient's inability to complete the approved project within the approved budget and period of performance. In these situations, the GMO may seek additional information from the recipient and may make any necessary and appropriate adjustments.

7.6 ALLOCATION OF COSTS AND CLOSELY RELATED WORK

When salaries or other activities are supported by two or more sources, issues arise as to how the direct costs should be allocated among the sources of support. In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit. A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles and the recipient's financial management system includes adequate internal controls (for example, no one person has complete control over all aspects of a financial transaction).

7.7 APPLICABLE CREDITS

The term applicable credits refers to those receipt or negative expenditure types of transactions that operate to offset or reduce direct or F&A cost items. Typical examples are purchase discounts, rebates or allowances, recoveries or indemnities on losses, and adjustments for overpayments or erroneous charges. Additional information concerning applicable credits is included in the cost principles.

Applicable credits to direct charges made to NIH grants must be treated as an adjustment on the recipient's FFR, whether those credits accrue during or after the period of grant support. (See Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout—Final Federal Financial Reports.) The NIH awarding IC will notify the recipient of any additional actions that may be necessary.

7.8 SERVICES PROVIDED BY AFFILIATED ORGANIZATIONS

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by Federal funds. Such legally independent entities are often referred to as "foundations," although this term does not necessarily appear in the name of the organization. Sometimes, the parent organization provides considerable support services, in the form of administration, facilities, equipment, accounting, and other services, to its foundation, and the latter, acting in its own right as an NIH recipient, includes the cost of these services in its F&A proposal.

Costs incurred by an affiliated, but separate, legal entity in support of a recipient foundation are allowable for reimbursement under NIH grants only if at least one of the following conditions is met:

- The affiliated organization is charged for, and is legally obligated to pay for, the services provided by the parent organization.
- The affiliated organizations are subject to State or local law that prescribes how Federal reimbursement for the costs of the parent organization's services will be expended and requires that a State or local official acting in his or her official capacity approves such expenditures.

- There is a valid written agreement between the affiliated organizations whereby the parent organization agrees that the recipient foundation may retain Federal reimbursement of parent organization costs. The parent organization may either direct how the funds will be used or permit the recipient foundation that discretion.

If none of the above conditions are met, the costs of the services provided by the parent organization to the recipient foundation are not allowable for reimbursement under an NIH grant. However, the services may be acceptable for cost-sharing (matching) purposes.

Foundations that represent already existing recipient organizations should contact DGP, OPERA before attempting to become a separately recognized applicant organization.

7.9 ALLOWABILITY OF COSTS/ACTIVITIES

The governing cost principles address selected items of cost, some of which are mentioned in this section for emphasis. This section is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of the allowability or unallowability of costs.

This section also includes NIH-specific requirements concerning costs and activities. The allowability of costs under specific NIH awards may be subject to other requirements specified in the program legislation, regulations, or the specific terms and conditions of an award, which take precedence over the general discussion provided here. Specific program requirement may also be covered in other sections of the NIH GPS. Applicants or recipients that have questions concerning the allowability of particular costs should contact the GMO.

If a cost is allowable, it is allocable as either a direct cost or an F&A cost, depending on the recipient's accounting system. For some costs addressed in this section, the text specifies whether the cost is usually a direct cost or an F&A cost.

Unless otherwise indicated in the NoA, an award based on an application that includes specific information concerning any costs or activities that require NIH prior approval constitutes the prior approval for those costs or activities. The recipient is not required to obtain any additional approval for those costs/activities. Post-award requests to incur costs or undertake activities requiring prior approval that are not described in the approved application are subject to the requirements in Administrative Requirements—Changes in Project and Budget.

Consortium participants and contractors under grants are subject to the requirements of the cost principles otherwise applicable to their type of organization and to any requirements placed on them by the recipient to be able to comply with the terms and conditions of the NIH grant.

The cost principles do not address profit or fee. NIH policy allows the payment of fee on SBIR/STTR grants (see Grants to For-Profit Organizations chapter in IIB) but NIH will not provide profit or fee to any other type of recipient under any other grant program or support mechanism. A fee may not be paid by a recipient to a consortium participant, including a for-profit organization. However, a fee (profit) may be paid to a contractor providing routine goods or services under a grant in accordance with normal commercial practice.

7.9.1 Selected Items of Cost

Exhibit 5: Selected Items of Cost

The table presents specific items that may or may not be included in the cost portion of grants

Items	Explanation of Allowable Costs
Advertising and Public Relations	1. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television, direct mail, exhibits, electronic or computer transmittals, and the like. 2. The only allowable advertising costs are those which are solely for: a. The recruitment of personnel required by the non-Federal entity for performance of a Federal award (See also 45 CFR 75.463); b. The procurement of goods and services for the performance of a Federal award; c. The disposal of scrap or surplus materials acquired in the performance of a Federal award except when non-Federal entities are reimbursed for disposal costs at a predetermined amount; or d. Program outreach and other specific purposes necessary to meet the requirements of the Federal award. 3. The term ‘‘public relations’’ includes community relations and means those activities dedicated to maintaining the image of the non- Federal entity or maintaining or relations with the community or public at large or any segment of the public. 4. The only allowable public relations costs are: a. Costs specifically required by the Federal award; b. Costs of communicating with the public and press pertaining to specific activities or accomplishments which result from performance of the Federal award (these costs are considered necessary as part of the outreach effort for the Federal award); or c. Costs of conducting general liaison with news media and government public relations officers, to the extent that such activities are limited to communication and liaison necessary to keep the public informed on matters of public concern, such as notices of funding opportunities, financial matters, etc. 5. Unallowable advertising and public relations costs include the following: a. All advertising and public relations costs other than as specified in paragraphs (2) and (4) of this section; b. Costs of meetings, conventions, convocations, or other events related to other activities of the entity (see also 45 CFR 75.432), including: i. Costs of displays, demonstrations, and exhibits; ii. Costs of meeting rooms, hospitality suites, and other special facilities used in conjunction with shows and other special events; and

Items	Explanation of Allowable Costs
	iii. Salaries and wages of employees engaged in setting up and displaying exhibits, making demonstrations, and providing briefings; c. Costs of promotional items and memorabilia, including models, gifts, and souvenirs; d. Costs of advertising and public relations designed solely to promote the non-Federal entity
Alcoholic Beverages	Unallowable as an entertainment expense, but allowable if within the scope of an approved research project.
Alteration and Renovation	Individual A&R projects that are treated as direct costs and that will not exceed $500,000 will be subject to the A&R policies specified in this exhibit and in the Construction Grants chapter, as applicable. Individual A&R projects exceeding $500,000 in direct costs will be subject to the requirements specified in the Construction Grants chapter. Routine maintenance and repair of the organization's physical plant or equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the recipient's accounting system. A&R costs are not allowable under grants to individuals, and grants in support of scientific meetings (conference grants). In all other cases, these costs are allowable unless the program legislation, implementing regulations, program guidelines, or other terms and conditions of the award specifically exclude such activity. The A&R must be consistent with the following criteria and documentation requirements: • The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required. • The A&R is essential to the purpose of the grant-supported project. • The space involved will be occupied by the project. • The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage. • If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period.

Items	Explanation of Allowable Costs
	• If the A&R will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in "Preservation of Cultural and Historic Resources" have been followed. Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost. A recipient may rebudget up to 25 percent of the total approved budget for a budget period into A&R costs without NIH prior approval unless such rebudgeting would result in a change in scope. If the rebudgeting will result in an A&R project exceeding $500,000, NIH will consider the rebudgeting to be a change in scope, and the recipient must submit to the NIH awarding IC the documentation specified in the Construction Grants chapter for prior approval of A&R projects above that dollar level. Under foreign grants or foreign components under domestic grants, major A&R (>$500,000) is unallowable. Minor A&R (<$500,000) is generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations.
Animals	Allowable for the acquisition, care, and use of experimental animals, contingent upon compliance with the applicable requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (see Public Policy Requirements and Objectives—Animal Welfare). If the recipient operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (PDF, 32 MB) - May 2000.
Audiovisual Activities	Allowable for the production of an audiovisual. "Audiovisual" means any product containing visual imagery, sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery, sound, or both are an integral part. "Production" refers to the steps and techniques used to create a finished audiovisual product including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing. A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual. If an audiovisual intended for members of the general public (i.e., people who are not researchers or health professions personnel or who are not directly involved in project activities as employees, trainees, or participants such as volunteers or patients) is produced under an NIH grant-supported project, the recipient must submit two copies of the finished product along with its annual or final progress report (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout). The costs of such copies are allowable project costs. Audiovisuals produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, such as the following:

Items	Explanation of Allowable Costs
	The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant No._____ from [name of NIH awarding IC]. Its contents are solely the responsibility of [name of recipient organization] and do not necessarily represent the official views of [name of NIH awarding IC].
Audit Services	1. A reasonably proportionate share of the costs of audits required by, and performed in accordance with, the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507), as implemented by requirements of 45 CFR 75, are allowable. However, the following audit costs are unallowable: a. Any costs when audits required by the Single Audit Act and Subpart F— Audit Requirements of 45 CFR 75 have not been conducted or have been conducted but not in accordance therewith; and b. Any costs of auditing a non- Federal entity that is exempted from having an audit conducted under the Single Audit Act and Subpart F—Audit Requirements of 45 CFR 75 because its expenditures under Federal awards are less than $750,000 during the non-Federal entity's fiscal year. 2. The costs of a financial statement audit of a non-Federal entity that does not currently have a Federal award may be included in the indirect cost pool for a cost allocation plan or indirect cost proposal. 3. Pass-through entities may charge Federal awards for the cost of agreed-upon-procedures engagements to monitor subrecipients (in accordance with Subpart D of 45 CFR 75.351 through 75.353) which are exempted from the requirements of the Single Audit Act and Subpart F of 45 CFR 75. This cost is allowable only if the agreed-upon-procedures engagements are: a. Conducted in accordance with GAGAS attestation standards; b. Paid for and arranged by the pass-through entity; and c. Limited in scope to one or more of the following types of compliance requirements: activities allowed or unallowed; allowable costs/cost principles; eligibility; and reporting.
Bad Debts	Bad debts (debts which have been determined to be uncollectable), including losses (whether actual or estimated) arising from uncollectable accounts and other claims, are unallowable. Related collection costs, and related legal costs, arising from such debts after they have been determined to be uncollectable are also unallowable. (See also 45 CFR 75.428).
Bonding	1. Bonding costs arise when the Federal awarding agency requires assurance against financial loss to itself or others by reason of the act or default of the non-Federal entity. They arise also in instances where the non-Federal entity requires similar assurance, including: bonds as bid, performance, payment, advance payment, infringement, and fidelity bonds for employees and officials.

Items	Explanation of Allowable Costs
	2. Costs of bonding required pursuant to the terms and conditions of the Federal award are allowable. 3. Costs of bonding required by the non-Federal entity in the general conduct of its operations are allowable as an indirect cost to the extent that such bonding is in accordance with sound business practice and the rates and premiums are reasonable under the circumstances.
Books and Journals	Allowable. If an organization has a library, books and journals generally should be provided as part of normal library services and treated as F&A costs.
Building Acquisition	Unallowable unless building acquisition or construction is specifically authorized by program legislation and is provided for in the NoA. For real property acquired with NIH grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees for recording the Federal interest in the real property in appropriate records of the applicable jurisdiction also may be charged to the grant. (Also see Construction Grants—Allowable and Unallowable Costs and Activities in IIB).
Capital Expenditures	See Equipment and Other Capital Expenditures.
Child Care Costs	Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see Fringe Benefits and Travel Costs in this exhibit).
Collection of Improper Payments	The costs incurred by a non-Federal entity to recover improper payments are allowable as either direct or indirect costs, as appropriate. Amounts collected may be used by the non-Federal entity in accordance with cash management standards set forth in 45 CFR 75.305. (See Improper Payment).
Communications	Allowable. Such costs include local and long-distance telephone calls, express mail, and postage, and usually are treated as F&A costs.
Conference Grant Costs	See Support of Scientific Meetings (Conference Grants) chapter in IIB for allowability of costs for scientific meetings (conferences).
Consortium Agreements/ Contracts under Grants	Allowable to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may require NIH approval as specified in Administrative Requirements—Changes in Project and Budget. (See also Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for policies that apply to the acquisition of routine goods and services and the Consortium Agreements chapter in IIB for policies that apply to recipient collaboration with other organizations in carrying out the grant-supported research).
Construction	Allowable only when program legislation specifically authorizes new construction, modernization, or major A&R, and NIH specifically authorizes such costs in the NoA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy

Items	Explanation of Allowable Costs
	(see Construction Grants chapter in IIB).
Consultant Services	See Professional Services and Salaries and Wages/Intra-IHE Consulting.
Contingency Provisions	Unallowable. Payments made by the NIH awarding IC to the non-Federal entity's "contingency reserve" or any similar payment made for events the occurrence of which cannot be foretold with certainty as to the time or intensity, or with an assurance of their happening, are unallowable under non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see Reserve Funds in this exhibit). (See also Construction Grants—Allowable and Unallowable Costs and Activities in IIB concerning contingency funds under construction grants).
Customs and Import Duties	Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (See Taxes in this exhibit).
Depreciation or Use Allowances	Allowable. Such costs usually are treated as F&A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable.
Donor Costs	Allowable as payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related. Donor costs are not considered a research patient care expense (see the Research Patient Care Costs chapter in IIB). Also see Incentive Costs in this exhibit.
Drugs	Allowable if within the scope of an approved research project. Project funds may not be used to purchase drugs classified by FDA as "ineffective" or "possibly effective" except in approved clinical research projects or in cases where there is no alternative other than therapy with "possibly effective" drugs.
Dues or Membership Fees	Allowable as an F&A cost for organizational membership in business, professional, or technical organizations or societies. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds. See also Membership, Subscription, and Professional Activity costs.
Entertainment Costs	Costs of entertainment, including amusement, diversion, and social activities and any associated costs are unallowable, except where specific costs that might otherwise be considered entertainment have a programmatic purpose and are authorized either in the approved budget for the Federal award or with prior written approval of the NIH awarding IC.
Equipment and Other Capital Expenditures	The following rules of allowability must apply to equipment and other capital expenditures:

Items	Explanation of Allowable Costs
	1. Capital expenditures for general purpose equipment, buildings, and land are unallowable as direct charges, except with the prior written approval of the NIH awarding IC or pass-through entity. 2. Capital expenditures for special purpose equipment are allowable as direct costs, provided that items with a unit cost of $25,000 or more, or that relate to a change in scope, have the prior written approval of the NIH awarding IC or pass-through entity. 3. Capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life are unallowable as a direct cost except with the prior written approval of the NIH awarding IC, or pass-through entity. See Depreciation for rules on the allowability of depreciation on buildings, capital improvements, and equipment. See also Rental Costs of Real Property and Equipment. 4. When approved as a direct charge pursuant to items (1) through (3) above, capital expenditures will be charged in the period in which the expenditure is incurred, or as otherwise determined appropriate and negotiated with the NIH awarding IC. 5. The unamortized portion of any equipment written off as a result of a change in capitalization levels may be recovered by continuing to claim the otherwise allowable depreciation on the equipment, or by amortizing the amount to be written off over a period of years negotiated with the Federal cognizant agency for indirect cost. 6. Cost of equipment disposal. If the non-Federal entity is instructed by the NIH awarding IC to otherwise dispose of or transfer the equipment the costs of such disposal or transfer are allowable. See also Capital Expenditures, Equipment, Special Purpose Equipment, General Purpose Equipment, Acquisition Cost, and Capital Assets.
Federal (U.S. Government) Employees	See Grants to Federal Institutions and Payments to Federal Employees under Grants—Allowable and Unallowable Costs in IIB for the allowability of payments made to, or on behalf of, Federal employees under NIH grants, including grants to Federal institutions.
Fines, Penalties, Damages and Other Settlements	Costs resulting from non-Federal entity violations of, alleged violations of, or failure to comply with, Federal, state, tribal, local or foreign laws and regulations are unallowable, except when incurred as a result of compliance with specific provisions of the Federal award, or with prior written approval of the NIH awarding IC.
Fringe Benefits	Fringe benefits are allowances and services provided by employers to their employees as compensation in addition to regular salaries and wages. Fringe benefits include, but are not limited to, the costs of leave (vacation, family related, sick or military), employee insurance, pensions, and unemployment benefit plans. Except as provided elsewhere in 45 CFR 75 Subpart E, the costs of fringe benefits are allowable provided that the benefits are reasonable and are required by law, non-Federal entity-employee agreement, or an established policy of the non-

Items	Explanation of Allowable Costs
	Federal entity. For policies applicable to tuition remission for students working on grant-supported research projects, see Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit. See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Allowable and Unallowable Costs—Tuition and Fees and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs—Trainee Tuition and Fees in IIB for the allowability of tuition costs for fellows and trainees.
Fringe Benefits / IHE *Tuition/Tuition Remission*	Tuition remission and other forms of compensation paid as, or in lieu of, wages to students under research grants are allowable, provided the following conditions are met: 1. The individual is conducting activities necessary to the Federal award. 2. Tuition remission and other support are provided, in accordance with established institutional policy, of the IHE and consistently provided in a like manner to students in return for similar activities conducted under Federal awards as well as other activities. 3. During the academic period, the student is enrolled in an advanced degree program at a non-Federal entity or affiliated institution and the activities of the student in relation to the Federal award are related to the degree program. 4. The tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work. 5. It is the IHE's practice to similarly compensate students under Federal awards as well as other activities Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to the reporting requirements in 45 CFR 75.430(i). NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of 45 CFR 75 Subpart E and its current operating guidelines. The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is the zero-level Kirschstein-NRSA stipend in effect when NIH issues the grant award (see current levels posted at http://grants.nih.gov/training/nrsa.htm). Payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project.
Fringe Benefits / Insurance	Allowable. Insurance usually is treated as an F&A cost. In certain situations, however, where special insurance is required as a condition of the grant because of risks peculiar to the project, the premium may be charged as a direct cost if doing so is consistent with organizational policy. Medical liability (malpractice) insurance is an allowable cost of research programs at all types of recipients only if the research involves human subjects. If so, the insurance must be treated as a

Items	Explanation of Allowable Costs
	direct cost and must be assigned to individual grants based on the manner in which the insurer allocates the risk to the population covered by the insurance. See also Reserve Funds. The cost of insuring equipment, whether purchased with project funds or furnished as federally owned property, normally should be included in F&A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy. Health insurance for trainees and fellows is addressed in the Ruth L. Kirschstein National Research Service Awards chapter in IIB.
Fringe Benefits / Pension Plan Costs	Pension plan costs which are incurred in accordance with the established policies of the non- Federal entity are allowable, provided that: 1. Such policies meet the test of reasonableness. 2. The methods of cost allocation are not discriminatory. 3. For entities using accrual based accounting, the cost assigned to each fiscal year is determined in accordance with GAAP. 4. The costs assigned to a given fiscal year are funded for all plan participants within six months after the end of that year. However, increases to normal and past service pension costs caused by a delay in funding the actuarial liability beyond 30 calendar days after each quarter of the year to which such costs are assignable are unallowable. Non-Federal entity may elect to follow the ''Cost Accounting Standard for Composition and Measurement of Pension Costs'' (48 CFR 9904.412). 5. Pension plan termination insurance premiums paid pursuant to the Employee Retirement Income Security Act (ERISA) of 1974 (29 U.S.C. 1301–1461) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and other penalties imposed under ERISA are unallowable. 6. Pension plan costs may be computed using a pay-as-you-go method or an acceptable actuarial cost method in accordance with established written policies of the non-Federal entity. a. For pension plans financed on a pay-as-you-go method, allowable costs will be limited to those representing actual payments to retirees or their beneficiaries.

Items	Explanation of Allowable Costs
	b. Pension costs calculated using an actuarial cost-based method recognized by GAAP are allowable for a given fiscal year if they are funded for that year within six months after the end of that year. Costs funded after the six month period (or a later period agreed to by the cognizant agency for indirect costs) are allowable in the year funded. The cognizant agency for indirect costs may agree to an extension of the six month period if an appropriate adjustment is made to compensate for the timing of the charges to the Federal government and related Federal reimbursement and the non-Federal entity's contribution to the pension fund. Adjustments may be made by cash refund or other equitable procedures to compensate the Federal government for the time value of Federal reimbursements in excess of contributions to the pension fund. c. Amounts funded by the non- Federal entity in excess of the actuarially determined amount for a fiscal year may be used as the non- Federal entity's contribution in future periods. d. When a non-Federal entity converts to an acceptable actuarial cost method, as defined by GAAP, and funds pension costs in accordance with this method, the unfunded liability at the time of conversion is allowable if amortized over a period of years in accordance with GAAP. e. The Federal government must receive an equitable share of any previously allowed pension costs (including earnings thereon) which revert or inure to the non-Federal entity in the form of a refund, withdrawal, or other credit.
Fringe Benefits / *Severance Pay*	1. Severance pay, also commonly referred to as dismissal wages, is a payment in addition to regular salaries and wages, by non-Federal entities to workers whose employment is being terminated. Costs of severance pay are allowable only to the extent that in each case, it is required by: a. law, b. employer-employee agreement, c. established policy that constitutes, in effect, an implied agreement on the non- Federal entity's part, or d. circumstances of the particular employment. 2. Costs of severance payments are divided into two categories as follows: a. Actual normal turnover severance payments must be allocated to all activities; or, where the non-Federal entity provides for a reserve for normal severances, such method will be acceptable if the charge to current operations is reasonable in light of payments actually made for normal severances over a representative past period, and if amounts charged are allocated to all activities of the non- Federal entity.

Items	Explanation of Allowable Costs
	b. Measurement of costs of abnormal or mass severance pay by means of an accrual will not achieve equity to both parties. Thus, accruals for this purpose are not allowable. However, the Federal government recognizes its obligation to participate, to the extent of its fair share, in any specific payment. Prior approval by the Federal awarding agency or cognizant agency for indirect cost, as appropriate, is required. 3. Costs incurred in certain severance pay packages which are in an amount in excess of the normal severance pay paid by the non-Federal entity to an employee upon termination of employment and are paid to the employee contingent upon a change in management control over, or ownership of, the non-Federal entity's assets, are unallowable. 4. Severance payments to foreign nationals employed by the non-Federal entity outside the United States, to the extent that the amount exceeds the customary or prevailing practices for the non-Federal entity in the United States, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC. 5. Severance payments to foreign nationals employed by the non-Federal entity outside the United States due to the termination of the foreign national as a result of the closing of, or curtailment of activities by, the non-Federal entity in that country, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC.
Fundraising and Investment Management Costs	1. Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred to raise capital or obtain contributions are unallowable. Fund raising costs for the purposes of meeting the Federal program objectives are allowable with prior written approval from the Federal awarding agency. (See also Proposal Costs). 2. Costs of investment counsel and staff and similar expenses incurred to enhance income from investments are unallowable except when associated with investments covering pension, self-insurance, or other funds which include Federal participation allowed by 45 CFR 75. 3. Costs related to the physical custody and control of monies and securities are allowable. 4. Both allowable and unallowable fund raising and investment activities must be allocated as an appropriate share of indirect costs under the conditions described in 45 CFR 75.413.
Genomic Arrays	Allowable as a direct cost, but with specialized treatment of F&A reimbursement for costs exceeding $50,000 in each budget year. See Cost Considerations-Reimbursement of Facilities and Administrative Costs for more information.
Hazardous Waste Disposal	Allowable; usually treated as an F&A cost.

Items	Explanation of Allowable Costs
Honoraria	Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable.
Hospitalization	See Research Patient Care in this exhibit.
Incentive Costs	Incentive payments to volunteers or patients participating in a grant-supported project or program are allowable. Incentive payments to individuals to motivate them to take advantage of grant-supported health care or other services are allowable if within the scope of an approved project. See Salaries and Wages/Incentive Compensation in this exhibit for incentive payments to employees.
Indemnification	Absent express statutory authority, unallowable if the indemnification would result in liability that is indefinite, indeterminate or potentially unlimited. In those rare cases where authority does allow this cost, it would be reflected in the NoA.
Independent Research and Development Costs	Independent research and development is research and development which is conducted by an organization, and which is not sponsored by Federal or non-Federal awards, contracts, or other agreements. Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development. The cost of independent research and development, including their proportionate share of indirect costs, are unallowable.
Intellectual Property (Invention, Copyright, Patent, or Licensing Costs)	Unallowable as a direct cost unless specifically authorized on the grant award. May be allowable as F&A costs, provided they are in accordance with 45 CFR 75.448 and are included in the negotiation of F&A cost rates.
Interest	Allowable as an F&A cost for certain assets as specified in 45 CFR 75.449. Unallowable for hospitals (45 CFR Pt 75, Appendix IX, I.o). (see Payment—Interest Earned on Advances of Grant Funds).
IRB or IACUC Costs	Costs associated with IRB review of human research protocols, or IACUC review of animal research protocols, are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.
Laboratory Directed Research & Development	NIH awards to DOE laboratories will not include the proportionate share of F&A costs for Laboratory Directed Research & Development (LDRD) in accordance with the MOU with the Department of Energy dated June 18, 1998, although the NIH will not restrict the DOE laboratory contractors from recovering LDRD costs within the total funding included in an award. In addition, DOE has agreed to waive the Overhead Rate on all NIH grant awards to DOE laboratory contractors.
Leave	Allowable for employees as a fringe benefit (see Fringe Benefits in this exhibit). See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Other Terms and Conditions—Leave and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Other Terms and Conditions—Leave in IIB for NIH policy on leave for fellows and trainees.

Items	Explanation of Allowable Costs
Legal Services	Allowable. Generally treated as an F&A cost but, subject to the limitations described in the applicable cost principles, may be treated as a direct cost for legal services provided by individuals who are not employees of the recipient organization. Before a recipient incurs legal costs that are extraordinary or unusual in nature, the recipient should make an advance agreement regarding the appropriateness and reasonableness of such costs with the GMO. Legal costs incurred in defending or prosecuting claims, whether equitable or monetary, including administrative grant appeals, are unallowable charges to NIH grant-supported projects, except as provided in the 45 CFR 75.
Library Services	General library support is not allowable as a direct cost but may be included in the recipient's F&A pool. However, such services are allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity (e.g., in those programs designed to develop and support such services).
Lobbying	Generally unallowable, in accordance with 45 CFR 75.450, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a State legislature. Under certain circumstances, as provided in 45 CFR 74.450(c)(2)(i), costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant may be allowable. The recipient should obtain an advance understanding with the GMO if it intends to engage in these activities. Unallowable for State and Local governments and for-profit organizations. (Also see Public Policy Requirements and Objectives—Lobbying Prohibition, Appropriation Mandates – Lobbying – Appropriation Prohibition, and Administrative Requirements—Monitoring—Reporting concerning lobbying restrictions, the required certification, and reporting).
Maintenance and Repair Costs	Costs incurred for utilities, insurance, security, necessary maintenance, janitorial services, repair, or upkeep of buildings and equipment (including Federal property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are allowable. Costs incurred for improvements which add to the permanent value of the buildings and equipment or appreciably prolong their intended life must be treated as capital expenditures (see § 75.439). These costs are only allowable to the extent not paid through rental or other agreements.
Materials and Supplies Costs, including Costs of Computing Devices.	1. Costs incurred for materials, supplies, and fabricated parts necessary to carry out a Federal award are allowable. 2. Purchased materials and supplies must be charged at their actual prices, net of applicable credits. Withdrawals from general stores or stockrooms should be charged at their actual net cost under any recognized method of pricing inventory withdrawals, consistently applied. Incoming transportation charges are a proper part of materials and supplies costs.

Items	Explanation of Allowable Costs
	3. Materials and supplies used for the performance of a Federal award may be charged as direct costs. In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award. 4. Where federally-donated or furnished materials are used in performing the Federal award, such materials will be used without charge.
Meals	Allowable for subjects and patients under study, or where specifically approved as part of the project activity, provided that such charges are not duplicated in participants' per diem or subsistence allowances, if any. When certain meals are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), grant funds may be used for such meals only when consistent with terms of award. The cost of meals served at a meeting or conference, for which the primary purpose is the dissemination of technical information, is no longer allowable on NIH grants where the primary purpose of the grant is to support a conference or meeting (see also Support of Scientific Meetings (Conference Grants) Section 14.10.1). However, when such a meeting/conference is an ancillary effort under a grant where the primary purpose is other than to support such a meeting/conference, then the cost of meals would be allowable. When allowable as a direct charge, the cost of any meal must meet a test of reasonableness. However, recurring business meetings, such as staff meetings, should not be broadly considered as meetings for the primary purpose of disseminating technical information in order to justify charging meals or refreshment costs to grants.
Membership, Subscription, and Professional Activity Costs	1. Costs of the non-Federal entity's membership in business, technical, and professional organizations are allowable as an F&A cost. 2. Costs of the non-Federal entity's subscriptions to business, professional, and technical periodicals are allowable. 3. Costs of membership in any civic or community organization are allowable with prior approval by the NIH awarding IC or pass-through entity. 4. Costs of membership in any country club or social or dining club or organization are unallowable. 5. Costs of membership in organizations whose primary purpose is lobbying are unallowable. See also Lobbying. 6. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds.
Moving	See Recruitment Costs, Relocation Costs, and Transportation Costs in this exhibit.

Items	Explanation of Allowable Costs
Nursery Items	Allowable for the purchase of items such as toys and games to allow patients to participate in research protocols.
Overtime	See Salaries and Wages/Extra Service Pay (Overtime) in this exhibit.
Participant Support Costs	Only allowable when identified in specific FOAs.
Pre-Award (Pre-Agreement) Costs	Allowable. A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs: • are necessary to conduct the project, and • would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award. Recipients may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above. The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the recipient's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. Pre-Award Costs are generally not applicable to training grants or fellowships. See respective sections for Individual Fellowships and Institutional Training Grants in the Ruth L. Kirschstein National Research Service Award chapter in IIB for additional information.
Professional Services Costs	1. Costs of professional and consultant services rendered by persons who are members of a particular profession or possess a special skill, and who are not officers or employees of the non-Federal entity, are allowable, subject to paragraphs (b) and (c) below when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Federal government. In addition, legal and related services are limited under 45 CFR 75.435. 2. In determining the allowability of costs in a particular case, no single factor or any special combination of factors is necessarily determinative. However, the following factors are relevant: a. The nature and scope of the service rendered in relation to the service required.

Items	Explanation of Allowable Costs
	b. The necessity of contracting for the service, considering the non-Federal entity's capability in the particular area. c. The past pattern of such costs, particularly in the years prior to Federal awards. d. The impact of Federal awards on the non-Federal entity's business (i.e., what new problems have arisen). e. Whether the proportion of Federal work to the non-Federal entity's total business is such as to influence the non- Federal entity in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under Federal awards. f. Whether the service can be performed more economically by direct employment rather than contracting. g. The qualifications of the individual or concern rendering the service and the customary fees charged, especially on non-federally funded activities. h. Adequacy of the contractual agreement for the service (e.g., description of the service, estimate of time required, rate of compensation, and termination provisions). 3. In addition to the factors in paragraph (b) above, to be allowable, retainer fees must be supported by evidence of bona fide services available or rendered. Recipients, consortium participants, and contractors under grants are encouraged to obtain written reports from consultants unless such a report is not feasible given the nature of the consultation or would not be useful. Documentation maintained by the receiving organization should include the name of the consulting firm or individual consultant; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise apparent from the nature of the services; the period of service; the basis for calculating the fee paid (e.g., rate per day or hour worked or rate per unit of service rendered); and the amount paid. This information may be included in the consultant's invoice, in the report, or in another document. See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter in IIB for allowable costs associated with consultant payments to Federal employees and the circumstances of allowability. See Salaries and Wages/Intra-IHE Consulting.
Profit or Fee	Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a for-profit organization, whether as a recipient or as a consortium participant. A profit or fee under a grant is not a cost, but is an amount in excess of actual allowable direct and F&A costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an NIH grant providing routine goods or services to the recipient.
Proposal Costs	Proposal costs are the costs of preparing bids, proposals, or applications on potential Federal and non-Federal awards or projects, including the development of

Items	Explanation of Allowable Costs
	data necessary to support the non-Federal entity's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect (F&A) costs and allocated currently to all activities of the non- Federal entity. No proposal costs of past accounting periods will be allocable to the current period.
Public Relations Costs	See Advertising and Public Relations.
Publication and Printing Costs	1. Publication costs for electronic and print media, including distribution, promotion, and general handling are allowable. If these costs are not identifiable with a particular cost objective, they should be allocated as indirect costs to all benefiting activities of the non-Federal entity. 2. Page charges for professional journal publications are allowable where: a. The publications report work supported by the Federal government; and b. The charges are levied impartially on all items published by the journal, whether or not under a Federal award. c. The non-Federal entity may charge the Federal award before closeout for the costs of publication or sharing of research results if the costs are not incurred during the period of performance of the Federal award. Publications and journal articles produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, as appropriate, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.
Rearrangement and Reconversion Costs	See Alteration and Renovation costs.
Recruiting Costs	1. Subject to paragraphs (2) and (3) of this section, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of "help wanted" advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to the non- Federal entity's standard recruitment program. Where the non-Federal entity uses employment agencies, costs not in excess of standard commercial rates for such services are allowable. 2. Special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel that do not meet the test of reasonableness or do not conform with the established practices of the non-Federal entity, are unallowable.

Items	Explanation of Allowable Costs
	3. Where relocation costs incurred incident to recruitment of a new employee have been funded in whole or in part as a direct cost to a Federal award, and the newly hired employee resigns for reasons within the employee's control within 12 months after hire, the non-Federal entity will be required to refund or credit the Federal share of such relocation costs to the Federal government. See also Relocation Costs of Employees. 4. Short-term, travel visa costs (as opposed to longer-term, immigration visas) are generally allowable expenses that may be proposed as a direct cost. Since short-term visas are issued for a specific period and purpose, they can be clearly identified as directly connected to work performed on a Federal award. For these costs to be directly charged to a Federal award, they must: a. Be critical and necessary for the conduct of the project; b. Be allowable under the applicable cost principles; c. Be consistent with the non-Federal entity's cost accounting practices and non-Federal entity policy; and d. Meet the definition of "direct cost" as described in the applicable cost principles. Project funds may not be used for a prospective trainee's travel costs to or from the recipient organization for the purpose of recruitment. However, other costs incurred in connection with recruitment under training programs, such as advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles (also see Travel, Relocation Costs, and Visa Costs in this exhibit).
Registration Fees (for Symposiums and Seminars)	Allowable if necessary to accomplish project objectives.
Relocation Costs of Employees	Allowable—in other than change of recipient organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the recipient's benefit rather than the individual's and that payment is made according to established organizational policies consistently applied regardless of the source of funds. Relocation costs may include the cost of transporting the employee and his or her family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home. If relocation costs have been incurred in connection with the recruitment of a new employee, whether as a direct cost or an F&A cost, and the employee resigns for reasons within his or her control within 12 months after hire, the recipient must credit the grant account for the full cost of the relocation charged to the grant. When there is a change in the recipient organization, the personal relocation expenses of the PD/PI and others moving from the original recipient to the new recipient are not allowable charges to NIH grants (see Administrative

Items	Explanation of Allowable Costs
	Requirements—Changes in Project and Budget—Prior Approval Requirements).
Rental or Lease of Facilities and Equipment	Allowable subject to the limitations below. Rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives. Because of the complexity involved in determining the allowable amount under certain types of leases, recipients are encouraged to consult the GMO before entering into leases that will result in direct charges to the grant project. In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for an exception to this general rule. Rental costs under leases that create a material equity in the leased property, as defined in 45 CFR 75 Subpart E, are allowable only up to the amount that would be allowed had the recipient purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, and insurance, but would exclude unallowable costs. When a recipient transfers property to a third party through sale, lease, or otherwise, and then leases the property back from that third party, the lease costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the recipient continued to own the property. Rental costs under “less-than-arms-length” leases are allowable only up to the amount that would be allowed under 45 CFR 75 Subpart E had title to the property been vested in the recipient. A less-than-arms-length lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest.
Research Patient Care	The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research programs are allowable. Incurrence of patient care costs if not previously approved by NIH and rebudgeting additional funds into, or rebudgeting approved amounts out of, the research patient care costs category may be considered a change in scope and require prior approval by the NIH awarding IC. Routine services include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. Ancillary services are those special services for which charges customarily are made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See the Research Patient Care Costs chapter in IIB for NIH policy concerning reimbursement of these costs. The following otherwise allowable costs are not classified as research patient care

Items	Explanation of Allowable Costs
	costs: items of personal expense such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the "Other Expenses" category of the grant budget.
Reserve Funds	Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see Fringe Benefits/Insurance and Contingency Provisions in this exhibit).
Salaries and Wages / *IHEs - Part-time faculty*	Charges for work performed on Federal awards by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for part-time assignments.
Salaries and Wages / *IHEs - Periods outside the academic year*	1. Except as specified for teaching activity in paragraph (2) below, charges for work performed by faculty members on Federal awards during periods not included in the base salary period will be at a rate not in excess of the IBS. 2. Charges for teaching activities performed by faculty members on Federal awards during periods not included in IBS period will be based on the normal written policy of the IHE governing compensation to faculty members for teaching assignments during such periods.
Salaries and Wages / *IHEs - Sabbatical Leave Costs*	Sabbatical leave costs may be included in a fringe benefit rate or in the organization's F&A rate. Salary may be charged directly to a project for services rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual's regular salary from his or her organization.
Salaries and Wages / *Standards for Documentation of Personnel Expenses*	Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate payroll distribution system that documents such distribution in accordance with Federal Cost Principles and consistently applied institutional policy and practices. See 45 CFR 75.430(i).
Salaries and Wages	Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reasonably reflect the percentage of time actually devoted to the NIH-funded project. Direct salary is exclusive of fringe benefits and F&A costs. This salary guidance does not apply to consultant payments or to contracts for routine goods and services but it does apply to consortium participants (see the Consortium Agreements chapter in IIB). Salaries of federal employees with permanent appointments are unallowable except in certain circumstances (see the Grants to Federal Institutions and Payments to Federal Employees Under Grants chapter in IIB).

Items	Explanation of Allowable Costs
Salaries and Wages / *Extra Service Pay (Overtime)*	Extra Service Pay normally represents overload compensation, subject to institutional compensation policies for services above and beyond IBS. Where extra service pay is a result of Intra-IHE consulting, it is subject to the reasonableness standards for Salaries and Wages above. It is allowable if all of the following conditions are met: 1. The non-Federal entity establishes consistent written policies which apply uniformly to all faculty members, not just those working on Federal awards. 2. The non-Federal entity establishes a consistent written definition of work covered by IBS which is specific enough to determine conclusively when work beyond that level has occurred. This may be described in appointment letters or other documentations. 3. The supplementation amount paid is commensurate with the IBS rate of pay and the amount of additional work performed. 4. The salaries, as supplemented, fall within the salary structure and pay ranges established by and documented in writing or otherwise applicable to the non-Federal entity. 5. The total salaries charged to Federal awards including extra service pay are subject to the Standards of Documentation as described in Salaries and Wages/IHEs.
Salaries and Wages / *Institutions of higher education (IHEs)*	Certain conditions require special consideration and possible limitations in determining allowable personnel compensation costs under Federal awards. Allowable activities: Charges to Federal awards may include reasonable amounts for activities contributing and directly related to work under an agreement, such as delivering special lectures about specific aspects of the ongoing activity, writing reports and articles, developing and maintaining protocols (human, animals, etc.), managing substances/chemicals, managing and securing project-specific data, coordinating research subjects, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences.
Salaries and Wages / *Intra-IHE Consulting*	Intra-IHE consulting by faculty is assumed to be undertaken as an IHE obligation requiring no compensation in addition to IBS. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the faculty member is in addition to his or her regular responsibilities, any charges for such work representing additional compensation above IBS are allowable provided that such consulting arrangements are specifically provided for in the Federal award or approved in writing by the NIH awarding IC. Recipients, consortium participants, and contractors under grants that want to be able to charge employee consulting costs to grant-supported projects must establish written guidelines permitting such payments regardless of the source of funding and indicating the conditions under which the payment of consulting fees to employees is proper. Under no circumstances may an individual be paid as a consultant and an employee under the same NIH grant.

Items	Explanation of Allowable Costs
	Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be documented in writing, on a case-by-case basis, by the head of the organization (or his/her designee) incurring the costs – i.e., the recipient organization, consortium participant, or contractor. If the designee is personally involved in the project, the authorization may be given only by the head of the recipient organization, consortium participant, or contractor. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest.
Salaries and Wages / *Nonprofit Organizations*	For compensation to members of nonprofit organizations, trustees, directors, associates, officers, or the immediate families thereof, determination should be made that such compensation is reasonable for the actual personal services rendered rather than a distribution of earnings in excess of costs. This may include director's and executive committee member's fees, incentive awards, allowances for off-site pay, incentive pay, location allowances, hardship pay, and cost-of-living differentials.
Salaries and Wages / *Professional Activities outside of the Non-Federal Entity*	Unless an arrangement is specifically authorized by an NIH awarding IC, a non-Federal entity must follow its written non-Federal entity-wide policies and practices concerning the permissible extent of professional services that can be provided outside the non-Federal entity for non-organizational compensation. Where such non-Federal entity-wide written policies do not exist or do not adequately define the permissible extent of consulting or other non-organizational activities undertaken for extra outside pay, the Federal government may require that the effort of professional staff working on Federal awards be allocated between: 1. Non-Federal entity activities, and 2. Non-organizational professional activities. If the NIH awarding IC considers the extent of non-organizational professional effort excessive or inconsistent with the conflicts-of-interest terms and conditions of the Federal award, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.
Salaries and Wages / *Special Considerations*	Special considerations in determining allowability of compensation will be given to any change in a non-Federal entity's compensation policy resulting in a substantial increase in its employees' level of compensation (particularly when the change was concurrent with an increase in the ratio of Federal awards to other activities) or any change in the treatment of allowability of specific types of compensation due to changes in Federal policy.
Salaries and Wages / *Unallowable Costs*	1. Costs which are unallowable under other sections of these principles must not be allowable under this section solely on the basis that they constitute personnel compensation.

Items	Explanation of Allowable Costs
	2. The allowable compensation for certain employees is subject to a ceiling in accordance with statute. For the amount of the ceiling for cost reimbursement contracts, the covered compensation subject to the ceiling, the covered employees, and other relevant provisions, see 10 U.S.C. 2324(e)(1)(P), and 41 U.S.C. 1127 and 4304(a)(16). For other types of Federal awards, other statutory ceilings may apply.
Salaries and Wages /*Incentive Compensation*	Incentive compensation to employees based on cost reduction, or efficient performance, suggestion awards, safety awards, etc., is allowable to the extent that the overall compensation is determined to be reasonable and such costs are paid or accrued pursuant to an agreement entered into in good faith between the non-Federal entity and the employees before the services were rendered, or pursuant to an established plan followed by the non-Federal entity so consistently as to imply, in effect, an agreement to make such payment.
Salaries and Wages /*Overtime Premiums*	Premiums for overtime generally are allowable; however, such payments are not allowable for faculty members at institutions of higher education. If overtime premiums are allowable, the categories or classifications of employees eligible to receive overtime premiums should be determined according to the formally established policies of the organization consistently applied regardless of the source of funds.
Salaries and Wages /*Payments for Dual Appointments*	For investigators receiving compensation from the institution (recipient/contractor) and separately organized clinical practice plans, compensation from such sources may be included in the institutional base salary (IBS) budgeted and charged to NIH sponsored agreements if all of the following criteria are met: • Clinical practice compensation must be set by the institution. * • Clinical practice activity must be shown on the institution's payroll or salary appointment forms and records approved by the institution. • Clinical practice compensation must be paid through or at the direction of the institution. • Clinical practice activity must be included and accounted for in the institution's effort reporting and/or payroll distribution system. • The institution must assure that all financial reports and supporting documents associated with the combined IBS and resulting charges to NIH grants are retained and made available to Federal officials or their duly authorized representatives consistent with the requirements of 45 CFR 75.430(h). * “Set by the institution” means the recipient/contractor institution must be in a position to document and certify that the specified amount of clinical practice compensation is being paid in essentially the same manner as other specified amounts of the committed IBS (compensation) of the investigator. Further, this requires that the IBS not vary based on the specific clinical services provided by investigator within the periods for which total IBS is certified by the recipient institution.

Items	Explanation of Allowable Costs
Salaries and Wages /*Support from Multiple Grants*	See Cost Considerations—Allocation of Costs and Closely Related Work.
Selling and Marketing Costs	Costs of selling and marketing any products or services of the non-Federal entity (unless allowed under 45 CFR 75.421) are unallowable, except as direct costs, with prior approval by the NIH awarding IC when necessary for the performance of the Federal award.
Service Charge	Allowable. The costs to a user of organizational services and central facilities owned by the recipient organization, such as central laboratory, technology infrastructure fees, computer services and next generation computing/communication costs, are allowable provided that they are not covered by F&A costs. They must be based on organizational fee schedules consistently applied regardless of the source of funds.
Specialized Service Facilities	1. The costs of services provided by highly complex or specialized facilities operated by the non-Federal entity, such as computing facilities, wind tunnels, and reactors are allowable, provided the charges for the services meet the conditions of either paragraphs (b) or (c) of this section, and, in addition, take into account any items of income or Federal financing that qualify as applicable credits under 45 CFR 75.406. 2. The costs of such services, when material, must be charged directly to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology that: a. Does not discriminate between activities under Federal awards and other activities of the non-Federal entity, including usage by the non- Federal entity for internal purposes, and b. Is designed to recover only the aggregate costs of the services. The costs of each service must consist normally of both its direct costs and its allocable share of all indirect (F&A) costs. Rates must be adjusted at least biennially, and must take into consideration over/under applied costs of the previous period(s). c. Where the costs incurred for a service are not material, they may be allocated as indirect (F&A) costs. d. Under some extraordinary circumstances, where it is in the best interest of the Federal government and the non-Federal entity to establish alternative costing arrangements, such arrangements may be worked out with the Federal cognizant agency for indirect costs.
Stipends	Allowable as cost-of-living allowances for trainees and fellows only under Kirschstein-NRSA individual fellowships and institutional research training grants. These payments are made according to a preestablished schedule based on the individual's experience and level of training. A stipend is not a fee-for-service payment and is not subject to the cost accounting requirements of the cost principles. Additional information, including NIH policy on stipend

Items	Explanation of Allowable Costs
	supplementation, is included in Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Supplementation of Stipends, Compensation, and Other Income—Stipend Supplementation and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Stipend Supplementation, Compensation, and Other Income—Stipend Supplementation in IIB. Stipends are not allowable under research grants even when they appear to benefit the research project. See Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit.
Subject Costs	See Research Patient Care and Donor Costs in this exhibit.
Taxes	For nonprofit organizations and IHEs: 1. In general, taxes which the non-Federal entity is required to pay and which are paid or accrued in accordance with GAAP, and payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable, except for: a. Taxes from which exemptions are available to the non-Federal entity directly or which are available to the non-Federal entity based on an exemption afforded the Federal government and, in the latter case, when the NIH awarding IC makes available the necessary exemption certificates, b. Special assessments on land which represent capital improvements, and c. Federal income taxes. 2. Any refund of taxes, and any payment to the non-Federal entity of interest thereon, which were allowed as Federal award costs, will be credited either as a cost reduction or cash refund, as appropriate, to the Federal government. However, any interest actually paid or credited to an non-Federal entity incident to a refund of tax, interest, and penalty will be paid or credited to the Federal government only to the extent that such interest accrued over the period during which the non-Federal entity has been reimbursed by the Federal government for the taxes, interest, and penalties.
Termination or Suspension Costs	Unallowable except as follows. If a grant is terminated or suspended, the recipient may not incur new obligations after the effective date of the termination or suspension and must cancel as many outstanding obligations as possible (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support). NIH will allow full credit to the recipient for the Federal share of otherwise allowable costs if the obligations were properly incurred by the recipient before suspension or termination—and not in anticipation of it—and, in the case of termination, are not cancelable. The GMO may authorize other costs in, or subsequent to, the notice of termination or suspension.
Trailers and Modular Units	Allowable only if considered equipment as provided below. A “trailer” is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a

Items	Explanation of Allowable Costs
	dwelling or place of business. A "modular unit" is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to NIH grant-supported projects depends on whether such units are classified as real property or equipment. The classification will depend on whether the recipient's intended use of the property is permanent or temporary. A trailer or modular unit is considered real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to an NIH grant-supported project unless authorizing legislation permits construction or acquisition of real property and the specific purchase is approved by the NIH awarding IC. A trailer or modular unit is considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to NIH grant-supported projects only if the terms and conditions of the award do not prohibit the purchase of equipment and NIH prior approval is obtained, as appropriate. A trailer or modular unit properly classified as real property or as equipment at the time of acquisition retains that classification for the life of the item, thereby determining the appropriate accountability requirements under 45 CFR Part 75.439 or 75.465, as applicable.
Trainee Costs	Allowable only under predoctoral and postdoctoral training grants. (See Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs in IIB for detailed information).
Transportation Costs	Costs incurred for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation cost may be charged to the appropriate indirect (F&A) cost accounts if the non-Federal entity follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms and conditions of the Federal award, should be treated as a direct cost.
Travel	Allowable as a direct cost where such travel will provide direct benefit to the project.
Travel/*Employees*	Consistent with the organization's established travel policy, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile. Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada.

Items	Explanation of Allowable Costs
	Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country. In all cases, travel costs are limited to those allowed by formally established organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. For-profit recipients' allowable travel costs may not exceed those established by the FTR, issued by GSA, including the maximum per diem and subsistence rates prescribed in those regulations. This information is available at http://www.gsa.gov. If a recipient organization has no established travel policy, those regulations will be used to determine the amount that may be charged for travel costs. Recipients are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets if travel schedules can be planned in advance (such as for national meetings and other scheduled events). Recipients must comply with the requirements of the Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S. flag air carriers and under applicable Open Skies Agreements. For additional information regarding the Fly America Act and its exceptions, see Public Policy Requirements and Objectives—Fly America Act. Applicants and recipients should consult application instructions to determine how to budget for travel costs under specific mechanisms and for certain types of travelers, because they are not all required to be budgeted as travel (e.g., research subjects).
Travel/*Research Patients*	If research patient care is an approved activity of the grant-supported project, the costs of transporting individuals participating in the research protocol to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose also may be allowable. (See also Research Patient Care in this exhibit).
Value Added Tax (VAT)	Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. Foreign tax refunds or applicable credits under Federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to Federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-Federal entity relate to allowable cost, these costs must be credited to the NIH awarding IC either as costs or cash refunds. If the costs are credited back to the Federal award, the non-Federal entity may reduce the Federal share of costs by the amount of the foreign tax reimbursement, or where Federal award has not expired, use the foreign government tax refund for approved activities under the Federal award with prior approval of the NIH awarding IC. For many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
Visa Costs	Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual. Visa

Items	Explanation of Allowable Costs
	costs may also be allowable when identified in specific FOAs or when within the scope of an approved research project. When included as a recruiting cost it is the responsibility of the institution to monitor the status of the individual's visa and ensure they have sufficient time to fulfill the obligations of the research they are being paid for on the grant. However, if the person is already an employee and the cost in question is a visa renewal then this isn't a recruiting cost so the cost would not be an allowable charge to a grant. Expedited processing fees are generally unallowable unless and until they become part of standard processing fees. Fraud prevention and detection fees are allowable if they are required fees. Department of Homeland Security SEVIS Form I-901 is a required fee and is allowable.

8 ADMINISTRATIVE REQUIREMENTS

8.1 CHANGES IN PROJECT AND BUDGET

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities. The recipient-initiated changes that may be made under the recipient's authority and the changes that require NIH approval are outlined below and, with respect to particular types of awards, activities, or recipients, in Subpart IIB. In addition, individual awards may restrict recipients' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained in writing from, the awarding IC GMO in advance of the change or obligation of funds as specified later in this chapter under Requests for Prior Approval.

Recipients shall immediately notify the Federal awarding agency of developments that have a significant impact on the award-supported activities. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

Changes in project or budget resulting from NIH-initiated actions are discussed in other sections of this chapter.

8.1.1 NIH Standard Terms of Award

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approvals; these are known as expanded authorities. In 2001, NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances. Certain award instruments, grant programs, and types of recipients are routinely excluded from the authority to automatically carry over unobligated balances. This includes centers (P50, P60, P30, and others); cooperative agreements (U); Kirschstein-NRSA institutional research training grants (T); non-Fast Track Phase 1 SBIR and STTR awards (R43 and R41); clinical trials (regardless of activity code); and awards to individuals.

One or more of these authorities may be overridden by a special term or condition of the award. Recipients must review the NoA to determine if a particular authority is withheld for a specific grant.

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Several authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding IC. Recipients should be aware that any consistent pattern of failure to adhere to those deadlines for reporting or notification will be grounds for excluding that recipient from a specific authority.

Exhibit 6. Summary of NIH Standard Terms of Award

Recipient Authorities as NIH Standard Terms of Award	Exceptions
Carryover of unobligated balances from one budget period to any subsequent period	Centers (P50, P60, P30 and others), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NoA indicates otherwise.
Cost-related prior approval changes, including research patient care costs and equipment	The cost would result in a change of scope.
Extension of final budget period of a project period without additional NIH funds (no-cost extension)	The recipient has already exercised its one-time authority to extend the award for up to 12 months; the NIH awarding IC has previously extended the project period; and/or a project is multi-year for 5 years (i.e., the entire 5-year project period is funded by a single award).
Transfer of performance of substantive programmatic work to a third party (by consortium agreement)	The transfer would be to a foreign component or it would result in a change in scope.
Direct charge the salaries of administrative and clerical staff if conditions in 45 CFR 75.413 are met and the charges also meet the criteria for allowable costs described in 45 CFR 75.403	
Direct charge payments of Incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) 45 CFR 75.430 (h)(ii). Such activities must be specifically provided for in the Federal award budget.	
Include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member's base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member's regular departmental load.	

8.1.1.1 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Recipients should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority, or if prior approval is required by the NIH awarding IC. Note the authority to automatically carry over unobligated balances includes the authority to carryover from one competitive segment to another.

Automatic carryover of unobligated balances applies to all awards except centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials (regardless of activity code), and awards to individuals. For these grants, carryover of unobligated balances requires NIH awarding IC prior approval unless otherwise noted in the NoA. Other awards may be excluded from this authority through a special term or condition in the NoA.

For awards under SNAP (see Administrative Requirements—Monitoring—Reporting—Streamlined Non-Competing Award Process for applicability), funds are automatically carried over to the subsequent budget period. However, the recipient will be required to indicate, as part of the grant's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance is greater than 25 percent of the total approved budget, the recipient must provide an explanation and indicate plans for expenditure of those funds within the current budget year.

For awards that require an annual FFR, the amount to be carried over must be specified under item 12, "Remarks."

For both SNAP and non-SNAP, when a recipient reports a balance of unobligated funds in excess of 25 percent of the total amount awarded for the budget period, plus any approved carryover of funds from a prior year(s), the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the recipient, including a revised budget, as part of the review.

If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset NIH funding for a subsequent budget period, or use a combination of these actions. The GMO also may indicate whether the balance may be carried forward to a budget period other than the succeeding one. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the terms and conditions of the NoA.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the availability of funds for carryover.

8.1.1.2 Cost-Related Prior Approvals

NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope.

8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds

The recipient may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original completion date shown in the NoA if:

- no term of award specifically prohibits the extension,
- no additional funds are required to be obligated by the NIH awarding IC, and
- the project's originally approved scope will not change.

Such an action affirms that additional work remains to be completed on the project and that resources are available to continue to support the project, or that additional time is needed to provide for an orderly closeout. The fact that funds remain at the completion date of the grant is not, in itself, sufficient justification for an extension without additional funds.

With the exception of grant programs that have an effort requirement, or where terms and conditions prohibit such reductions, NIH will not require prior approval for the reduction in effort for Senior/Key personnel named in the NOA. The recipient is reminded that active awards must have a measurable level of effort.

Recipients must use the eRA Commons No-Cost Extension feature to electronically notify NIH that they are exercising their one-time authority to extend without funds the completion date of an award. This extension feature becomes available to the recipient 90 days before the project period end date. Extensions may be up to 12 months beyond the final budget period end date. In the eRA Commons, this notification can be made up to the last day of the current project end date. An e-mail notification is automatically sent to the GMO. No further action by the recipient is required.

Notifications may not be submitted via e-mail or fax. If a no-cost extension notification is submitted late, the eRA Commons No-Cost Extension feature cannot be used. Instead, the extension notification becomes a request and that requires the approval of the IC GMO. Recipients who miss the window (or opportunity) to extend the grant in eRA Commons must submit a written prior approval request to the NIH awarding IC for consideration. (See Administrative Requirements—Prior Approval Requirements for extension requiring additional funds.)

In extending the final budget period of the project period through this process, the recipient agrees to update all required certifications and assurances, including but not limited to those pertaining to human subjects and vertebrate animals, in accordance with applicable regulations and policies. Recipients are reminded that all terms and conditions of the award apply during the extension period.

Recipients may not extend project periods that were previously extended by the NIH awarding IC. Any additional project period extension requires NIH prior approval. (See Administrative Requirements—Prior Approval Requirements for extensions requiring additional funds.)

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit or eliminate this authority to extend the final budget period when an entire project period is funded by a single award.

The provisions in this subsection do not apply to fellowship awards.

8.1.1.4 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement

Prior approval by the NIH awarding IC is not required to transfer the performance of already peer reviewed programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

8.1.1.5 Direct Charging Salaries of Administrative and Clerical Staff

The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:

1. Administrative or clerical services are integral to a project or activity;
2. Individuals involved can be specifically identified with the project or activity;
3. Such costs are explicitly included in the budget; and
4. The costs are not also recovered as indirect costs.

Such charges must also meet the criteria for allowable costs described in 45 CFR 75.403.

NIH prior approval is not required to rebudget funds for this direct cost item post-award. Prior approval is only required when additional funds are being requested for such a position.

8.1.1.6 Supplemental Compensation under Written Institutional Policy for IHEs

IHEs may direct charge payments of incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) and not include them in the records described in 45 CFR 75.430 (h)(ii). Such activities must be specifically provided for in the Federal award budget.

8.1.1.7 Intra-IHE Faculty Consulting that Exceed a Faculty Member's Base Salary, Under Certain Conditions.

IHEs may include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member’s base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member’s regular departmental load.

8.1.2 Prior Approval Requirements

This section describes the activities and/or expenditures that require NIH prior approval. NIH prior approval requirements are summarized in Exhibit 7, which is provided for guidance only. For the prior approval requirements specified in the exhibit, approval is required whether or not the change has a budgetary impact. The circumstances under which prior approval is required also are summarized in the exhibit.

Recipients also should consult Subpart IIB for prior approval requirements that apply to specific mechanisms, types of grants, and types of recipients.

Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the GMO.

Exhibit 7. Summary of Actions Requiring NIH Prior Approval

NIH prior approval is required for	Under the following circumstances
Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension (8.1.2.1)	All instances.
A&R (8.1.2.2)	Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period. If rebudgeting would not meet this threshold but would result in a change in scope. Any single A&R project exceeding $500,000.
Capital expenditures (construction, land, or building acquisition) (8.1.2.3)	All instances. Also, any proposals to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds.
Carryover of unobligated balances (8.1.2.4)	If the NoA indicates that the recipient does not have the authority to automatically carry over unobligated balances.
Change in scope (8.1.2.5)	All instances.
Change in status of the PD/PI or senior/key personnel named in the NoA (8.1.2.6)	A significant change in the status including but not limited to withdrawal from the project; absence for any continuous period of 3 months or more; reduction of the level of effort devoted to project by 25 percent or more from what was approved in the initial competing year award.
Change of recipient organization (8.1.2.7)	All instances.
Change of recipient organization status (8.1.2.8)	All instances.
Deviation from award terms and conditions (8.1.2.9)	All instances. Includes undertaking any activities disapproved or restricted as a condition of the award.
Foreign component added to a grant to a domestic or foreign organization (8.1.2.10)	All instances.
Make subawards based on fixed amounts (8.1.2.11)	All instances
Need for additional NIH funding (8.1.2.12 and 8.1.2.13)	All instances, including extension of a final budget period of a project period with additional funds.
Pre-award costs (8.1.2.14)	More than 90 days before effective date of the initial budget period of a new or competing continuation award; always at the recipient's own risk.

NIH prior approval is required for	Under the following circumstances
Rebudgeting funds from trainee costs (8.1.2.15)	All instances.
Rebudgeting of funds between construction and non-construction work (8.1.2.16)	All instances.
Retention of research grant funds when CDA awarded (8.1.2.17)	All instances.

8.1.2.1 Additional No-cost Extension or Extension Greater Than 12 Months or Late Notification of Initial No-Cost Extension

The NIH Standard Terms of Award provide the recipient the authority to extend the final budget period of a previously approved project period one time for a period of up to 12 months beyond the original completion date down in the NoA. Any additional project period extension beyond the initial extension of up to 12 months requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the funds available to support the extension. Further any late notification of the initial no-cost extension provided by the NIH Standard Terms of Award also requires prior approval.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period.

8.1.2.2 Alterations and Renovations

NIH prior approval is required if a recipient wishes to rebudget more than 25 percent of the total approved budget for a budget period into A&R costs. NIH prior approval also is required for lesser rebudgeting into A &R costs if the rebudgeting would result in a change in scope. If rebudgeting results in an A&R project exceeding $500,000, NIH always will consider the rebudgeting to be a change in scope. (See the Construction Grants chapter in IIB for documentation requirements for A&R projects exceeding $500,000).

8.1.2.3 Capital Expenditures

Capital expenditures for land or buildings require NIH prior approval. In addition, real property acquired with NIH grant funds may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient without the written prior approval of the NIH awarding IC or its successor organization.

8.1.2.4 Carryover of Unobligated Balances

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority or if prior approval is

required by the NIH awarding IC. When NIH prior approval is required, the AOR should submit a request to the GMO that includes at a minimum the following information:

- A detailed budget by direct cost category with the F&A cost information (base and rate) for the proposed use of the carryover funds. If personnel costs are requested, include a detailed breakdown of personnel costs, including base salary, salary requested and effort to be spent on the project during the extension. In general, carryover action requiring prior approval will be approved using the F&A rate that was in effect at the time the initial funds were awarded for the year to which the funds are being carried over. For example, if the carryover is approved from year -01 to year -03, the F&A rate used to calculate the revised -03 year award will be the rate used to initially calculate year -03. However, actual expenditures will still be based on the rate applicable when the cost is incurred.
- A scientific justification for the use of funds.
- The reason for the unobligated balance.

8.1.2.5 Change in Scope

In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the recipient must obtain prior approval from the NIH awarding IC for a change in scope. A change in scope is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project. The recipient must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Potential indicators of a change in scope include, but are not limited to, the following:

- Change in the specific aims approved at the time of award.
- Substitution of one animal model for another.
- Change from the approved use of live vertebrate animals.

- Change from the approved involvement of human subjects that would result in an increased risk. This includes:
    - An addition or change that would result in changing the overall human subjects or clinical trial designation of the award;
        - From non-human subjects research to human subjects research (exempt or non-exempt);
        - From exempt to non-exempt human subjects research; or
        - From "No Clinical Trial" to "Includes a Clinical Trial." Requests for this change must be submitted to a clinical trial FOA as a competitive revision. See NIH definition of clinical trial and 2.3.5 - Types of Funding Opportunity Announcements.
    - The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR 46 subparts B, C or D (pregnant women, human fetuses, and neonates; prisoners; or children).
    - Any change to the study protocol that would increase the risk level for subjects including physical, psychological, financial, legal or other risks. This could include the addition of a new study population that would be at higher risk from existing research procedures, the addition of new study procedures that are greater than minimal risk, any modification of existing study procedures that would increase overall risk, or the addition of a new clinical study or a new clinical trial intervention arm not originally proposed that is greater than minimal risk.
    - New information indicating a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.
- Shift of the research emphasis from one disease area to another.
- A clinical hold by FDA under a study involving an IND or an IDE.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, NIH prior approval is always required.
- Change in other senior/key personnel not specifically named in the NoA (see Change in Status, Including Absence, of PD/PI and Other Senior/Key Personnel Named in the NoA below for requirements for NIH approval of alternate arrangements for or replacement of named senior/key personnel).
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is $200,000, any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.

- Incurrence of research patient care costs if costs in that category were not previously approved by NIH or if a recipient desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.
- Purchase of a unit of equipment exceeding $25,000.

8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

The recipient is required to submit a prior approval request to the GMO if:

- There is a significant change in the status of the PD/PI or other Senior/Key Personnel specifically named in the NoA including but not limited to withdrawing from the project entirely, being absent from the project during any continuous period of 3 months or more, or reducing time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award (for example, a proposed change from 40 percent effort to 30 percent or less effort or in calendar months a change from 4.8 to 3.6 calendar months). Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting **Yes** in the RPPR constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.
- There is a change from a multiple PD/PI model to a single PD/PI model.
- There is a change from a single PD/PI model to a multiple PD/PI model.
- There is a change in the number or makeup of the PD/PIs on a multiple PD/PI award.

NIH must approve any alternate arrangement proposed by the recipient, including any replacement of the PD/PI or senior/key personnel named in the NoA, and the addition of any new PD/PIs.

The request for approval of any additional or substitute PD/PIs or Senior/Key Personnel named in the NoA, or change from a multiple PD/PI model to a single PD/PI model, must be accompanied by a strong scientific justification related to the scientific project, including any proposed changes in scope, the biographical sketch of any new individuals proposed and other sources of support, and any budget changes resulting from the proposed change. A new or revised Leadership Plan is required if the request is to change from a single PD/PI model to a multiple PD/PI model, or to change the number or makeup of the PD/PIs on a multiple PD/PI award. The Commons ID must be provided for any new PD/PIs.

If the arrangements proposed by the recipient, including the qualifications of any proposed replacement, are not acceptable to the NIH awarding IC, the grant may be suspended or terminated. If the recipient wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

The requirement to obtain NIH prior approval for a change in status pertains only to those personnel NIH designates in the NoA regardless of whether the applicant organization designates others as senior/key personnel for its own purposes.

8.1.2.7 Change of Recipient Organization

NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment). A change of recipient organization may be accomplished under most NIH grants if any of the following conditions are met:

- The original recipient has agreed to relinquish responsibility for an active project before the completion date of the approved project period. This includes any proposed change of recipient as a result of a PD/PI on a research project transferring from one organization to another organization. The project under the same PD/PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.
- The grant to be transferred has been terminated in accordance with 45 CFR part 75.372.
- A non-competing continuation award that is within an approved project period has been withheld because of the recipient's actions (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

A change of recipient that involves the transfer of a grant to or between foreign organizations or international organizations also must be approved by the IC's Advisory Council or Board.

A grant to an individual may not be transferred.

A successor-in-interest or a name change is not considered a change of recipient (see Change in Recipient Organizational Status below).

A change of recipient organization may involve the transfer of equipment purchased with grant funds. The transfer may be accomplished as part of the original recipient's relinquishment of the grant; otherwise, NIH reserves the right to transfer title to equipment to the new organization as indicated in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

A change of recipient request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project. NIH will also consider the length of time, the percentage of funds, and the amount of work remaining in the project period. A change may be made without peer review, provided the PD/PI plans no significant change in research objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding IC may require peer review or may disapprove the request and, if appropriate, terminate the award.

A change of recipient organization request must be made before the anticipated start date at the new organization and preferably several months in advance. Failure to provide timely notification may result in disapproval of the request or significant delays in processing. Recipients are encouraged to discuss any potential issues with the awarding IC(s) prior to submitting a change of recipient organization request. If requesting a transfer in the middle of a budget period or at the end of the Federal fiscal year, recipients should contact the awarding IC for IC-specific guidance on the timing and preparation of the change of institution application.

A request for a change of recipient organization must be submitted to the GMO. The original institution must include an Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement). The relinquishing statement may be submitted in paper or electronically via the eRA Commons. Final FFR Expenditure Data and a Final Invention Statement are due to NIH from the relinquishing organization no later than 120 days after the end of NIH support of the project. Final FFR Expenditure Data should not be submitted until the original institution has received a revised NoA for the relinquished grant.

The proposed new recipient institution must provide the GMO with a change of institution application which may be submitted using the PHS 398 or PHS 416-1 paper application forms, or electronically via Grants.gov using the Parent Funding Opportunity Announcement listed at http://-grants.nih.gov/grants/guide/parent_announcements.htm. If the original award was the result of a modular application and the recipient will submit a paper change of institution application, the modular procedures apply to the request for change of recipient. If the original award was the result of a modular application and the recipient will submit an electronic change of institution application, the recipient may submit a detailed budget or streamlined-detailed budget (as described in the FOA).

The paper application from the proposed new recipient institution should include, at a minimum, the following:

- PHS 398 Face page
- Budget pages (current and future years). (Under awards resulting from modular applications, the application should include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs (plus applicable F&A costs) previously recommended for any budget period. For transfers in the middle of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC. For these applications, recipients will also need to include the Other Project Information and the Senior/Key Personnel components.
- Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel.
- If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- Updated “other support” page(s), if necessary.
- Resources page, including probable effect of the move on the project.
- Checklist page
- Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
- Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment).

The electronic application from the proposed recipient institution should include, at a minimum, the following:

- SF 424 (R&R) Cover Component
- SF 424 (R&R) Project Performance Site Location(s)

- SF 424 (R&R) Other Project Information:
  - Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
  - Facilities and Other Resources, including probable effect of the move on the project.
  - Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of the list in the transfer application from the new organization indicates its acceptance of title to that equipment).
- SF 424 (R&R) Senior/Key Person Profile:
  - Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel, and updated "other support" page(s) as necessary.
- Budget pages applicable for activity code (current and future years). If the budget for the original award was submitted in a modular format, use the R&R Detailed Budget form for all electronic applications. Recipients may either complete all of the fields in the R&R Detailed Budget as appropriate or complete only the costs for the PD/PI (Section A), and include the remainder of the direct costs under Section F (Other Direct Costs) Item 8, and Section H (Indirect Costs). (For awards resulting from modular applications, include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs previously recommended for direct costs (plus applicable F&A costs) for any budget period. For transfers during the course of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC.
- PHS 398 Research Plan
  - If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- PHS 398 Cover Page Supplement
- PHS 398 Checklist

And, as applicable:

- PHS 398 Career Development Supplemental Form
- PHS 398 Fellowship Supplemental Form
- SBIR/STTR Information

NIH may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by NIH does not guarantee approval of a transfer application for the continued funding of a project.

NIH will accomplish a change of recipient organization by issuing a revised NoA to the original recipient reflecting the revised budget/project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. (A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement or the available balance in PMS, whichever is less.)

Concurrently, the new recipient will receive the NoA reflecting the direct cost balance reported on the relinquishing statement plus applicable F&A costs, if funds are available. If the change of recipient

organization occurs on the anniversary date of the project, the NoA to the new recipient will reflect the previously committed direct cost level plus applicable F&A costs if funds are available. If the change of recipient organization occurs during the course of the budget period, the policy of the awarding IC will determine if the NoA to the new recipient will reflect the direct cost relinquished by the former recipient plus applicable F&A costs or the total costs relinquished by the former recipient. This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs before the beginning date of a transfer award. The recipient may do so only if those costs are necessary to conduct the project and would not require prior approval if incurred under an awarded grant. For the purposes of pre-award costs, transfers are treated like non-competing continuation awards. Therefore, the pre-award costs incurred are not limited to 90 days prior to the beginning date of the initial budget period of that transferred award to the new recipient organization.

8.1.2.8 Change in Recipient Organizational Status

Recipients must give NIH advance notice of the following types of change in organizational status (not a change of recipient organization as described above):

- ***Merger.*** Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.
- ***Successor-in-Interest (SII).*** Process whereby the rights to and obligations under an NIH grant (s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
- ***Name Change.*** Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.

Advance notification is required to ensure that the recipient remains able to meet its legal and administrative obligations to NIH, and payments are not interrupted.

Recipients are encouraged to contact the GMO of the lead NIH awarding IC to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or SII. The lead awarding IC ordinarily will be the IC with which the organization has the most NIH grants. NIH reserves the right to review the material provided, seek clarification or additional information, and make an independent determination.

A recipient's formal request for a change in organizational status should be submitted to NIH as soon as possible so that NIH can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a SII, a letter signed by the AORs of the current recipient (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding IC, following consultation with the GMO of that awarding IC. The letter must include the following:

- Stipulate that the transfer will be properly affected in accordance with applicable law.
- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.
- Request that the awarding IC(s) modify its (their) records to reflect the transferee as the recipient of record.

- State the effective date of the transfer.
- Provide the transferee's EIN. If EIN is new, include completed Form W-9.
- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance).
- Include a list of all affected NIH grants (active and pending) with the following information for each:
    - Complete grant number (e.g., 5 R01 GM 12345-04).
    - Name(s) of PD/PI(s).
    - Current budget period and project period.
    - The total direct costs (as originally recommended) plus applicable F&A costs for each remaining budget period. If the SII will occur during a budget period rather than on the anniversary date, the transferor also must provide estimated levels of current-year direct and F&A costs remaining as of the SII effective date. The estimate may be reported on the PHS 3734 (Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant), which may be submitted on paper or electronically through the eRA Commons, or may be itemized by grant number as an attachment to the letter. When an SII occurs during a budget period, the deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as reported on the relinquishing statement or the available balance in PMS, whichever is less.
- Include a complete face page (PHS 398) for each affected grant showing the transferee as the applicant organization. Each face page must be signed by an AOR at the transferee organization.
- Include a copy of the current negotiated F&A rate agreement for the transferee.

NIH is currently piloting the electronic submission of some of the items required for a successor-in-interest request. After discussions with the lead NIH awarding IC, recipients may choose to submit an electronic application for a successor-in-interest request to satisfy the requirement for the face page(s), confirmation of the transferee's EIN, verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance), and Relinquishing Statement. The electronic application is submitted via Grants.gov using the Parent Funding Opportunity Announcement at http://grants.nih.gov/grants/guide/parent_announcements.htm.

In order to be recognized as the SII, the "new" (transferee) organization must meet each grant program's eligibility requirements; except for grants awarded under the SBIR/STTR programs. See Small Business Innovation Research and Small Business Technology Transfer Programs—Eligibility in IIB for additional guidance. Upon review and acceptance of this information, NIH will revise the NoA(s) to show the transferee as the recipient of record.

For name changes, the recipient's written notification to the lead NIH awarding IC must include the effective date of the change. Revised face pages are not required for name changes because name changes are reported and processed with the next award action (e.g., non-competing continuation award).

8.1.2.9 Deviation from Award Terms and Conditions, including Restrictions in the NoA

NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NoA, including those in the NIHGPS. This includes undertaking any activities disapproved or restricted as a condition of the award.

8.1.2.10 Foreign Component Added to a Grant to a Domestic or Foreign Organization

Adding a foreign component under a grant to a domestic or foreign organization requires NIH prior approval.

8.1.2.11 Provide Subawards Based on Fixed Amounts

With NIH prior approval, a pass-through entity may provide subawards based on fixed amounts (as defined in 45 CFR Part 75.2), to which the following conditions apply:

1. The Fixed amount subaward is negotiated using the cost principles (or other pricing information) as a guide. The pass-through entity may use fixed amount subawards if the project scope is specific and if adequate cost, historical, or unit pricing data is available to establish a fixed amount subaward based on a reasonable estimate of actual cost. Payments are based on meeting specific requirements of the subaward. Accountability is based on performance and results. Except in the case of termination before completion of the subaward, there is no governmental review of the actual costs incurred by the non-Federal entity in performance of the subaward. Some of the ways in which the fixed amount subaward may be paid include, but are not limited to:
    a. In several partial payments, the amount of each agreed upon in advance, and the "milestone" or event triggering the payment also agreed upon in advance, and set forth in the subaward;
    b. On a unit price basis, for a defined unit or units, at a defined price or prices, agreed to in advance of performance of the subaward and set forth in the subaward; or,
    c. In one payment at subaward completion.
2. A fixed amount subaward cannot be used in programs which require mandatory cost sharing or match.
3. The non-Federal entity must certify in writing to the pass-through entity at the end of the subaward that the project or activity was completed or the level of effort was expended. If the required level of activity or effort was not carried out, the amount of the subaward must be adjusted.
4. Periodic reports may be established for each fixed amount subaward.
5. Changes in principal investigator, project leader, project partner, or scope of effort must receive the prior written approval of the pass-through entity.

When considering the use of a fix amount subaward, note the distinction between a fixed-amount subaward and a fixed-rate agreement.

In a fixed amount subaward, the total value of the award is negotiated upfront. This requires the pass-through entity to know both the unit price and the total number of units that will be provided. In a fixed-rate agreement, while there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study), the total amount of the award may be unknown when the agreement is created. Since this type of agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by 45 CFR 75.201, prior approval is not required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement.

8.1.2.12 Need for Additional NIH Funding without Extension of Budget and Project Period

A request for additional funding for a current budget period to meet increased costs that are within the scope of the approved application, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted, is a non-competing supplemental application. Such requests are submitted, in writing, directly to the GMO and are not required to compete with other applications for funding. Other recipient-initiated requests for supplemental funding during a current budget period are considered to change the scope of the approved project and may be required to compete for funding with other applications. When calculating the award for additional funds, NIH will 1) prorate funding if the requested budget is adjusted at the time of award, and 2) use the institution's current F&A rate; i.e., the rate in effect when the new funding is provided.

8.1.2.13 Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period

A request for a non-competing extension of the final budget period of a project period with a minimal amount of additional funds should be submitted to the GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests usually are for a period of up to 12 months and must be either for work that remains to be completed on the project or to permit orderly phase-out of project activities for which there will be no further NIH support. Resources must be available to continue to support the project. The request must specify the proposed revised ending date and must include justification for both the extension and the additional funds requested. Special justification will be required for an extension that would exceed 12 months. NIH will not approve such requests if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. All terms and conditions of the award apply during the extended period.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period with funding.

8.1.2.14 Pre-Award Costs

See Cost Considerations—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs.

8.1.2.15 Rebudgeting of Funds from Trainee Costs

The rebudgeting of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other categories of expense requires NIH prior approval. This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses (see Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Rebudgeting of Funds in IIB).

8.1.2.16 Rebudgeting of Funds Between Construction and Non-construction Work

Under awards that provide for both construction and non-construction work, NIH prior approval is required to transfer funds between the two types of work.

8.1.2.17 Retention of Research Grant Funds When a Career Development Award is Issued

Funds budgeted under an NIH grant for an individual's salary and fringe benefits, but available as a result of receiving a K award for that individual, may not be used for any other purpose without NIH prior approval.

8.1.3 Requests for Prior Approval

All requests for NIH awarding IC prior approval must be made in writing (including submission by e-mail) to the GMO no later than 30 days before the proposed change, and signed by the AOR. If the request is e-mailed, it must provide evidence of the AOR's approval; a cc to the AOR is not acceptable. A request by a subrecipient for prior approval will be addressed in writing to the recipient. The recipient will promptly review such request and shall approve or disapprove the request in writing. A recipient will not approve any budget or project revision which is inconsistent with the purpose or terms and conditions of the Federal-award to the recipient. If the revision, requested by the subrecipient would result in a change to the recipient's approved project which requires Federal prior approval, the recipient will obtain the awarding IC's approval before approving the subrecipient's request. Failure to obtain required prior approval from the appropriate awarding IC may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority. While the PD/PI signature is no longer required as part of the submission to NIH, the recipient must secure and retain such a signature for each prior approval request and make it available to NIH or other authorized DHHS or Federal officials upon request. When multiple PD/PIs are recognized for a particular grant, this requirement applies to all PD/PIs. (See Policies Affecting Applications-Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance).

E-mail requests must be clearly identified as prior approval requests, must reflect the complete grant number in the subject line, and should be sent by the AOR to the GMO that signed the NoA. Contact information is provided on each NoA and is also available in the eRA Commons. E-mail addresses for NIH staff can be also obtained from the NIH Enterprise Directory at: https://ned.nih.gov/search/. E-mail requests must include the name of the recipient, the name of the initiating PD/PI, the PD/PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOR.

The GMO will review the request and provide a response to the AOR indicating the final disposition of the request, with copies to the PD/PI and to the cognizant NIH PO. Only responses provided by the GMO are considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

Whenever recipients contemplate rebudgeting or other post-award changes and are uncertain about the need for prior approval, they are strongly encouraged to consult, in advance, with the GMO.

Under a consortium agreement or contract, the prior approval authority usually is the prime recipient. However, the prime recipient may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a consortium participant will result in a change in the overall grant project or budget requiring NIH approval, the prime recipient must obtain that approval from NIH before giving its approval to the consortium participant.

8.2 AVAILABILITY OF RESEARCH RESULTS: PUBLICATIONS, INTELLECTUAL PROPERTY RIGHTS, AND SHARING RESEARCH RESOURCES

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also Availability and Confidentiality of Information—Confidentiality of Information—Access to Research Data in Part I for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR 401, apply.

As long as recipients abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the recipient to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources—"research tools"—may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

8.2.1 Rights in Data (Publication and Copyrighting)

In general, recipients own the rights in data resulting from a grant-supported project. Special terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use (as provided in 45 CFR 75.322). The disposition of royalties and other income earned from a copyrighted work is addressed in Administrative Requirements—Management Systems and Procedures—Program Income.

All recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Each publication, press release, or other document about research supported by an NIH grant must include:

1) An acknowledgment of NIH grant support such as:

   "Research reported in this [publication, release] was supported by [name of the Institute, Center, or other funding component] of the National Institutes of Health under grant number [specific NIH grant number in this format: R01GM012345]."

2) A disclaimer that says:

   "The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

If the recipient plans to issue a press release about research supported by an NIH grant, it should notify the NIH funding component in advance to allow for coordination. See http://www.nih.gov/news/media_contacts.htm for media contact information.

Publications resulting from work performed under an NIH grant-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports and Administrative Requirements—Closeout—Final Reports—Final Progress Report). When publications are available electronically, the url or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report. See also NIH Public Access Policy below for additional requirements for publications resulting from NIH funded research.

8.2.2 NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH funded research at the NIH NLM PMC, a free digital archive of full-text biomedical and life sciences journal literature (http://www.pubmedcentral.nih.gov/). Under the policy NIH-funded investigators are required by Federal law to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication on or after 4/7/2008, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIHMS ID. The NIHMSID may be used to indicate compliance with the Public Access Policy in applications and progress reports for up to three months after a paper is published. After that period, a PMCID must be provided to demonstrate compliance.

This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH, including research grant and career development awards, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, SBIR/STTR awards, and NIH intramural research studies.

Additional information can be found at: http://publicaccess.nih.gov/.

8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of recipients and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page: http://grants.nih.gov/grants/intell-property.htm.

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

To provide further clarification of the NIH policy on disseminating unique research resources, NIH published *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999; http://grants.nih.gov/grants/intell-property_64FR72090.pdf). This document will assist recipients in determining reasonable terms and conditions for disseminating and acquiring research tools.

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding IC, the recipient also must provide a copy of documents or a sample of any material developed under an NIH grant award. The recipient may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see Administrative Requirements—Management Systems and Procedures—Program Income).

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

8.2.3.1 Data Sharing Policy

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to

serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. All investigator-initiated applications with direct costs of $500,000 or more (excluding consortium F&A costs) in any single year are expected to address data-sharing in their application. In some cases, FOAs may request data-sharing plans for applications that are less than $500,000 (excluding consortium F&A costs) in any single year.

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the HIPAA Privacy Rule (see Public Policy Requirements and Objectives—Confidentiality of Patient Records: Health Insurance Portability and Accountability). The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to meet these expectations should promptly contact the GMO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

8.2.3.2 Sharing Model Organisms

All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

This expectation is for **all** applications where the development of model organisms is anticipated, regardless of funding amount.

For additional information on this policy, see the NIH Model Organism for Biomedical Web site.

8.2.3.3 Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)

The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health.

The GDS Policy, an extension of the 2008 NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (the NIH GWAS Policy), applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. For the purposes of this Policy, the genome is the entire set of genetic instructions found in a cell and large-scale genomic data include GWAS, single nucleotide polymorphisms

(SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the GDS Policy provides examples of genomic research projects that are subject to the Policy and the timeline for submission and sharing of data from such projects.

The GDS Policy became effective on January 25, 2015 for grant applications with due dates on or after that date. Research that was initiated prior to the effective date of the GDS Policy will continue to operate under the terms of the policies that were in effect when the research began, such as the NIH GWAS Policy, however, NIH strongly encourages investigators to comply with the expectations outlined in the GDS Policy. All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to include a genomic data sharing plan (see Developing GDS Plans for guidance on developing a genomic data sharing plan).

Effective March 27, 2015, investigators who wish to use cloud computing for storage and analysis will need to indicate in their Data Access Request (DAR) that they are requesting permission to use cloud computing and identify the cloud service provider or providers that will be employed. They also will need to describe how the cloud computing service will be used to carry out their proposed research.

As with data stored in institutional systems, the institution's signing official, Program Director/Principal Investigator, IT Director, and any other personnel approved by NIH to access the data are responsible for ensuring the protection of the data. The institution, not the cloud service provider, assumes responsibility for any failure in the oversight of using cloud computing services for controlled-access data.

The NIH Security Best Practices for Controlled Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy, which have been updated to include best practices for cloud computing, are available at http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf. The Model Data Use Certification has also been updated and is available at http://gds.nih.gov/pdf/Model_DUC.pdf.

For additional information including best practices see: Genomic Data Sharing Policy. Questions about the GDS policy can be e-mailed to GDS@mail.nih.gov.

8.2.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212; Executive Order 12591; 37 C.F.R. 401 et al; updated April 14, 2018.) provides NIH funding recipients incentives to promote the utilization of inventions conceived or reduced to practice (Subject Invention) in the performance of federally supported research and development. Unless waived by NIH or the funding agreement is for educational purposes, e.g. fellowships, training grants or certain types of career development awards, the Bayh-Dole Act applies to all NIH research and development funding granted to for-profit organizations regardless of size and all non-profit entities. (See 45 CFR 75 and 37 CFR 401.1(b)).

To retain rights and title to Subject Inventions, the NIH funding recipient must comply with the Bayh-Dole statute and implementing regulations that ensure the Invention will be brought to practical application while protecting certain rights of the Federal government. The compliance actions required by the Bayh-Dole Act are summarized below at Exhibit 8.

Failure of the recipient to comply with any of the Bayh-Dole regulations cited at 37 CFR 401 or other requirements may result in the loss of patent rights or the suspension, termination or withholding of NIH funding support. See also Section 8.5.2 for additional remedies for noncompliance of the Bayh-Dole Act.

All Bayh-Dole compliance actions are required to be submitted to NIH by using the iEdison data base (See 37 C.F.R. 401.16). All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to the Division of Extramural Inventions and Technology Resources, OPERA/OER at edison@nih.gov.

Exhibit 8. Extramural Invention Reporting Compliance Responsibilities

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR 401 Reference
Employee Agreement to Disclose All Subject Inventions	Recipient employees working under a federal funding award (other than clerical and nontechnical employees) must sign an agreement with the recipient organization. This agreement requires the Recipient employee to: (1) disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under NIH funding; (2) assign to the Recipient the entire right, title and interest in and to each Subject Invention made under the funding agreement; (3) execute all papers necessary to file patent applications on Subject Inventions; and, (4) establish the government's right in the Subject Inventions.	Before a Recipient or a consortium employee participates in NIH-funded research and development.	401.14(f)(2)
Consortium Participant Rights in Inventions	All consortium participants, regardless of tier, for experimental, developmental or research work retain all rights and obligations provided to the Consortium Participant in the NIH funding agreement.	At the time of issuance of a consortium agreement, recipient must include in all consortium agreements, regardless of tier, for experimental, development, or research work 37 C.F.R. 401 *et seq* suitably modified to identify the parties and the rights and obligations awarded to the contractor.	401.14(g)(1) 401.14(g)(2) 401.14(g)(3)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR 401 Reference
Invention Disclosure	**The term "Subject Invention"** means any invention of a recipient/consortium participant conceived or first actually reduced to practice in the performance of work under a funding agreement. The recipient must submit to NIH a disclosure for all Subject Inventions. There is no single format for disclosing the invention to NIH. However, the disclosure of the Subject Invention must include: a detailed technical description of the invention conveying a clear understanding of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention; the names of all inventors; title of the Subject Invention; all federal funding agreement numbers; date of disclosure of the Subject Invention from the researcher or inventor to the Recipient; and whether a manuscript describing the invention was submitted, accepted and/or published.	Within 2 months of the inventor's disclosure to the recipient organization.	401.14(a)(2) 401.14(c)(1)
Government Assignment to Recipient of Rights in Invention of Government Employee	Disclosure to NIH that a federal employee is a co-inventor on a Subject Invention.	Within 2 months of receipt of the initial invention report.	401.14(f)(2) 401.10
Acceptance of Manuscript following Submission of Initial Invention Disclosure	The recipient needs to promptly notify NIH of the acceptance of any manuscript describing the Subject Invention.	Promptly following the acceptance of a manuscript describing a Subject Invention.	401.14(c)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR 401 Reference
Election of Title to a Subject Invention	The recipient must notify NIH of its decision to retain title to a Subject Invention and any associated patent rights. Election of title is made before the filing of an **Initial Patent Application**. **Statutory Period** is defined as the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102(b) as amended by the Leah-Smith American Inventions Act, Public Law 112-29.	Within 2 years of the disclosure of the invention to NIH. In any case where a patent, a printed publication, public use, sale or other availability to the public has initiated the one-year **Statutory Period** wherein valid patent protection can still be obtained in the United States, the period for election of title is shortened by NIH to a date that is no more than 60 days prior to the end of the statutory period.	401.14(b) 401.14(c)(2) 401.2(n)
Confirmatory License	For each Subject Invention, the recipient must provide a license to NIH confirming the rights the Government has throughout the world in the Subject Invention. When a confirmatory license is filed on the **Initial Patent Application** the license applies to all subsequent patent applications linked in the patent family.	When the **Initial Patent Application** is filed.	401.14(f)(1)
Government Support Clause	The recipient must include, within the specification of all United States patent applications and any patent issuing thereon covering a Subject Invention, the following statement, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."	Must be included within the specifications of any United States patent applications and any patent(s) issuing thereon covering a Subject Invention.	401.14(f)(4)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR 401 Reference
Patent Applications and Issued Patents	The recipient must inform NIH of the filing date of its **Initial Patent Application**, the **Initial Patent Application** number and title and all subsequently filed patent applications. **Initial Patent Application** is defined as the first provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(2) and (3), respectively, the first international application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) that designates the United States, or the first application for a Plan Variety Protection certificate, as applicable, a non-provisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3).	Within 1 year after election of title, or, if earlier, prior to the end of any Statutory Period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use, unless there is an extension of time granted by NIH.	401.14(c)(3) 401.14.(f)(6) 401.2(n)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR 401 Reference
Notification to NIH to Not to Continue Prosecution	Notify NIH of any decision to: not to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a part to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office including but not limited to post-grant review, review of a business method patent, *inter partes* review, and deviation proceeding; or to request, be a part to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination.	Notify NIH no less than 60 days prior to taking any action defined under "Action Required."	401.14(f)(3)
Assignment of Rights to Third Party	If the recipient is a non-profit organization, it must request NIH prior approval to assign a Subject Invention or U.S. patent rights to any third party, including the inventor(s). Recipients that are for-profit entities (including small businesses) do not need to request approval for the assignment of a Subject Invention or U.S. patent rights to any third party.	Recipient must submit a Third-Party Waiver Request or an Inventor Waiver Request and must have NIH approval before any rights of the recipient are transferred or assigned.	401.10 401.14(k)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR 401 Reference
Preference for United States Industry	Recipient cannot grant to any person, unless approved by NIH in advance, the exclusive right to use or sell any Subject Invention in the United States unless any such product embodying the Subject Invention or produced through the use of the Subject Invention is manufactured substantially in the United States.	For a waiver of this compliance requirement, a request is required to NIH providing specific details and reasons why the Subject Invention cannot be substantially manufactured in the United States.	401.14(i)
Issued Patent	Recipient must notify NIH of the date a patent is issued, patent number, and the expiration date of the issued patent.	When patent is issued.	401.5(f)(2)
Extension of Time to Disclose a Subject Invention	The recipient may request for NIH's approval for an extension of time to disclose a Subject Invention.	Not less than 30 days in advance of the 60-day disclosure reporting deadline.	401.14(c)(5)
Extension of Time to Elect Title to a Subject Invention	Recipient may request with justification, NIH's approval of a request for an extension of up to 2 years to elect title to a Subject Invention.	As needed before the expiration of the time allowed.	401.14(c)(5)
Extension of Time to File a Patent Application	The recipient may request, subject to NIH's approval, an extension time up to 1 year to file a patent application. The request must include details of why an extension is needed.	As needed before the expiration of the time allowed.	401.14(c)(5)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR 401 Reference
Extension of Time to File a Non-provisional Patent Application following the Filing of a Provisional Application as the Initial Patent Application	When a recipient requests an extension of time for filing a non-provisional application, after filing a provisional application as an **Initial Patent Application**, a 1-year extension will be granted unless NIH notifies the recipient within 60 days of receiving the request. Recipient must submit this request citing an extension of time pursuant to 401.14(c)(5). No additional details for the request are required.	As needed before the expiration of the time allowed.	401.14(c)(5)
Invention Utilization Report	The recipient must submit an annual utilization report with information about the status of commercialization of any Subject Invention for which title has been elected.	Annually, based on the fiscal year of the recipient.	401.14(h)
Annual Invention Statement	The recipient must indicate any inventions made during the previous budget period in Section C of the Research Performance Progress Report (RPPR).	Part of all competing applications and non-competing continuation progress reports.	SF424, (R&R) PHS 2590, RPPR
Final Invention Statement and Certification	The recipient must submit to the NIH awarding IC CGMO through the eRA Closeout Module a summary of all inventions made during the entire term of each grant award.	Within 120 days after the project period (competitive segment) ends.	401.14(f)(5)

8.2.5 Interim Research Products

Interim Research Products are complete, public research products that are not final. A common form is the preprint, which is a complete and public draft of a scientific document. Interim research products are effective ways for NIH funded scientists to speed dissemination, establish priority, obtain feedback, and reduce bias. They may also be cited in applications for NIH funding.

NIH intends to maximize impact of interim research products that are developed with NIH funds. Therefore, NIH expects awardees to ensure a high level of public access to NIH supported interim products. To facilitate text mining and other analysis of these products as data, the NIH expects standardized terms of use. NIH also expects awardees will adhere to other norms of responsible scientific communication.

Specifically, to claim an interim research product as a product of an NIH award, the NIH expects that the awardee will:

- Make the product publicly available. To maximize the impact of an interim research product, the NIH strongly encourages awardees to select a Creative Commons Attribution (CC-BY) license or dedicate their work to the public domain.
- In the text of the document:
    - Acknowledge NIH funding in accordance with NIH Grants Policy Statement Chapter 8.2.1
    - Clearly state that the work is not peer-reviewed
    - Declare any competing interests, as an author would do for any journal article

8.3 MANAGEMENT SYSTEMS AND PROCEDURES

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage NIH grant funds and activities as long as they are consistently applied regardless of the source of funds and meet the standards and requirements set forth in 45 CFR 75 and the NIHGPS. NIH may review the adequacy of those systems and may take appropriate action, as necessary, to protect the Federal government's interests, including, but not limited to, the use of special terms and conditions. NIH also will oversee the recipient's systems as part of its routine post-award monitoring. The recipient's systems also are subject to audit (see Administrative Requirements—Monitoring—Audit).

NIH seeks to foster within recipient organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

8.3.1 Financial Management System Standards

Recipients are required to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR 75.302, as applicable. The standards and requirements for a financial management system are essential to the grant relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Recipients must have in place accounting and internal control systems that provide for appropriate monitoring of grant accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify large unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds. Recipients must notify NIH when problems are identified.

A recipient's failure to establish adequate control systems constitutes a material violation of the terms of the award. Under these circumstances, NIH may include special conditions on awards or take any of the range of actions specified in Administrative Requirements—Enforcement Actions, as necessary and appropriate.

8.3.2 Program Income

Program income is gross income—earned by a recipient, a consortium participant, or a contractor under a grant—that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed; charges for the use or rental of real property, equipment or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; registration fees for grant-supported conferences, and license fees and royalties on patents and copyrights. (Note: Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements unless otherwise specified in the terms and conditions of award.) The requirements for accountability for these various types of income under NIH grants are specified in this subsection. Accountability refers to whether NIH will specify how the income is to be used and whether the income needs to be reported to NIH and for what length of time. Unless otherwise specified in the terms and conditions of the award, NIH recipients are not accountable for program income accrued after the period of grant support.

NIH applies the additive alternative to all recipients, including for-profit entities, unless there is a concern with the recipient or activity and NIH uses special terms and conditions, or the program requires a different program income alternative. NIH may require a different use of program income if a recipient has deficient systems; if the PD/PI has a history of frequent, large annual unobligated balances on previous grants; or if the PD/PI has requested multiple extensions of the final budget period of the project period. Regardless of the alternative applied, program income may be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the award. Each NoA will indicate the allowable treatment of program income. Program income alternatives and their usage are noted below in Exhibit 9.

Consortium agreements and contracts under grants are subject to the terms of the agreement or contract with regard to the income generated by the activities, but the terms specified by the recipient must be consistent with the requirements of the grant award. Program income must be reported by the recipient as discussed in this subsection.

8.3.2.1 Reporting Program Income

The amount of program income earned and the amount expended must be reported on the appropriate annual financial report, currently the FFR. Any costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported. Program income must be reported in the Program Income section of the FFR (lines 10 L – O). (See Administrative Requirements—Monitoring—Reporting—Financial Reporting.) For awards under SNAP, the amount of program income earned must be reported in the non-competing continuation progress report.

Income resulting from royalties or licensing fees is generally exempt from reporting as program income.

When applicable, income earned from the sale of equipment must be reported on the FFR for the period in which the proceeds are received in accordance with the reporting requirements for the program income alternative specified. Amounts due NIH for unused supplies must be reflected as a credit to the grant on the FFR using line 10 m.

Reporting requirements for accountable income accrued after grant support ends will be specified in the NoA.

Exhibit 9. Use and Applicability of Program Income Alternatives

Program income alternative	Use of program income	Applicability
Additive Alternative	Added to funds committed to the project or program and used to further eligible project or program objectives.	Applies to all NIH awards unless there is a concern with the recipient or activity or the program requires a different alternative.
Deductive Alternative	Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based.	Available for use by NIH programs on an exception basis.
Combination Alternative	Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative.	Available for use by NIH programs on an exception basis.
Matching Alternative	Used to satisfy all or part of the non-Federal share of a project or program.	Available for use by NIH programs that require matching.

8.3.2.2 Sale of Real Property, Equipment, and Supplies

The requirements that apply to the sale of real property are addressed in the Construction Grants chapter. For equipment and supplies purchased under NIH grants for basic or applied research by non-profit institutions of higher education or non-profit organizations whose principal purpose is the conduct of scientific research, the recipient is exempt from any requirement to account to NIH for proceeds from the sale of the equipment or supplies; however, NIH has certain rights with respect to such property as specified in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

All other types of grants and recipients are subject to the requirements in 45 CFR 75.320 and 75.439 if title to the equipment vests in the recipient rather than in NIH. If the grant-supported project or program for which equipment was acquired is still receiving NIH funding at the time of sale, the recipient must credit the NIH share of the proceeds to the grant and use that amount under the deductive alternative for program income. If the recipient is no longer receiving NIH grant support, the amount due should be paid in accordance with instructions from NIH. These grants and recipients also are subject to the requirements in 45 CFR 75.321 and 75.453 with respect to the use or sale of unused supplies. If the recipient retains the supplies for use on other than federally sponsored activities, an amount is due NIH as if they were sold.

8.3.2.3 Royalties and Licensing Fees from Copyrights, Inventions, and Patents

NIH recipients do not have to report program income resulting from royalties or licensing fees from sale of copyrighted material unless specific terms and conditions of the award provide otherwise. The NoA may include special terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

However, the regulations implementing the Bayh-Dole Act (37 CFR 401.14(h)) require reporting of income resulting from NIH-funded inventions and patents. Specifically, as part of the annual invention

utilization report, recipients must report income generated by all subject inventions to which title has been elected and by inventions such as research tools that have been licensed but not patented (see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources and Administrative Requirements—Monitoring—Reporting).

8.3.3 Property Management System Standards

Generally, recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH grant funds, provided they observe the requirements in 45 CFR Parts 75.316 through 75.323, as applicable, and the following. State governments will use, manage, and dispose of equipment acquired under a grant in accordance with state laws and procedures as specified in 45 CFR 92.32.

The dollar threshold for determining the applicability of several of the requirements in those regulations is based on the unit acquisition cost of an item of equipment. As defined in 45 CFR 75.2, the acquisition cost of an item of equipment to the recipient includes necessary modifications and attachments that make it usable for the purpose for which it was acquired or fabricated. When such accessories or attachments are acquired separately and serve to replace, enhance, supplement, or otherwise modify the equipment's capacity and they individually meet the definition of equipment (see Glossary in Part I), any required NIH prior approval for equipment must be observed for each item. However, the aggregate acquisition cost of an operating piece of equipment will be used to determine the applicable provisions of 45 CFR 75.320. If property is fabricated from individual component parts, each component must itself be classified as equipment if it meets the definition of equipment. In this case, the aggregate acquisition cost of the resulting piece of equipment will determine the appropriate accountability requirements in 45 CFR part 75.320.

Recipients are required to be prudent in the acquisition of property under a grant-supported project. It is the recipient's responsibility to conduct a prior review of each proposed property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization. If prior approval is required for the acquisition, the recipient must ensure that appropriate approval is obtained in advance of the acquisition. The recipient also must follow appropriate procurement procedures in acquiring property as specified in Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements.

Recipients of NIH grants other than Federal institutions cannot be authorized to use Federal supply sources.

8.3.3.1 Real Property

See Construction Grants—Real Property Management Standards in IIB for requirements that apply to the acquisition, use, and disposition of real property. Fixed equipment that is part of a construction grant is subject to those requirements.

8.3.3.2 Equipment and Supplies

In general, title to equipment and supplies acquired by a recipient with NIH funds vests in the recipient upon acquisition, subject to the property management requirements of 45 CFR Parts 75.317, 75.320, 75.321, and 75.323. Limited exceptions to these general rules are States, which may use, manage, and dispose of equipment acquired under a grant in accordance with State laws and procedures, and certain research grant recipients with exempt property (see 45 CFR 75.326). These requirements do not apply to equipment for which only depreciation or use allowances are charged, donated equipment, or equipment acquired primarily for sale or rental rather than for use.

8.3.3.2.1 Exempt Property

Under the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6306, NIH may permit non-profit institutions of higher education and non-profit organizations whose primary purpose is the conduct of scientific research to obtain title to equipment and supplies acquired under grants for support of basic or applied scientific research without further obligation to the Federal government. However, there is one exception: NIH has the right to require transfer of title to equipment with an acquisition cost of $5,000 or more to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 45 CFR 75.319. NIH may exercise this right within 120 days of the completion or termination of an award or within 120 days of receipt of an inventory, as provided in 45 CFR 75.320(e)(2), whichever is later.

8.3.3.2.2 Nonexempt Property

All other equipment and supplies acquired under all other NIH grant-supported projects by any other type of recipient are subject to the full range of acquisition, use, management, and disposition requirements of 45 CFR Parts 75.320 and 75.321. Property acquired or used under an NIH grant-supported project, including any federally owned property, also is subject to the requirements for internal control specified in 45 CFR 75.303. Pursuant to 45 CFR 75.323, equipment (and intangible property and debt instruments) acquired with, or improved with, NIH funds must not be encumbered without NIH approval.

The recipient's management system for equipment must meet the requirements of 45 CFR part 75.320 (d), which include the following:

- Records that adequately identify (according to the criteria specified in the regulations) items of equipment owned or held by the recipient and state the current location of each item.
- A physical inventory of the equipment, at least once every 2 years, to verify that the items in the records exist and either are usable and needed or are surplus (a statistical sampling basis is acceptable).
- Control procedures and safeguards to prevent loss, damage, and theft.
- Adequate maintenance procedures to keep the equipment in good condition.
- Proper sales procedures when the recipient is authorized to sell the equipment.

For items of equipment having a unit acquisition cost of $5,000 or more, NIH has the right to require transfer title to the equipment to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 45 CFR 75.320(e)(3). Such transfer shall be subject to the following standards: (1) The equipment shall be appropriately identified in the award or otherwise made known to the recipient in writing. (2) The awarding IC may require submission of a final inventory that lists all equipment acquired with NIH funds and federally-owned equipment. (3) If the awarding IC fails to issue disposition instructions within 120 calendar days after receipt of the inventory or if so instructed, the recipient shall sell the equipment and reimburse the HHS awarding agency an amount computed by applying to the sales proceeds the percentage of HHS share in the cost of the original project or program. However, the recipient shall be permitted to deduct and retain from the NIH share $500 or ten percent of the proceeds, whichever is less, for the recipient's selling and handling expenses. If the recipient is instructed to ship the equipment elsewhere, the recipient shall be reimbursed by the awarding IC an amount which is computed by applying the percentage of the recipient's share in the cost of the original project or program to the current fair market value of the equipment, plus any reasonable shipping or interim storage costs incurred. If the recipient is instructed to otherwise dispose of the equipment, the recipient will be reimbursed by the HHS awarding agency for such costs incurred in its disposition. If the recipient's project or program for which or under which the equipment was acquired is still receiving

support from the same HHS program, and if the HHS awarding agency approves, the net amount due may be used for allowable costs of that project or program. Otherwise the net amount must be remitted to the HHS awarding agency by check. This right applies to nonexempt property acquired by all types of recipients, including Federal institutions, under all types of grants under the stipulated conditions.

If there is a residual inventory of unused supplies exceeding $5,000 in aggregate fair market value upon termination or completion of the grant and if the supplies are not needed for other federally sponsored programs or projects, the recipient may either retain them for use on other than federally sponsored activities or sell them, but, in either case, the recipient must compensate the NIH awarding IC for its share as a credit to the grant.

Recipients of NIH grants must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise.

8.3.3.2.3 Revocable License

As permitted under Federal property management statutes and regulations and NIH property management policies, federally owned tangible personal property may be made available to recipients under a revocable license agreement. The revocable license agreement between NIH and the recipient provides for the transfer of the equipment for the period of grant support under the following conditions:

- Title to the property remains with the Federal government.
- NIH reserves the right to require the property to be returned to the Federal government should it be determined to be in the best interests of the Federal government to do so.
- The use to which the recipient puts the property does not permanently damage it for Federal government use.
- The property is controlled and maintained in accordance with the requirements of 48 CFR 45.5 (the FAR).

8.3.4 Procurement System Standards and Requirements

8.3.4.1 General

Recipients may acquire a variety of goods or services in connection with a grant-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. States may follow the same policies and procedures they use for procurements from non-Federal funds and ensure that every purchase order or other contract includes any clauses required by 75.335. All other recipients must follow the requirements in 45 CFR parts 75.327 through 75.335 for the purchase of goods or services through contracts under grants. ***(Note: OMB has provided a one-year grace period for implementation of these subsections for IHEs and nonprofit organizations. Thus, these requirements are expected to take effect for these entities for their first fiscal year after December 26, 2015.)*** The requirements for third-party activities involving programmatic work are addressed under Consortium Agreements chapter in IIB.

A contract under a grant must be a written agreement between the recipient and the third party. The contract must, as appropriate, state the activities to be performed; the time schedule; the policies and requirements that apply to the contractor, including those required by 45 CFR 75, Appendix II - Contract Provisions for Non-Federal Entity Contracts Under Federal Awards and other terms and conditions of the grant (these may be incorporated by reference where feasible); the maximum amount of money for which the recipient may become liable to the third party under the agreement; and the cost principles to

be used in determining allowable costs in the case of cost-type contracts. The contract must not affect the recipient's overall responsibility for the direction of the project and accountability to the Federal government. Therefore, the agreement must reserve sufficient rights and control to the recipient to enable it to fulfill its responsibilities.

When a recipient enters into a service-type contract in which the term is not concurrent with the budget period of the award, the recipient may charge the costs of the contract to the budget period in which the contract is executed even though some of the services will be performed in a succeeding period if the following conditions are met:

- The NIH awarding IC has been made aware of this situation either at the time of application or through post-award notification.
- The project has been recommended for a project period extending beyond the current year of support.
- The recipient has a legal commitment to continue the contract for its full term.

However, costs will be allowable only to the extent that they are for services provided during the period of NIH support. To limit liability if continued NIH funding is not forthcoming, it is recommended that recipients insert a clause in such contracts of $100,000 or less stipulating that payment beyond the end of the current budget period is contingent on continued Federal funding. The contract provisions prescribed by 45 CFR 75, Appendix II - Contract Provisions for Non-Federal Entity Contracts Under Federal Awards, paragraph B specify termination provisions for contracts in excess of $100,000.

8.3.4.2 Approval Requirements

The procurement standards in 45 CFR 75.333 allow NIH to require approval of specific procurement transactions under the following circumstances (and provide a mechanism for governmental recipients to be exempt from this type of review):

- A recipient's procurement procedures or operations do not comply with the procurement standards required by those regulations.
- The procurement is expected to exceed the "simplified acquisition threshold" (currently $250,000 per OMB memo M-18-18) (formerly the "small purchase threshold") established by the Federal Property and Administrative Services Act, as amended, and is to be awarded without competition or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the simplified acquisition threshold specifies a "brand name" product.
- A proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When NIH prior approval is required, the recipient must make available sufficient information to enable review. This may include, at NIH discretion, presolicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the applicant or recipient or may be conditioned on the receipt of additional information. Any resulting NIH approval does not constitute a legal endorsement of the business arrangement by the Federal government nor does such approval establish NIH as a party to the contract or any of its provisions.

8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, and Women's Business Enterprises

Recipients must make positive efforts to use small businesses, minority-owned firms, and women's business enterprises as sources of goods and services whenever possible. Recipients should take the steps outlined in the applicable administrative requirements (45 CFR 75.330) to implement this policy.

8.4 MONITORING

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH awarding ICs monitor their grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to NIH. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is administratively closed out and NIH is no longer providing active grant support (see Administrative Requirements—Closeout).

8.4.1 Reporting

NIH requires that recipients periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Recipients also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and available for all closeout documents (final grant progress reports, final invention statements and certifications, and final financial status reports). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to OFM (see Financial Reports below) through the eRA Commons eFFR feature unless otherwise indicated in the award's terms and conditions.

Recipients are allowed a specified period of time to submit required financial and final progress reports (see 45 CFR Parts 75.341 and 75.342, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

8.4.1.1 Non-Competing Continuation Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The "Non-Competing Continuation Progress Report" (PHS 2590) or equivalent documentation (e.g., Research Performance Progress Report [RPPR]) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information.

NIH requires the use of the RPPR for all Type 5 progress reports, including accessing the Human Subjects System link in the RPPR, if applicable, that will allow reporting of inclusion enrollment data.

Recipients should routinely query and review the list of pending grant progress reports and due dates available at the NIH Web site (https://public.era.nih.gov/chl/public/search/progressReportByIpf.era). Late submission of a grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

Recipients also have an obligation to submit a complete and accurate progress report. NIH program or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award. Incomplete or inadequate progress reports may result in a delay of continued support.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the recipient does not submit an application for continued support, a final RPPR is required (see Final Research Performance Progress Report).

The NIH awarding IC will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, major alteration and renovation, and non-construction activities.

8.4.1.1.1 Requirement for Commons ID

The paper non-competing Progress Report includes an All Personnel Report on which the recipient must report the PD/PI(s) and all individuals who devoted one person month or more effort to the project. The eRA Commons ID must be provided on this report for the PD/PI(s) and those who worked on the project in a postdoctoral role.

For progress reports using the RPPR, the Commons ID requirement is part of the Participants Section and is required for the PD/PI(s) and those who worked on the project in a postdoctoral role. This could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

For undergraduate and graduate students supported on a particular research grant, a Commons ID will be required effective with RPPRs submitted October 17, 2014 and beyond. Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now. For graduate students, this could include project roles of graduate research assistant or graduate student.

When an individual is assigned the Undergraduate, Graduate Student, and/or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used

for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

8.4.1.1.2 Expectation for Institutions to Develop Individual Development Plans for Graduate Students and Postdoctoral Researchers

In an effort to assist graduate students and post-doctoral researchers in achieving their career goals and become contributing members of the biomedical workforce, NIH encourages recipients to develop an institutional policy requiring that an Individual Development Plan (IDP) be implemented for every graduate student and postdoctoral researcher supported by any NIH grant and reportable on the progress report, regardless of the type of NIH grant that is used for support. This is an expectation that should be broadly implemented by institutions for all graduate students and postdoctoral researchers supported by NIH. The actual reporting of the implementation of this expectation is in the RPPR; recipients must report in RPPR *Section B. Accomplishments*, Question B.4 the use of the IDP for graduate students and/or postdoctoral researchers included in RPPR *Section D*. Participants or on a Statement of Appointment Form (PHS 2271). Do not include the actual IDP; instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.

8.4.1.2 Streamlined Non-Competing Award Process

SNAP includes a number of provisions that modify annual progress reports, NoAs, and financial reports.

The NoA will specify whether an award is subject to SNAP. Awards routinely included in SNAP are "K" awards and "R" awards, except R35. Awards excluded from SNAP are those that generally do not have the authority to automatically carry over unobligated balances (centers; cooperative agreements, Kirschstein-NRSA institutional research training grants, non-Fast Track Phase I SBIR and STTR awards), clinical trials (regardless of activity code), P01, R35, and awards to individuals. However, these grants can be included in SNAP on a grant-specific basis. In addition, specific awards may be excluded from SNAP if:

- they require close project monitoring or technical assistance, e.g., high-risk recipients, certain large individual or multi-project grants, or grants with significant unobligated balances, or
- the recipient has a consistent pattern of failure to adhere to appropriate reporting or notification deadlines.

8.4.1.2.1 Modified Annual Progress Reports

While a modified, streamlined, progress report is still a feature of grants awarded under the SNAP authorities, a streamlined version of the RPPR has replaced the eSNAP module in the eRA Commons. For all SNAP awards, the progress report is submitted using this streamlined version of the RPPR that does not include detailed budget information.

8.4.1.2.2 Modified NoAs

Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and any negotiations, and reduces the information NIH requires to review, approve, and monitor non-competing continuation awards. SNAP NoAs are issued with only total direct and F&A costs awarded for the budget period. While direct costs categorical breakdowns are not awarded, recipients

are required to allocate and account for costs by category in accordance with applicable cost principles. Future year commitments on SNAP awards reflect total cost commitments (direct plus F&A costs).

8.4.1.2.3 Modified Financial Reporting Requirements

For awards under SNAP (other than awards to foreign organizations issued prior to October 1, 2012 or Federal institutions), an FFR is required only at the end of a competitive segment rather than annually. The FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

For awards under SNAP (other than awards to foreign organizations and Federal institutions), recipients also are required to submit a quarterly FFR cash transaction data to PMS.

Annual FFRs are required for awards issued to foreign organizations prior to October 1, 2012 and all awards issued to Federal institutions, even if an award is under SNAP. (Also see Administrative Requirements—Monitoring—Reporting—Financial Reports.)

SNAP awards issued to foreign and international organizations after October 1, 2012, will be required to submit FFR expenditure data within 120 days of the end of the competitive segment instead of annually. These awards are not required to submit a quarterly FFR cash transaction data to PMS.

8.4.1.2.4 Submitting SNAP Progress Reports

All SNAP progress reports are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). If the 15th falls on a weekend or Federal holiday, the due date is automatically extended to the next business day. Paper submissions are not acceptable, will not be used for consideration for funding, and will not become part of the official file. If a paper SNAP progress report is submitted, recipients will be required to resubmit the information electronically.

The RPPR module in the eRA Commons allows recipients to electronically prepare and submit progress reports and supporting documentation. The RPPR module provides the user with dedicated screens to collect the required progress report information, including appropriate uploads for text documents. Data submitted through RPPR for Performance Sites and Participants is retained in the system to assist the recipient in completion of future progress reports.

The RPPR may be routed to authorizing officials at the applicant institution for review and approval prior to submission to NIH. For SNAP awards, the RPPR module provides recipients with the option to delegate to the PD/PI the authority to submit the progress report directly to NIH. This optional authority is managed on a PD/PI basis in the eRA Commons; such authority can be rescinded at any time.

Guidance on RPPR submission is documented in the RPPR Instruction Guide found at: http://grants.nih.gov/grants/RPPR/.

8.4.1.3 Progress Reports for Multiyear Funded Awards

A limited number of NIH grant awards are multi-year funded, i.e., not funded in budget years but funded in full at the start of the project period from a single fiscal year appropriation. The project period and the budget period are the same in a multi-year funded (MYF) award, and are longer than one year. Progress reports for MYF awards are due annually on or before the anniversary of the budget/project period start date of the award. A progress report is not required if the award is in a no-cost extension period unless specifically required by the IC. The reporting period for a MYF progress report is the calendar year

preceding the anniversary date of the award. For example, if an award is made on 04/01/2014, the MYF progress report is due on or before 04/01/2015, and should report on the activities performed under the award between 04/01/2014 and 03/31/2015. For the subsequent year the MYF progress report will be due 04/01/2016, and should report on the activities performed under the award between 04/01/2015 and 03/31/2016. Information on the content of a MYF progress report and instructions on how to submit the report through the eRA Commons are posted at http://grants.nih.gov/grants/policy/myf.htm and http://-grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. The multi-year research performance progress report (MYRPPR) link to upload the report will be available two months before the anniversary date of the award, on the eRA Commons Status search page in the folder "List of Applications/Grants" in the "Action" column. Progress reports for MYF awards must be completed by the PD/PI, and then submitted by a Signing Official (SO) or a PD/PI with delegated authority from the SO to submit a progress report. Information about SO delegation of authority to a PD/PI to submit a progress report appears in the eSNAP User Guide under Section 2. Delegating Authority.

8.4.1.4 Final Research Performance Progress Report (F-RPPR)

The F-RPPR has replaced the Final Progress Report for closeout. NIH is no longer accepting Final Progress Reports. Generally, the F-RPPR format is the same as the current annual RPPR. As part of the F-RPPR recipients will be required to report on Project Outcomes. This section will be made publicly available, allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).

NIH will not maintain its previous Type 2 policy which stated that "whether funded or not" the progress report contained in the Type 2 application may serve in lieu of a separate final progress report. NIH now requires that organizations submit an Interim-RPPR while their Type 2 is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's F-RPPR.

See the F-RPPR Instructions posted at https://grants.nih.gov/grants/rppr/index.htm. Recipients should also review the information found in Final Research Performance Progress Report.

8.4.1.5 Financial Reports

Two types of financial reports are typically used. Cash transaction data is submitted on a quarterly basis directly to PMS. Expenditure data is submitted directly to the NIH. Historically this data was submitted using 2 separate forms, the SF272 and the SF269. Now the SF425, called the Federal Financial Report (FFR), is used for collecting both types of financial data. For NIH recipients, it is important to note that while the data is now submitted using the same form, there is no change in the actual receipt and processing of data. Cash transaction data continues to be submitted directly to and processed by PMS. Expenditure data continues to be submitted directly to and processed by NIH.

8.4.1.5.1 Cash Transaction Reports

The FFR has a dedicated section to report Federal cash receipts and disbursements. For domestic recipients this information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

For awards issued to foreign organizations after October 1, 2012, even though payment is now through PMS, the requirement for quarterly cash reporting does not apply. These awards are now administered in

PMS using subaccounts and payments will be specific to each grant at the time the recipient draws funds. (See also Grants to Foreign Organizations – Administrative Requirements – Reporting and Record Retention.)

8.4.1.5.2 Financial Expenditure Reports

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the recipient organization. NIH requires all financial expenditure reports to be submitted using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to NIH. The eRA Commons Federal Financial Report (FFR) system allows participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted by OFM. NIH IC grants management staff also review these expenditure reports.

Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. An annual FFR is required for awards to foreign organizations made prior to October 1, 2012 and Federal institutions made prior to October 1, 2013, whether or not they are under SNAP. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date.

In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

Before submitting FFRs to NIH, recipients must ensure that the information submitted is accurate, complete, and consistent with the recipient's accounting system. When submitting the FFR through the eRA Commons, the AOR or the individual designated to submit this report on behalf of their institution, certifies that the information in the FFR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government. Filing a false claim may result in the imposition of civil or criminal penalties.

8.4.1.5.3 Revised Financial Reports and Expenditures

Revisions for F&A Changes. Each Financial Report and Cash Expenditure Report submitted by the recipient shall reflect the proper amount of F&A costs applicable to the grant period. If a provisional or an earlier period's permanent rate is used in the report, a subsequent adjustment to the FSR is necessary if a lower permanent rate(s) applicable to the grant is established, except for Institutions of Higher Education (IHEs) subject to 45 CFR 75.

Revised Expenditure Reports. NIH requires all financial expenditure reports (domestic and foreign) to be submitted using the electronic FFR system located in eRA Commons. This includes the initial FFR and any FSR/FFR revisions being submitted or re-submitted to NIH. In some cases the recipient may

have to revise or amend a previously submitted FSR/FFR. The revised report should be submitted in the same format as the original; e.g., if the original was an FSR, the revision will also be submitted using the FSR format. When the revision results in a balance due to NIH, the recipient must submit a revised report whenever the overcharge is discovered, no matter how long the lapse of time since the original due date of the report. Revised expenditure reports representing additional expenditures by the recipient that were not reported to NIH within the 90-day time frame may be submitted electronically through the eFSR/FFR system to OFM with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the recipient to preclude similar situations in the future. This should be done as promptly as possible, but no later than 1 year from the due date of the original report for annual FFRs and no later than 60 calendar days from the due date of the original report for final FFRs (i.e., 180 days from the project end date). If an adjustment is to be made, the NIH awarding IC will advise the recipient of actions it will take to reflect the adjustment.

8.4.1.5.4 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. (See Administrative Requirements—Changes in Project and Budget for NIH approval authorities for unobligated balances.) Using the principle of "first in-first out," unobligated funds carried over are expected to be used before newly awarded funds.

Upon receipt of the annual FSR/FFR for awards other than those with authority for the automatic carry-over of unobligated balances, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget period with the NIH share of the approved budget for the current budget period. If the funds available exceed the NIH share of the approved budget for the current budget period, the GMO may select one of the following options:

- In response to a written request from the recipient, revise the current NoA to authorize the recipient to spend the excess funds for additional approved purposes.
- Offset the current award or a subsequent award by an amount representing some or all of the excess.

8.4.1.5.5 Recipient Reporting of Subrecipient Data and Executive Compensation Information for Federal Funding Accountability and Transparency Act (FFATA)

A component of Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires most recipients of new Federal funds awarded on or after October 1, 2010 to report on subawards/subcontracts/consortiums equal to or greater than $25,000. This includes awards that are initially below $25,000 but subsequent grant modifications result in an award equal to or greater than $25,000.

The FFATA Subaward Reporting System (FSRS) tool can be accessed directly at www.fsrs.gov, and will serve as the collection tool for subaward data which will ultimately be distributed for publication and display on www.USASpending.gov. Recipients are required to register with FSRS, collect the necessary data from subawardees, and file subaward reports by the end of the month following the month in which the prime recipient awards any subaward greater than $25,000.

FFATA specifies the data that should be captured for each prime recipient and first-tier subrecipient of Federal awards, regardless of award type. To promote data consistency and reduce reporting burdens, existing agency data sources will be leveraged to pre-populate reports for prime awardees as well as for subawardees when available. Recipients are responsible for confirming the pre-populated data and providing any additional required information.

Included in these requirements is the need to report the names and total compensation of the five most highly compensated officers of the entity if the entity as part of their registration profile in SAM in the preceding fiscal year: 1) received 80 percent or more of its annual gross revenues in Federal grants, subawards, contracts, and subcontracts; and 2) received $25,000,000 or more in annual gross revenues from Federal grants, subawards, contracts, and subcontracts; and 3) had gross income, from all sources, of $300,000 or more; and 4) the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1). Additionally, recipient organizations may be required to verify the following information in FSRS:

- Organization DUNS number
- Name and Address of organization
- Parent DUNS number
- CFDA number
- FAIN
- Federal Awarding Agency of the grant

8.4.1.6 Invention Reporting

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR 401.14. The requirements also are specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

In addition to complying with Bayh-Dole-related regulations, each NIH competing grant application and non-competing continuation progress report must indicate whether or not any subject inventions were made during the preceding budget period. If inventions were made, the recipient must also indicate whether they were reported.

The recipient also must submit an annual invention utilization report for all subject inventions to which title has been elected and inventions that have been licensed but not patented (research tools). The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

A recipient's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights or a withholding of grant funds or other enforcement actions, including the imposition of special terms and conditions.

Bayh-Dole regulations allow recipients to report inventions electronically (37 CFR 401.16). NIH requires electronic reporting through an Internet-based system, Interagency Edison (http://iEdison.gov). To meet the objectives of the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107), recipients should make all reasonable efforts to submit invention reports using iEdison. The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, are on the iEdison site. Recipients also may contact the Division of Extramural Inventions and Technology Resources Branch, OPERA, OER. See Part III for contact information.

8.4.1.7 Financial Conflict of Interest Reports

Information related to FCOI reporting requirements can be found within Public Policy Requirements -- Financial Conflict of Interest.

8.4.2 Record Retention and Access

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. For awards under SNAP (other than those to Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. Federal institutions must retain records for 3 years from the date of submission of the annual FFR to NIH. See 45 CFR 75.361 for exceptions and qualifications to the 3-year retention requirement (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Those sections also specify the retention period for other types of grant-related records, including F&A cost proposals and property records. See 45 CFR Parts 75.361 and 75.364 for record retention and access requirements for contracts under grants.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

NIH, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the NIH award, in order to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents. The rights of access in this section are not limited to the required retention period but lasts as long as the records are retained. Pass-through entities must not impose any other access requirements upon non-Federal entities.

8.4.3 Audit

An audit is a systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of the following:

- Financial operations are properly conducted.
- Financial reports are timely, fair, and accurately.
- The entity has complied with applicable laws, regulations, and other grant terms.
- Resources are managed and used economically and efficiently.
- Desired results and objectives are being achieved effectively.

NIH recipients (other than Federal institutions) are subject to the audit requirements in 45 CFR Subpart F and in the NIHGPS (for types of organizations to which 45 CFR 75, Subpart F-Audit Requirements does not directly apply). In general, 45 CFR 75, Subpart F- Audit Requirements requires a State government, local government, or non-profit organization (including institutions of higher education) that expends $750,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing

standards (GAGAS). The audit requirements for foreign recipients and for-profit recipients are addressed in the chapters of this NIHGPS that provide specific requirements for those types of recipients.

As specified in the NoA, all awards issued by NIH meet the definition of "Research and Development" at 45 CFR 75.2. As such, NIH grant awards are subject to the R&D cluster of program requirements in the compliance supplement. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Exhibit 10. Summary of Audit Requirements

Recipient Type	Source of Audit Requirement (Non-Federal Entity Fiscal Years Beginning Prior to 12/16/2014)	Source of Audit Requirement (Non-Federal Entity Fiscal Years Beginning On/After 12/16/2014)	Where to Submit Audit Reports
State & Local Governments	OMB Circular A-133	45 CFR 75.501	Federal Audit Clearinghouse (See contact information in Part III)
Colleges & Universities (IHEs)	OMB Circular A-133	45 CFR 75.501	Federal Audit Clearinghouse (See contact information in Part III)
Non-Profits	OMB Circular A-133	45 CFR 75.501	Federal Audit Clearinghouse (See contact information in Part III)
Hospitals	OMB Circular A-133	45 CFR 75.501(h) through 45 CFR 75.501(k)	Federal Audit Clearinghouse (See contact information in Part III)
For-Profits	45 CFR 74.26(d)	45 CFR 75.501(h) through 45 CFR 75.501(k)	National External Audit Review Center (See contact information in Part III)
Foreign	NIH Grants Policy Statement (same as For-Profits)	NIH Grants Policy Statement (same as For-Profits)	National External Audit Review Center (same as For-Profits, see contact information in Part III)

When a recipient procures audit services, the procurement must comply with the procurement standards of 45 CFR 75, as applicable, including obtaining competition and making positive efforts to use small businesses, minority-owned firms, and women's business enterprises. Recipients should ensure that comprehensive solicitations made available to interested firms include all audit requirements and specify the

criteria to be used for selection of the firm. Recipients' written agreements with auditors must specify the rights and responsibilities of each party.

45 CFR 75, Subpart F- Audit Requirements explains in detail the scope, frequency, and other aspects of the audit. Some highlights of this regulation are as follows:

- Covered organizations expending $750,000 or more per year in Federal awards are required to have an audit performed in accordance with the regulation. However, if the awards are under one program, the organization can have either a single organization-wide audit or a program-specific audit of the single program, subject to the provisions 45 CFR 75.507. NIH's research awards may not be considered a single program for this purpose. Covered organizations expending less than $750,000 in any year are exempt from these audit requirements in that year but must have their records available for review as required by Administrative Requirements—Monitoring—Record Retention and Access.
- The reporting package must contain the following:
    - Financial statements and schedule of expenditures of Federal awards.
    - Independent auditor's report, including an opinion on the financial statements and the schedule of expenditures of Federal awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements.
    - A schedule of findings and questioned costs.
    - If applicable, a summary of prior audit findings and a corrective action plan.
- An audit under 45 CFR 75, Subpart F- Audit Requirements is in lieu of a financial audit of individual Federal awards. However, Federal agencies may request additional audits necessary to carry out their responsibilities under Federal law or regulation. Any additional audits will build upon work performed by the independent auditor.
- The data collection form (SF-SAC) and a copy of the Single Audit reporting package must be submitted electronically to the FAC at the address provided in Part III.
- A senior level representative of the auditee (e.g., state controller, director of finance, chief executive officer, or chief financial officer) must sign a statement to be included as part of the data collection that says that the auditee complied with the requirements of this part, the data were prepared in accordance with this part (and the instructions accompanying the form), the reporting package does not include protected personally identifiable information, the information included in its entirety is accurate and complete, and that the FAC is authorized to make the reporting package and the form publicly available on a Web site. Exception: An auditee that is an Indian tribe or a tribal organization (as defined in the Indian Self- Determination, Education and Assistance Act (ISDEAA), 25 U.S.C. 450b(l)) may opt not to authorize the FAC to make the reporting package publicly available on a Web site, by excluding the authorization for the FAC publication. If this option is exercised, the auditee becomes responsible for submitting the reporting package directly to any pass-through entities through which it has received a Federal award and to pass-through entities for which the summary schedule of prior audit findings reported the status of any findings related to Federal awards that the pass-through entity provided. Unless restricted by Federal statute or regulation, if the auditee opts not to authorize publication, it must make copies of the reporting package available for public inspection.

If the schedule of findings and questioned costs discloses an audit finding related to an HHS or NIH award or if the schedule of prior audit findings reports the status of any audit finding relating to an HHS or NIH award, the FAC will provide copies of the audit report to NEARC, OIG, HHS. NEARC will, in

turn, distribute them within HHS for further action, as necessary. Audit reports should not be sent directly to the GMO. (Note: 45 CFR 75.516 raised the threshold for reporting questioned costs to $25,000).

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of a Federal audit or a recipient-initiated audit. Recipients usually are allowed 30 days from the date of request to respond to the responsible audit resolution official (Action Official) concerning audit findings. Failure to submit timely responses may result in cost disallowance or other actions by NIH or HHS. At the completion of the audit resolution process, the recipient will be notified of the Action Official's final decision. The recipient may appeal this decision if the adverse determination is of a type covered by the NIH or HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures). Refunds owed to the Federal government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official or OFM.

It is imperative that recipients submit required 45 CFR 75, Subpart F audits within the time limits specified in the regulation. If recipients are delinquent in complying with the provisions of the regulation, NIH will take one or more actions that may result in the loss of Federal funds. No audit costs will be allowed either as F&A costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of 45 CFR 75, Subpart F.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of audit costs.

8.5 SPECIAL AWARD CONDITIONS AND REMEDIES FOR NONCOMPLIANCE (SPECIAL AWARD CONDITIONS AND ENFORCEMENT ACTIONS)

A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the recipient an opportunity to correct the deficiencies before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing special conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

8.5.1 Specific or Special Award Conditions: Modification of the Terms of Award

During grant performance, the GMO may include special award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When special conditions are imposed, the GMO will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR 52.9 and 45 CFR 75.371.

The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case,

the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel.

Generally, the decision to modify the terms of an award (e.g., by imposing special award conditions) is discretionary on the part of the NIH awarding IC and is not appealable.

8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If a recipient has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action. NIH may also terminate the grant for cause. The regulatory procedures that pertain to suspension and termination are specified in 45 CFR Parts 75.371 through 75.373.

NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. However, NIH may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency. Termination for cause may be appealed under the NIH and HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures).

A grant also may be terminated, partially or totally, by the recipient or by NIH with the consent of the recipient. If the recipient decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the recipient of the possibility of termination of the entire grant and allow the recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant for cause.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated for cause by NIH, terminated at the request of the recipient, or terminated by mutual agreement.

Withholding of support is a decision not to make a non-competing continuation award within the current competitive segment. Support may be withheld for one or more of the following reasons:

- Adequate Federal funds are not available to support the project.
- A recipient failed to show satisfactory progress in achieving the objectives of the project.
- A recipient failed to meet the terms and conditions of a previous award.
- For whatever reason, continued funding would not be in the best interests of the Federal government.

The recipient may appeal NIH's determination to deny (withhold) a non-competing continuation award because the recipient failed to comply with the terms and conditions of a previous award.

8.5.3 Other Enforcement Actions

Depending on the nature of the deficiency, NIH may use other means of promoting recipient compliance. Other options available to NIH include, but are not limited to conversion from an advance payment method to a reimbursement method or disallow (deny) all or part of the cost of the activity or action not in compliance. Other actions may include suspension or debarment of an organization or individual under

Government-wide Debarment and Suspension rules provided at 45 CFR 76, and other available legal remedies, such as civil action. Suspension under 45 CFR 76, implementing E.O.s 12549 and 12689, "Debarment and Suspension," is a separate action from the "suspension" of an award as a post-award remedy, as described in Suspension, Termination, and Withholding of Support above. The subject of debarment and suspension as an eligibility criterion is addressed in Completing the Pre-Award Process—Determining Eligibility of Individuals and Public Policy Requirements and Objectives—Debarment and Suspension.

8.5.4 Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of a grant. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances. NIH guidance on the repayment of grant funds that are unrelated to audit findings can be found on the OER Web site found at http://-grants.nih.gov/grants/compliance/compliance.htm.

8.5.5 Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for HHS in 45 CFR 30. NIH is required to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

When NIH determines the existence of a debt under a grant, written debt notification will be provided to the recipient. Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent if they are not paid within 30 days from the date the debt notification is mailed to the recipient. Delinquent debts are subject to the assessment of interest, administrative cost charges, and penalties. The interest on delinquent debts accrues on the amount due beginning on the date the debt notification is mailed to the recipient.

If a recipient appeals an adverse monetary determination under 42 CFR 50, Subpart D, or 45 CFR 16, interest will accrue but assessment will be deferred pending a final decision on the appeal. If the appeal is not successful, interest will be charged beginning with the date the debt notification was mailed to the recipient, not the date of the appeal decision. Interest charges will be computed using the prevailing rate in effect on the date the debt notification is mailed, as specified by the Department of the Treasury and 45 CFR 30.13(a)(2).

8.6 CLOSEOUT

The requirement for timely closeout is generally a recipient responsibility. However, NIH may initiate unilateral closeout if a recipient does not provide timely accurate closeout reports or dose not respond timely to NIH requests to reconcile discrepancies in grant records. Failure to submit timely and accurate closeout documents may affect future funding to the organization. Failure to correct recurring reporting problems may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding or further awards, suspension or termination. NIH will close out a grant as soon as possible after the end date of the period of performance (no later than 270 days after the project period end date) if the grant will not be extended or after termination as provided in 45 CFR Parts 75.371 through 75.373. Closeout includes ensuring timely and accurate submission of all required reports and

adjustments for amounts due the recipient or NIH. Closeout of a grant does not automatically cancel any requirements for property accountability, record retention, or financial accountability. Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of the grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. (See 8.4.2 Record Retention and Access, for further information). Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal government may recover amounts based on the results of an audit covering any part of the period of grant support.

Recipients must submit a final FFR, Final RPPR, and Final Invention Statement and Certification within 120 calendar days of the end of the period of performance (project period). The reports become overdue the day after the 120 calendar day period ends.

8.6.1 Final Federal Financial Report

A final FFR is required for

- any grant that is terminated,
- any grant that is transferred to a new recipient, or
- any award, including awards under SNAP, which will not be extended through award of a new competitive segment.

Recipients are required to electronically submit the final FFR through the eRA Commons. The final FFR must cover the entire competitive segment or as much of the competitive segment as has been funded before termination. Final FFRs must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the Federal share of expenditures reported on the final FFR and the net cash disbursements reported to PMS on the Transactions section of the FFR. Unobligated funds must be returned to NIH or must be reflected by an appropriate accounting adjustment in accordance with instructions from the GMO or from the payment office. Final cash transaction reports, as specified by PMS, must be submitted to that office. It is the recipient's responsibility to reconcile reports submitted to PMS and to the NIH awarding IC. Withdrawal of the unobligated balance following completion date or termination of a grant is not considered an adverse action and is not subject to appeal (see Administrative Requirements—Enforcement Actions—Recovery of Funds).

When the submission of a revised final FFR results in additional claims by the recipient, NIH will consider the approval of such claims subject to the following minimum criteria:

- The recipient must indicate why the revision is necessary and explain and implement internal controls that will preclude similar occurrences in the future.
- The charge must represent otherwise allowable costs under the provisions of the grant.
- There must be an unobligated balance for the budget period sufficient to cover the claim.
- The funds must still be available for use.
- NIH must receive the revised final FFR within 60 days of its original due date.

8.6.2 Final Research Performance Progress Report

A Final RPPR required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. If a competitive renewal (Type 2) application has been submitted, the recipient must submit an Interim-RPPR while their renewal application is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for

the final year of the previous competitive segment. If the Type 2 is not funded, the Interim RPPR will be treated by NIH staff as the institution's Final RPPR.

A Final RPPR should be prepared in accordance with the requirements in the RPPR Instructions found on the NIH RPPR website and any specific requirements set forth in the terms and conditions of the award. In addition to the standard requirements detailed in those Instructions, recipients should also report additional information required by the awarding IC in program-specific final progress report instructions.

Final RPPR Instructions for SBIR/STTR Phase II Reports are in Section 7.3. of the RPPR Instructions.

8.6.3 Final Invention Statement and Certification

The recipient must submit a Final Invention Statement and Certification (HHS 568), whether or not the funded project results in any subject inventions, and whether or not inventions were previously reported. The HHS 568 must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, and it must be signed by an AOR. The completed form should cover the period from the original effective date of support through the completion date or termination of the award, and it should be submitted to the NIH awarding IC. If there were no inventions, the form must indicate "None." For certain programs (activity codes = C06, , D42, D43, D71, DP7, G07, G08, G11, G13, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UH4, UC6, UC7, UG4, UR2, X01, X02, Ts, and Fs), the Final Invention Statement and Certification is not currently required. For questions, the recipient should contact NIH awarding IC for specific instructions.

When invention reporting is required, the HHS 568 does not relieve the responsible party of the obligation to assure that all inventions are promptly and fully reported directly to the NIH, as required by terms of the award. Copies of the HHS 568 form are available on the iEdison Web site at http://iEdison.gov and at http://grants.nih.gov/grants/forms.htm.

8.6.4 Submission of Closeout Documents

All closeout documents must be submitted electronically via eRA Commons. NIH no longer accepts paper or e-mail submissions.

8.7 GRANT APPEALS PROCEDURES

HHS permits recipients to appeal certain post-award adverse administrative decisions made by HHS officials (see 45 CFR 16 and appendix to Part 16). NIH has established a first-level grant appeal procedure that must be exhausted before an appeal may be filed by the recipient with the Departmental Appeals Board (DAB) (see 42 CFR 50, Subpart D). NIH will assume jurisdiction for the following adverse determinations set forth in 42 CFR 50.404:

- Termination, in whole or in part, of a grant for failure of the recipient to carry out its approved project in accordance with the applicable law and the terms and conditions of award or for failure of the recipient otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
- Determination that an expenditure is not allowable under the grant has been charged to the grant or that the recipient has otherwise failed to discharge its obligation to account for grant funds.
- Denial (withholding) of a non-competing continuation award for failure to comply with the terms of a previous award.

- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

The formal notification of an adverse determination will contain a statement of the recipient's appeal rights. In the first level appeal of an adverse determination, the recipient must submit a request for review to the NIH official specified in the notification, detailing the nature of the disagreement with the adverse determination and providing supporting documents in accordance with the procedures contained in the notification.

"The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the recipient's position with respect to such issue(s) and the pertinent facts and reasons in support of the recipient's position. In addition to the required written statement, the recipient shall provide copies of any documents supporting its claim." 42 CFR 50.406(b).

The recipient's request to NIH for review must be submitted no later than 30 days after the written notification of the adverse determination is received; however, an extension may be granted if the recipient can show good cause why an extension is warranted (42 CFR 50.406(a)).

If the NIH decision on the appeal is adverse to the recipient or if a recipient's request for review is rejected on jurisdictional grounds, the recipient then has the option of submitting a request to the DAB for a further review of the case in accordance with the provisions of 45 CFR 16. A prospective appellant must submit a notice of appeal to the DAB within 30 days after receiving the final NIH decision. "The appellant must have exhausted any preliminary appeal process required by regulation." 45 CFR 16.3(c).

In addition to the adverse determinations indicated above, the DAB is the single level of appeal for disputes related to the establishment of F&A cost rates, research patient care rates, and certain other cost allocations used in determining amounts to be reimbursed under NIH grants (e.g., cost allocation plans negotiated with State or local governments and computer, fringe benefit, and other special rates); http://www.hhs.gov/dab/divisions/appellate/index.html. The determination leading to such disputes may be made by an HHS official other than the GMO and may affect NIH grants as well as other HHS grants.

PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities

This Subpart includes terms and conditions that vary from, are in addition to, elaborate on, or highlight the standard requirements and terms and conditions in IIA because of the type of grant, recipient, or grant-supported activity. Each chapter of IIB specifies how the coverage relates to that in IIA and must be used in conjunction with IIA to determine all of the applicable terms and conditions of a covered type of activity, recipient, or award.

This Subpart contains the following chapters:

- Multiple Program Director/Principal Investigator Applications and Awards
- Construction, Modernization, or Major Alteration and Renovation of Research Facilities (this chapter also includes requirements for specified A&R activities under non-construction grants)
- Individual Fellowships and Institutional Research Training Grants (also termed “fellowships” and “training grants”) under the Kirschstein-NRSA program
- Career Development Awards
- Modular Applications and Awards
- Support of Scientific Meetings (Conference Grants)
- Consortium Agreements
- Grants to Foreign Organizations, International Organizations, and Domestic Grants with a Foreign Component
- Grants to Federal Institutions and Payments to Federal Employees Under Grants
- Grants to For-Profit Organizations
- Research Patient Care Costs.

9 MULTIPLE PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR APPLICATIONS AND AWARDS

9.1 GENERAL

Multiple Program Director/Principal Investigator (multiple PD/PI) awards are an opportunity for multidisciplinary efforts and collaboration through a team of scientists under a single grant award. All PD/PIs share equally the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the applicant organization, or as appropriate to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI. The applicant/recipient organization is responsible for securing and retaining the required written assurance signatures from each identified PD/PI on all applications, post-submission information, progress reports, and post-award prior approval requests and must make these signatures available to NIH or other authorized DHHS or Federal officials upon request.

NIH implementation of Multiple PD/PIs is in accordance with the January 4, 2005 Office of Science Technology Policy directive to Federal research agencies. Additional information on Agency implementation plans can be found at: http://rbm.nih.gov/toolkit.htm. NIH also maintains a Web site dedicated to the Multiple PD/PI initiative at: http://grants.nih.gov/grants/multi_pi/index.htm.

9.2 APPLICABILITY

Applications submitted electronically through Grants.gov for most award mechanisms permit multiple PD/PIs, with the exception of awards for which multiple PD/PIs would not be appropriate such as individual fellowship and career awards, dissertations grants (R36), Pioneer Awards (DP1), Construction Grants (C06/UC6), Grants for Repair, Renovation and Modernization of Existing Research Facilities (G20), and Shared Instrumentation Grants (S10). Applications submitted on the paper PHS 398 Grant Application may only include multiple PD/PIs if the option is clearly specified in the Funding Opportunity Announcement. SBIR/STTR applicants may use the multiple PD/PI option; refer to the SBIR/STTR multiple PD/PI section for specific requirements affecting small business concerns. For active awards, changing from a multiple PD/PI model to a single PD/PI model or changes in the number or makeup of the PD/PIs on a multiple PD/PI award requires the prior approval of the funding IC (see Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA).

9.3 APPLICATION REQUIREMENTS

The decision to submit a multiple PD/PI application is that of the applicant organization and the PD/PIs, and should be consistent with the scientific goals of the project. A single applicant organization may designate multiple PD/PIs from the applicant organization or may designate multiple PD/PIs from multiple institutions. Multiple organizations may not submit the same multiple PD/PI application.

All PD/PIs must be qualified and have appropriate expertise to serve as a PD/PI and the appropriate level of authority and responsibility to direct the project or program as part of the leadership team. Each PD/PI must have a defined role on the project. There is no limit on the number of PD/PIs that may be designated, and no minimum person months requirement, except STTR applicants where each PD/PI must commit a minimum of 1.2 calendar months (10%) effort (see Grants to For-Profit Organizations—SBIR and STTR Programs—Multiple PD/PI Applications and Awards).

Contact PD/PI. The applicant organization must designate one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. The Contact PD/PI must be listed first on the application and must be associated with the applicant organization. The Contact PD/PI is responsible for communication between the PD/PIs and the NIH, but has no special authorities or responsibilities within the leadership team. Responsibilities of the Contact PD/PI may include communication between the leadership team and the NIH, assembly of the application materials, and coordination of progress reports. On complex projects the Contact PD/PI may request additional effort for coordination responsibilities if necessary.

eRA Commons Registration Required. All PD/PIs must have established eRA Commons accounts with a PI role prior to application submission. When multiple PD/PIs are at different organizations, all organizations must also be registered in the eRA Commons. If the contact PD/PI is at a different institution from the applicant organization, then the applicant organization must also affiliate the contact PD/PI with their institution. Beyond the contact PD/PI, it is not necessary for all other PD/PIs to be affiliated with the applicant organization.

Leadership Plan. All multiple PD/PI applications are required to include a Leadership Plan. The purpose of the Leadership Plan is to facilitate and enhance scientific productivity and establish a decision-making process. The Plan must describe a rationale for choosing the multiple PD/PI approach. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs, including responsibilities for human subject studies or studies with vertebrate animals as appropriate.

New Investigators (Including Early Stage Investigators). Multiple PD/PI applications may designate senior and new investigators, including early stage investigators. However, the application will only be considered a new investigator application when all of the PD/PIs meet the NIH definition of new investigator, and will only be considered an early stage investigator application when all of the PD/PIs meet the NIH definition of early stage investigator. For the purposes of classification as a new investigator, serving as a PD/PI on a substantial independent PD/PI research award is equivalent to serving as a PD/PI on a substantial independent PD/PI research award. Thus, if a new investigator successfully competes as a PD/PI on a substantial independent multiple PD/PI grant, she or he no longer qualifies as a new (or early stage) investigator on a substantial independent single PD/PI application. However, if a new investigator is added as a PD/PI to an active substantial independent research award, the individual will retain his or her new investigator status.

Multi-Project Applications. Assuming the FOA for Multi-project applications (e.g., P01, P30) specifically allows multiple PD/PIs, applications may include multiple lead investigators for subprojects as well as multiple PD/PIs for the entire program. Do not confuse lead investigator(s) of a subproject or component of a multi-project application with multiple PD/PIs of the entire program. Lead investigator(s) of subprojects or components are not automatically considered to be PD/PIs of the entire application. When a lead investigator of a subproject or component is also a PD/PI of the entire program, that individual must specifically be designated as a PD/PI of the application.

Budgets. In general, multiple PD/PI applications will submit a single budget for the entire project. This applies to both modular and detailed budgets. When determining if a modular budget should be submitted, the $250,000 threshold is for the entire project, not per PD/PI. When multiple PD/PIs are at different institutions, the standard instructions for submitting consortium budgets apply. Applicants can choose to include budget allocation information for specific PD/PIs as part of the Leadership Plan. In the event of an award, the requested allocations may be reflected in a term in the NoA (see Leadership Plan above).

Renewal or Resubmission Applications. A renewal or resubmission application may change from a single PD/PI to multiple PD/PIs, or may change the number or makeup of the multiple PD/PIs, however,

the applicant must provide a rationale for the change in the Introduction, and include the required Leadership Plan in the application. Likewise, a previously submitted multiple PD/PI application may change to a single PD/PI application in a renewal or resubmission; the applicant must provide a rationale for the change in the Introduction.

Competing Revision Applications. A competing revision application to an existing Multiple PD/PI grant must be submitted using the same Contact PD/PI as the parent grant, and may propose changes in the Leadership Plan or in the composition of the leadership (by adding or removing PD/PIs), and should provide a rationale for any such changes. A competitive revision to a single PD/PI grant may be submitted proposing multiple PD/PIs provided a Leadership Plan is also included.

9.4 APPLICATION REVIEW AND AWARD

The review criteria applied to multiple PD/PI applications are the same criteria applied to single PD/PI applications and each application will be evaluated on its own merit (see The Peer Review Process in Part I). Peer reviewers will consider each PD/PI's qualifications and identified role in the project. The leadership approach will be used to facilitate understanding of the complexities of the science and the management of the project. The quality of the Leadership Plan will be considered as part of the assessment of the overall approach, and incorporated into the scientific and technical merit determination. Peer reviewers will not recommend that individual PD/PIs be removed; however, reviewers may recommend deletion of the specific aims and budget of a PD/PI, which would effectively remove the PD/PI's effort.

All PD/PIs are listed on the Summary Statement, in the NoA, and in NIH databases.

9.5 POST-AWARD ADMINISTRATION

If multiple PD/PIs are from multiple organizations, NIH will issue the award to the applicant organization which will administer the award using consortium or subaward arrangements in accord with the Consortium Agreements chapter. Budgets, including F&A costs associated with subawards, will be determined according to existing policy. Changes in the allocation and the size of subawards will be handled in the same way as single PD/PI awards.

Responsibility for all required reports is shared by the PD/PIs and the recipient institution. Only one of each required report should be submitted. Although all PD/PIs are responsible for the content of all reports, only one PD/PI should upload information in the eRA Commons. As with most other Commons features, only the recipient Signing Official may submit the reports to NIH, including closeout reports (final invention statement, progress report and financial status report).

Requests for administrative supplements must be submitted from an authorized official at the recipient organization and include the grant number and name of the Contact PD/PI in the request. For all applications, post-submission information, progress reports, and prior approval requests including requests to add or drop a PI, the recipient organization remains responsible for securing and retaining the required written assurance signatures from each identified PD/PI.

A change in Contact PD/PI may be designated in a non-competing continuation progress report; the Contact PD/PI must be a member of the existing leadership team and associated with the recipient organization. Revision of the Leadership Plan during the project period may be accomplished through a joint decision of the PD/PIs and reported in a non-competing continuation progress report.

All existing prior approval requirements apply to multiple PD/PI awards, including the change in status of any one of the PD/PIs or the addition of a PD/PI; refer to Administrative Requirements—Prior Approval Requirements in IIA. If a PD/PI withdraws from the grant or is no longer able to work on the project, a revised Leadership Plan or description of the impact on the project of a change to a single

PD/PI award must be submitted as part of the prior approval request. NIH will evaluate the request considering the project as a whole, including the impact on the scope of work and budget.

If the Contact PD/PI changes institutions, the recipient institution will need to consider options. Since it is required that the Contact PD/PI be affiliated with the recipient institution in the Commons, the institution may choose to designate another PD/PI as the Contact. Another option would be to relinquish the grant and allow it to be transferred. Contact PD/PIs considering transferring should consult with the NIH awarding IC early in the process to discuss options.

10 CONSTRUCTION, MODERNIZATION, OR MAJOR ALTERATION AND RENOVATION OF RESEARCH FACILITIES

10.1 GENERAL

The chapter uses the following definitions:

- ***Construction.*** Construction of new buildings, or completion of shell space in, existing buildings (including the installation of fixed equipment, but excluding the cost of land acquisition and off-site improvements). The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities. New construction, or activities that would change the "footprint" of an existing facility (e.g., relocation of existing exterior walls, roofs, or floors, attachment of fire escapes) is considered construction.
- ***Modernization.*** Alteration, renovation, remodeling, improvement, and/or repair of an existing building and the provision of equipment necessary to make the building suitable for use for the purposes of a particular program. The entire purpose of the modernization grant is to modernize biomedical research facilities. A modernization grant cannot support the conduct of any research.
- ***Major Alteration and Renovation (A&R).*** An A&R project under a grant whose primary purpose is other than construction or modernization, including a project involving modernization, improvement or remodeling, exceeding $500,000 in direct costs awarded for the project. Major A&R may include improvement, conversion, rearrangement, rehabilitation or remodeling. Major A&R does not apply to minor alterations, renovations or repairs funded under a research project grant or alterations or renovations funded under an NIH center grant. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants.

To provide support for these types of activities, an IC must have specific statutory authority allowing construction or modernization. Even if NIH has this authority, a recipient may not incur costs for any of these activities unless NIH specifically authorizes such costs.

NIH generally solicits applications, and makes awards, for construction or modernization under grants or cooperative agreements specifically for that purpose. The recipient retains the primary responsibility for the project as a whole, including all phases of design and construction. When needed, NIH staff provides technical assistance in designing, constructing, and commissioning the facility and coordinating collaboration with other IC-funded construction activities. Under cooperative agreements, there is substantial scientific/programmatic staff involvement during the performance of the activity.

In addition, an applicant/recipient may propose to undertake an A&R project(s) under a grant whose primary purpose is other than construction or modernization. NIH characterizes these A&R projects as “minor” or “major,” depending on the type of activity proposed and the cost of the project. An A&R project under a grant whose purpose is other than construction or modernization that costs $500,000 or less in direct costs is generally treated as minor A&R. If a recipient believes a post-award change that would result in an A&R project of $500,000 or less in direct costs meets the definition of construction, it should notify the GMO in order for the IC to determine whether it is construction and whether the IC has the necessary statutory authority. The requirements that apply to minor A&R projects are addressed in IIA. Minor A&R projects are not required to satisfy all of the requirements of this chapter. Major A&R projects are subject to the requirements of this chapter as indicated.

Except where indicated, the requirements in this chapter apply to NIH grant-supported construction or modernization in lieu of the requirements in IIA. For major A&R projects, this chapter applies to the A&R activity only and IIA pertains to the other grant-supported activities under the same award, if any. However, there may be areas of overlap (e.g., a rebudgeting action that causes a minor A&R project to become a major A&R project). See Exhibit 11 for a summary of the requirements specified in this chapter and their potential applicability to construction, modernization, or major A&R.

This chapter addresses all aspects of grant-supported construction, modernization, and major A&R from application through closeout. Due to the size and complexity of these activities, this chapter describes in detail requirements and recipient responsibilities related to procurement of construction services (see Procurement Requirements for Construction Services below). Applicants and recipients also should refer to the construction grant program regulations (42 CFR 52b), which, by their terms, apply to construction and modernization grants as well as major A&R under a research grant mechanism; 45 CFR part 75; and program guidelines, as applicable. Questions concerning construction or modernization grants or major A&R requirements or policies should be directed to the GMO or other official designated in the NoA.

10.1.1 Eligibility

In addition to any program-specific eligibility criteria, only public or private non-profit entities located in the United States or in U.S. territories or possessions are eligible to apply for construction or modernization grants. For-profit organizations and foreign organizations are not eligible to receive NIH construction or modernization grants.

10.1.2 Funding Opportunity Announcements

Construction grant applicants are required to apply in response to a specific FOA. RFAs generally are used to solicit construction or modernization grant applications. PAs also may be issued to solicit construction or modernization grant applications for ongoing programs for which applications may be submitted under multiple cycles or years.

In addition to the FOA, NIH awarding ICs also may develop program guidelines that include detailed policy and procedural information applicable to specific construction and modernization grant programs/activities. Any program-specific requirements will be included in or referenced in the FOA and NoA. Applicants should consult the FOA and program guidelines, if any, when applying for construction or modernization grants.

10.1.3 Application Review and Award

Construction and modernization grant applications and applications requesting funding for a major A&R project are subject to peer review. Specific review criteria are included in the FOA.

Construction and modernization grants usually involve a single award, covering more than one year, made on the basis of an application for the entire project. Incremental funding (budget periods) within a project period normally is not used for construction or modernization grants and funding may be limited by the requirements of Federal appropriations law (31 U.S.C. §1552(a)) which may limit NIH's ability to approve no-cost extensions. Recipients must consult with the GMO if it is expected that the construction or modernization activity is unlikely to be concluded within the project period specified in the NoA.

Unlike other grants awarded by NIH, under which a recipient's signature is not required to indicate acceptance of an award, under construction and modernization grants, the AOR must sign the NoA and return it to the GMO to indicate acceptance of the terms and conditions of award.

10.1.4 Title to Site

NIH expects that the applicant holds (or will hold) fee simple title (i.e., absolute ownership of real property or absolute title to land, free of any claims against the title) to the property or other estate or interest in the site (e.g., leasehold interest) on which the construction, modernization, or major A&R is performed. NIH will determine whether an applicant meets this requirement as part of the administrative review of an application.

The applicant must include with the application a legal opinion describing the interest the applicant has in the performance site. The legal opinion should describe any mortgages or other foreclosable liens on the property, including the principal amount of the mortgage (and rate of interest); the dates of the mortgage; the terms and conditions of repayment; the appraised value of the property; and any provisions designed to protect the Federal interest in the property.

10.1.5 Matching Requirement

The requirements for recipients to share in the cost of the project are set forth in 42 CFR 52.b.6, *What is the rate of federal financial participation?* Unless otherwise specified by statute, the rate of federal financial participation in a construction project cannot be more than 50 percent of allowable construction or modernization costs. The NIH can waive this requirement; however, it is not automatic and must be requested from the IC prior to application submission.

Matching may be in the form of allowable costs incurred by the recipient or a contractor under the grant. NIH generally does not allow recipients to use the value of third party in-kind contributions as a source to meet a matching requirement; however, the GMO may allow third party in-kind contributions included in the application budget on an exception basis. Third party in-kind contributions are the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property and the value of goods and services directly benefiting and specifically identifiable to the project or program. To be allowable as matching, costs and in-kind contributions (if authorized) must meet the allowability and documentation requirements of 45 CFR 75.306, as applicable. Costs and third party in-kind contributions claimed as matching also are subject to the requirements in IIA that apply to the expenditure of NIH funds.

The source and amount of funds proposed by an applicant to meet a matching requirement must be identified in the application. The applicant also will be required to demonstrate that the funds are committed or available at the time of, and for the duration of, the award. Exception to “cash on hand” will require negotiation with the NIH prior to award. This may take the form of an assurance, as specified by the NIH awarding IC. The amount of NIH (Federal) funds awarded, combined with the non-Federal share, will constitute the total approved budget as shown in the NoA. The prior approval and other dollar thresholds contained in this chapter are based on the total approved budget unless otherwise specified. Downward adjustments to the matching requirement after award are a prior approval action. If NIH approval is not received in advance it is considered a violation of the terms and conditions of the construction award and may warrant enforcement action.

In addition to sharing in the costs of a construction or modernization grant, the recipient must ensure the availability of sufficient funds for operation (or continued operation) of the facility when construction or modernization is completed to allow the effective use of the facility for the grant-supported purposes.

10.2 PROCUREMENT REQUIREMENTS FOR CONSTRUCTION SERVICES

10.2.1 General

Construction, modernization, and major A&R activity usually is carried out through one or more contracts under the grant. Therefore, the circumstances of the procurement are critical to the successful completion of the grant-supported project. Recipient procurement must comply with the requirements specified in 45 CFR Parts 75.327 through 75.335, as applicable. Recipients must use only those contracting methods that will:

- Ensure that all qualified contractors are given an opportunity to bid or propose and to have their bids/proposals fairly considered.
- Ensure that the contract(s) will result in the completion of a facility—ready for occupancy—that conforms to the design and specifications approved by NIH (or any appropriate modification thereof also approved by NIH), at a cost that is within the owner's ability to pay.

Unless otherwise authorized by NIH, all work associated with NIH grant-supported construction, modernization, or major A&R must be procured by formal advertising, resulting in lump-sum, fixed-price contracts using the Design-Bid-Build model. NIH may authorize other procurement methods and other types of contracts when sealed bidding is impractical (see Construction-Alternate Contracting Methods). The recipient must obtain NIH approval of final construction documents both before bids or proposals are solicited and prior to the award of the contract. The recipient must ensure that the project is completed in accordance with the approved plans and specifications or secure NIH approval of any changes that materially alter the scope or costs of the project, use of space, or functional layout.

The two basic means of ensuring that a contract can be awarded at, or very near, the budgeted amount are accurate cost estimating and the use of bid alternates.

A precise description of the scope of work, specifications, materials, and construction techniques will facilitate accurate cost estimating by the recipient and, ultimately, the responsive bidders. The description of the scope of work is especially important when multiple contracts will be awarded in support of the same project, because each contractor must know exactly what is involved in the portions of the job being bid.

Where practical, the recipient may request in the invitation for bids, alternates to the base bid which are keyed to specified, and explicitly stated, changes in the project scope, materials, or construction techniques. The invitation may contain either additive alternates (adjustments increasing the amount of the base bid), or deductive alternates (adjustments reducing the amount of the base bid), or both. Additive alternates will make it possible to incorporate necessary features that otherwise would not have been included in the project as long as the features do not expand the scope of the peer reviewed and approved project. Alternates that are selected may be included in determining the low aggregate bid.

If, notwithstanding the use of deductive alternates, all bids exceed the funds available, the recipient may:

- Decline to award the contract(s) and instead, after NIH approval, issue a revised invitation for bids containing changes in the bid documents or other factors affecting price.
- Negotiate with the low bidder. All changes in design and specifications resulting from such negotiations must be approved by NIH. If the low bidder refuses to negotiate, negotiations may be entered into with the next lowest bidder. If efforts to negotiate are unsuccessful, all bids must be cancelled and the project rebid.

If the NIH-supported project is less than the entire facility or project, the recipient must obtain bids or proposals that provide the costs for that portion of the total job that will be paid by NIH funds and any required matching. This may be done in one of the following ways:

- If the project consists of more than one building or site and can be divided for purposes of obtaining a price or cost estimate and for carrying out the construction or modernization, showing the cost for each building or site, or
- If the project is a single site or contains common space and cannot be divided for pricing and construction or modernization purposes, identifying or prorating the applicable costs or price.

10.2.2 Liquidated Damages

Invitations for bids must stipulate a time for completion of the project, expressed either in calendar days or as a fixed date, for each prime contract to be awarded under the project.

At the option of the recipient, a liquidated damages provision may be included in the contract, allowing for assessment of damages when the contractor has not completed the construction by the date specified in the contract. Liquidated damages must be realistic and justified and must be approved by NIH before solicitation. Where damages are assessed, any amounts paid belong to the recipient.

10.3 CONTRACTING METHODS

10.3.1 Design-Bid-Build

The traditional three-phase project delivery method in which the recipient contracts with separate entities for each the design and construction phase of a project. It begins with a project design phase, followed by the construction bid phase (including solicitation and selection of a construction contractor), and then the active construction phase.

10.3.2 Alternate Contracting Methods

The use of a contracting method other than Design-Bid-Build, including the use of construction management services or design-build services as described below, may be authorized by NIH when cost, time, and quality benefits will result. In making such determinations, NIH will consider the scope of the project, estimated cost, and other factors deemed relevant. NIH approval must be received before the recipient begins the process of using an alternate contracting method.

If a construction management firm is currently employed, the recipient may choose to authorize that firm to perform the construction work. Such authorization requires NIH prior approval and the price for the work involved must not exceed the GMP also approved by NIH.

10.3.2.1 Construction Manager

10.3.2.1.1 Construction Manager as Agent

Use of construction management services, under which the recipient contracts for technical consultation during the design stage of a project and for organization and general project oversight of construction activities during the construction phase, is considered professional services and, therefore, may be procured on a negotiated basis rather than by formal advertising. However, the services of CMs may be procured by formal advertising in those cases where State or local governments prohibit the award of construction management contracts on a negotiated basis. Where bids are invited, the bidders should be pre-qualified. Under this procedure, the CM, operating as a member of a recipient-architect-CM team, is

responsible for cost estimates during the design and construction as well as cost control, review of design(s) with a view toward value engineering, consultation on construction techniques, construction coordination and scheduling, and oversight of all construction activities. The CM's fee is considered an eligible cost for the purpose of determining the total eligible cost of the project.

10.3.2.1.2 Construction Manager-at-Risk

A CM-at-Risk is considered a sole proprietorship, partnership, corporation, or other legal entity that assumes the financial risk for construction, rehabilitation, alteration, or repair of a facility at a GMP (see Construction-Alternate Contracting Methods-Guaranteed Maximum Price). The CM-at-Risk serves as a general contractor and provides consultation to the client during the design of the facility and through construction. The terms of the CM's employment must be such as to preclude any conflict of interest. The recipient may authorize the CM as Agent to become the CM-at-Risk to perform the construction services when authorized by NIH.

Under this procedure:

- The construction management contract must place total financial responsibility on the CM to complete construction of the project at or below a GMP. The CM is required to provide 100 percent performance and payment bonds to ensure that the facility can be completed with the amount of funds available.
- The GMP must be obtained from the CM before NIH will authorize the award of the first construction contract. This requirement applies whether or not phased construction techniques are employed. Each portion of the work for which a separate contract is expected shall be separately priced as an individual line item in the GMP contract.

10.3.2.2 Design-Build Services

Design-build is a method of project delivery in which one entity works under a single contract with the project owner to provide design and construction services. In design-build contracting, construction firms respond to a request for proposals by submitting building designs that meet the recipient's performance requirements within a GMP (see Construction-Alternate Contracting Methods-Guaranteed Maximum Price) covering all architectural, engineering, and construction services required. The design-build firm must be selected in a manner that will allow maximum feasible competition. Because of the nature of design-build contracting, the following departures from formal advertising are authorized:

- Cost will be treated as a competitive factor although the recipient may insert in the request for proposals a specified maximum permissible figure.
- A contract may be awarded regardless of the number of proposals received or the number of firms determined to have met qualification standards.
- The recipient may negotiate cost or design with one or any number of firms.

The selection of a design-build firm must be accomplished by a process that includes the following activities:

- Preparation of a RFP describing the recipient's design requirements, cost requirements, standards for qualifying firms, and the criteria on which proposals will be judged.
- Public announcement of the RFP.
- Consideration of all proposals from firms that are determined to be qualified.
- Selection of that firm that, in the recipient's judgment, represents the best offer considering both the firm's qualifications and satisfaction of the criteria in the RFP.

On all design-build projects, the recipient must:

- Ensure a firm total cost by including in the contract a provision that extra costs resulting from errors or omissions in the drawings or estimates will be the design-build firm's responsibility.
- Justify cost on the basis of comparability with similar construction.

10.3.2.3 Guaranteed Maximum Price

Under this procedure:

- The Guaranteed Maximum Price (GMP) contracting method can be used in either Construction Manager at Risk contracts or as part of Design-Build Services contracts. In either case, the project must be completed at or below the GMP.
- The recipient must transmit all GMP bids to the GMO, with its recommendation for award to the lowest responsive, responsible bidder.
- The GMP must be completely itemized, by trade, to include a separation of labor and materials, all markups, and no contingency other than that which will cover change orders as approved by the recipient.
- After approval of the GMP, all GMP subcontracts must be competed, and there must be at least three bidders to allow for an award.
    - Issue a "sources sought" announcement describing the nature of the construction work required, the separate contracts to be awarded, and the standards for prequalification. It must also describe the complete scope of work with sufficient specificity to ensure response from all interested sources.
    - Pre-qualify all firms that respond to the announcement who are determined by the recipient to meet the prequalification standards.
    - Establish bidder's lists for each of the invitations to bid. The lists must include all firms qualified on the basis of responses to the "sources sought" announcement and may also include other qualified firms known to the recipient.
    - By written invitation, solicit bids from all firms on the bidders list.
    - Consider bids from any contractor who requests permission to bid and who is determined by the recipient to meet the prequalification standards.
    - If three bids cannot be obtained, the recipient must submit, in writing, to the GMO a detailed explanation of why the GMP contractor is unable to comply, along with supporting documentation for NIH consideration and approval of another alternate contracting method.
    - Funds unexpended, due to lower construction costs than estimated in the GMP, must be refunded or credited to the recipient by the contractor and by the recipient to NIH. All costs in excess of the GMP are the responsibility of the GMP contractor.
    - All subcontract prices must be approved by the GMO before making individual awards. The awards shall be made to the lowest-priced responsible, responsive bidders.

10.4 DESIGN DOCUMENTATION REQUIREMENTS

Unless otherwise specified in the NoA, following award acceptance for construction or modernization grants or award of funds for a major A&R project, the recipient may begin the design phase of the award, which includes the review, and approval of the design documents with the IC program or other

designated NIH staff. Funds for construction, modernization, or major A&R will not be released until the final architectural drawings, specifications, construction schedule, and updated cost estimates are reviewed and approved by the NIH IC unless otherwise indicated in the NoA. The release of funds is accomplished by a revised NoA. The purpose of the NIH design review is to ensure that applicable design standards, including, as applicable, the minimum requirements contained in 42 CFR 52b.12 (see Minimum Requirements for Construction, Modernization, and Major A&R below), have been incorporated into the working drawings and specifications to ensure that program requirements are met, and that the facility will suitably accommodate the activities for which it is planned to be used.

Advertisement for bids may be initiated only after approval of the final construction documents by the NIH awarding IC. The procurement methods to be employed, including any plans that involve a construction management contract with a GMP clause, must be reviewed and approved by the NIH awarding IC.

10.4.1 Minimum Design Requirements for Construction, Modernization and Major A&R

The minimum design requirements for NIH grant-supported construction or modernization are set forth in 42 CFR 52b.12. The *NIH Design Requirements Manual* incorporates the regulatory standards for construction or modernization grants and those for major A&R projects. The *NIH Design Requirements Manual* is available at http://orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines.aspx.

Specific requirements for construction grants are contained in Appendix A, "References, Design and Safety Guidelines, Health and Safety Regulations, Codes and Standards," of the *NIH Design Requirements Manual*. The recipient will be subject to the standards in effect at the time of design or construction (modernization or A&R), as appropriate. Working drawings and specifications submitted for NIH approval (see Design Documentation Requirements above) must conform to the minimum standards in the *NIH Design Requirements Manual*. The *NIH Design Requirements Manual* also include policies, design standards, and technical criteria for use in planning, designing, and constructing or altering/renovating buildings owned or leased for use by NIH. Recipients are not subject to the NIH site specific requirements contained in the *NIH Design Requirements Manual* but should meet the intended design objectives in such cases.

Recipients also must ensure that each project meets the requirements of the applicable State and local codes and ordinances. Where State or local codes are proposed as a basis for facility design in lieu of the NIH design requirements, a prior determination must be made by the NIH awarding IC that the specific State or local code is equivalent to, or exceeds, NIH requirements. If State and local codes or requirements exceed the design requirements set forth in NIH regulations, the *NIH Design Requirements Manual* or program guidelines, the more stringent requirements will apply.

In planning and designing construction or modernization projects, recipients must consider that the facility is generally subject to an extended usage requirement, e.g., 10 or 20 years, after the date of occupancy and it should be constructed accordingly.

NIH will monitor compliance with design requirements during the project's design and construction phase. Recipients (or applicants) with questions concerning the applicability of requirements contained in the *NIH Design Requirements Manual* should consult with the NIH PO.

10.5 EQUAL OPPORTUNITY AND LABOR STANDARDS

Labor standards and equal employment opportunity requirements for federally assisted construction must be specified in the information provided to potential bidders/offerors on contracts for construction services under NIH construction and modernization grants and major A&R projects and must be included in the resulting contract documents (see 45 CFR 75, Appendix II to Part 75-Contract Provisions for Non-Federal Entity Contracts Under Federal Awards). NIH construction and modernization grants and major A&R projects (and contracts under them) are not subject to the requirements of the Davis-Bacon Act, unless the authorizing statute for the program/award specifically requires compliance.

10.5.1 Equal Employment Opportunity

Contracts (and subcontracts) for construction (including modernization or major A&R) are subject to the requirements of EO 11246 (September 24, 1965), as amended and implemented in 41 CFR 60-1 by OFCCP, DoL. The recipient is required to include the "Equal Opportunity Clause" at 41 CFR 60-1.4(b) in any contract for construction services under the grant. The contractor must be directed to include this clause in any applicable subcontracts.

In addition, recipients and contractors providing construction services under NIH grants are required to comply with the solicitation and contract requirements for affirmative action specified in 41 CFR 60-4 for contracts in specified geographical areas that will exceed $10,000. These requirements are specified in the "Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity" and the "Standard Federal Equal Employment Opportunity Construction Contract Specifications" subsections of 41 CFR 60-4.

The OFCCP regulations also require that the recipient notify the applicable OFCCP regional, area, or field office when it expects to award a contract for construction services that will exceed $10,000.

Further information about these requirements and the full text of these regulations are available at http://www.dol.gov/ofccp/.

10.5.2 Nonsegregated Facilities

Pursuant to 41 CFR 60-1.8, for any contract for construction services that will exceed $10,000, the recipient must require that each prospective contractor:

- Does not, and will not, maintain any facilities it provides for its employees in a manner that is segregated on the basis of race, color, religion, sex or national origin;
- Does not, and will not, permit its employees to perform their services at any location, under the contractor's control, where segregated facilities are maintained; and
- Will ensure that prospective subcontractors under any covered subcontract do not maintain segregated facilities or perform services at segregated facilities.

10.5.3 Labor Standards

10.5.3.1 Contract Work Hours and Safety Standards

Contractors and subcontractors providing construction services under NIH construction or modernization grants or major A&R projects with contracts or subcontracts exceeding $100,000 are subject to the requirements of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 3701, et seq., concerning the payment of overtime and the maintenance of healthful and safe working conditions.

Wages paid any laborer or mechanic employed by the contractor or subcontractor must be computed on the basis of a standard workweek of 40 hours. For all work in excess of the standard workweek, mechanics and laborers shall be compensated at a rate not less than one-and-a-half times the basic rate of pay. If this requirement is violated, the contractor or subcontractor is liable to the employee for the unpaid wages and may be liable to the Federal government for liquidated damages. NIH or the recipient may withhold otherwise payable funds to satisfy any such liability. The statute also specifies penalties for intentional violation of these requirements.

Further, pursuant to standards issued by the Secretary of Labor, no contractor or subcontractor under an NIH grant shall require any laborer or mechanic employed in the performance of the contract to work in surroundings or under working conditions that are unsanitary, hazardous, or dangerous to an individual's health or safety. Violation of these requirements may be cause for debarment from future Federal contracts or financial assistance.

10.5.3.2 Disposition of Unclaimed Wages

During or after the period of performance of a contract for construction services under an NIH grant, if it is discovered that an employee is entitled to wages but cannot be located for the purposes of payment (or for some reason refuses to accept payment), the recipient may eventually have to repay the Federal government. Therefore, NIH suggests that the contractor be required to turn over any unclaimed wages to the recipient.

The recipient should notify the GMO that an escrow account has been established in the affected employee's name and should maintain the account for 2 years (or longer if required by State or local law) following the completion of the contract. Upon the expiration of this period, any amounts still unclaimed will be disbursed by refunding to NIH either the entire amount, if the construction, modernization, or major A&R project was 100 percent funded by NIH, or an amount representing the percentage of NIH participation in the project. If the project was funded by more than one NIH or HHS program at differing rates, the refund should be based on an average percentage calculated by weighting each program's rate of participation by the dollar amount of that program's contribution.

If the contractor has made a reasonable effort to locate the employee by having mail forwarded and contacting the employee's union, the recipient need not repeat such attempts. If there is reason to believe that the contractor's efforts to locate employees that are due wages were not thorough, the recipient should attempt to locate the employees. Doing so will reduce the likelihood of future claims against the recipient.

If any wages held in escrow are paid to an employee or an employee's legal representative while the account is maintained, a complete report must be made to the GMO when the account is closed.

10.6 REAL PROPERTY MANAGEMENT STANDARDS

10.6.1 General

Unless alternate requirements are specified in the governing statute:

- Construction, modernization and major A&R under research grants are subject to the requirements of 42 CFR 52b.
- Major A&R under center grants or minor A&R under other types of grants/mechanisms is subject to the provisions of 45 CFR Parts 75.316 through 75.319 and 75.323, as applicable, regarding use, transfer of title, and disposition.

Statutory provisions may specify alternate requirements for the length of the recipient's accountability obligations, the Federal right of recovery, or waivers. To the extent statutory provisions differ from the requirements of 42 CFR 52b and/or 45 CFR 75, including those described in this subsection, the statutory provisions, as reflected in the terms and conditions of the award, apply.

Real property constructed, modernized, or otherwise altered as part of a major alteration with NIH grant support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by NIH. If the recipient defaults in any way on a mortgage, the recipient shall immediately notify the GMO by telephone and in writing. If the mortgagor intends to foreclose, the recipient must notify the GMO in writing at least 30 days before the foreclosure action is initiated.

The mortgage agreement must specifically allow, in the case of default, that NIH or its designee may assume the role of mortgagor and continue to make payments. If NIH (or its designee) chooses not to assume the role of mortgagor, the mortgagee (recipient) must pay NIH an amount equal to the share of the sales proceeds otherwise due the recipient (mortgagor) times the Federal share in the property.

Any NIH assignment of the property and mortgage responsibilities to any party other than NIH shall be subject to prior approval of the mortgagor.

10.6.2 Notice of Federal Interest

To protect the Federal interest in real property constructed, or where applicable, improved with NIH grant funds, recipients shall record a NFI in the appropriate official records of the jurisdiction in which the property is located as required by 45 CFR 75.323 and the NIHGPS. The NFI is required when use and disposition conditions apply to the property as stated in the NoA. The time of recordation shall be when construction begins. The recipient should consult with the GMO prior to recording the NFI, if necessary, to determine if the NFI is required under the award. Fees charged for recording the NFI may be charged to the grant (see Allowable and Unallowable Costs and Activities in this chapter). A copy of the recorded NFI must be provided to the GMO within 10 days following the date of recordation. To obtain a sample NFI, contact the GMO.

10.6.3 Insurance Requirements

Builder's risk insurance is required at the time construction begins. The insurance must cover potential losses after initiation, but before completion, of the construction or modernization caused by theft, fire, vandalism, and other types of accidental loss or damage to the structure.

Immediately upon completion of construction, a nongovernmental recipient shall, at a minimum, provide the same type of insurance coverage as it maintains for other property it owns, consistent with the minimum coverage specified below. "Completion of construction" means either the point at which the builder turns a facility constructed with NIH grant support, or portion of a facility modernized or modified under a major A&R project, (that conforms to the design and specifications approved by the NIH and is available for occupancy) over to the recipient (i.e., the date of the final acceptance of the building or portion of a building) or the date of beneficial occupancy, whichever comes first.

If title to real property constructed, modernized, or altered under a major A&R project under an NIH grant vests (or will vest upon completion) in the recipient, the following minimum insurance coverage is required:

- Title insurance policy that insures the fee interest in the real property for an amount not less than the full appraised value of the property. When the Federal participation covers only a portion of

a building, title insurance should cover the total cost of the facility to prevent liens on the unsecured portion from having an adverse impact on the portion with a Federal interest. In those instances where the recipient already owns the land, such as a building being constructed in the middle of a campus setting, in lieu of a title insurance policy, the recipient may provide evidence satisfactory to the NIH awarding IC, such as legal or title opinion, that it has good and merchantable title free of all mortgages or other foreclosable liens to all land, rights of way, and easements necessary for the project. In instances where a recipient is given land by the State, if the State recently acquired the land in a land swap transaction, the recipient should obtain title insurance. However, if the State has owned the land for a considerable period of time (i.e., 5 years or more), title insurance would not be necessary; a copy of the State documents giving the land to the recipient would be sufficient. If the recipient must buy the land on which to build, a legal opinion would not be sufficient; title insurance must be obtained in order to protect the Federal interest in the building to be constructed.

- Physical destruction insurance policy that insures the full appraised value of the facility (whether owned or leased by the recipient) from risk of partial and total physical destruction. When the Federal participation covers only a portion of a building, the insurance should cover the total cost of the facility, because any damage to the building could make the building unusable and could thus affect the Federal interest. The insurance policy is to be maintained for the duration of the Federal interest in the property (see Real Property Management Standards—Use of Facility and Disposition in this chapter). The cost of insurance coverage after the period of grant support must be borne by a source other than the grant that provided the funds for the grant-supported project. The grant account will not remain active for this purpose.

Governmental recipients may follow their own insurance requirements. Federally owned property provided to a recipient for use need not be insured by the recipient.

The NIH awarding IC may waive one or both of the requirements above if the recipient shows that it is effectively self-insured against the risks involved. The term “effectively self-insured” means that the recipient has sufficient funds to pay for any damage to the facility, including total replacement if necessary, or to satisfy any liens placed against the facility. If the recipient claims self-insurance, the recipient must provide to NIH assurance that it has sufficient funds available to replace or repair the facility or to satisfy all liens. This assurance should state the source of the funds, such as the organization’s endowment or other special funds set aside specifically for this purpose.

10.6.4 Use of Facility and Disposition

NIH construction grants require that the facility be used for biomedical or behavioral research for as long as needed for that purpose for the period prescribed in the NoA. The date of beneficial occupancy is the date that a facility constructed or modernized with NIH grant support conforming to the design and specifications approved by the NIH are available for occupancy and fully operational to carry out all intended facility/research activities. During that time, the recipient must use the facility for the originally authorized purpose unless it obtains prior approval from the NIH awarding IC to use the facility for an alternate purpose. To ensure a recipient’s compliance with the facility usage requirement, the IC GMO will periodically (e.g., at least every two years) survey the recipient throughout the usage period and request a self-certification concerning continued use. NIH may also obtain the names of the investigator (s) occupying the space and an indication of their research interests. Most of the monitoring will be accomplished in this manner. However, NIH staff may perform periodic site visits to observe the use of the grant-supported space throughout the usage period. After the required usage period, NIH will no longer directly monitor the use of the space.

When use and disposition conditions apply to real property supported under an NIH award, the recipient may not convey, transfer, assign, mortgage, lease, or in any other manner encumber such property without the prior written approval from the awarding office. If the recipient decides that the grant-support space is no longer needed before the expiration of the period of Federal interest, the recipient must request written disposition instruction from the awarding office. This action must be done prior to the recipient's making any irreversible commitment related to property disposition. In this case, NIH may consider an alternate use of the facility or provide disposition instructions.

In determining whether to approve an alternate use of the facility, NIH will take into consideration the extent to which the facility will be used for:

- Other health-related purposes consistent with the authorizing legislation of the program.
- Other health-related activities that are consistent with the mission of the IC; or
- Training and instruction in health fields for health professionals or health-related information programs for the public.

The usage obligation may also be transferred to another facility with the prior approval of NIH. If approved, the remaining usage obligation shall be released from the original facility constructed with grant funds and transferred to the new facility. The recipient remains subject to all other requirements imposed by the NoA or successor document (if the change occurs following the period of grant support).

For disposition of property acquired on an amortized acquisition basis, the computation of the Federal share of real property acquired with long-term debt financing will be computed for each year of grant support in which Federal funds are used to meet all or a portion of the down payment and/or principal on the mortgage.

10.6.5 Real Estate Appraisals

If a real estate transaction funded in whole or in part by NIH requires the use of a real estate appraisal (including, but not limited, to appraisals to determine the Federal share of real property and appraisals to determine required insurance levels), the appraisal must be performed by appraisers certified or licensed by the applicable State in accordance with the requirements established by Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (Public Law 101-73).

10.7 ALLOWABLE AND UNALLOWABLE COSTS AND ACTIVITIES

The following lists indicate types of costs and activities generally allowable and unallowable under NIH construction or modernization grants and major A&R projects unless otherwise noted in the FOA. The lists are not all-inclusive. Program guidelines, the NoA, and other terms and conditions of the award should be consulted for the specific costs allowable under a particular program or grant.

Major A&R is unallowable under foreign grants and foreign components in domestic grants.

The allowability and unallowability of costs and activities applies to the use of Federal funds and funds expended by the recipient to satisfy a matching requirement (see Matching Requirement in this chapter).

Allowable costs and activities include the following:

- Acquisition and installation of fixed equipment.
- Appraisals
- Architectural and engineering services. Also see Pre-award costs below.

- Bid advertising
- Bid guarantees and performance and payment bonds. Bid guarantees and performance and payment bonds are allowable as provided in 45 CFR Part 75.334 and 75.427. A bid guarantee is a form of security assuring that the bidder will not withdraw a bid within the period specified for acceptance and will execute a written contract and furnish required bonds. Performance bonds secure fulfillment of all the contractor's obligations under the contract and payment bonds assure payment as required by law to all persons supplying labor and material in the execution of the work provided for in the contract.
- Contingency fund. (See 45 CFR 75.433). To provide for unanticipated costs, applicants for construction grants may include a project contingency amount with the initial total allowable cost estimates. Contingency funds will be limited to 15 percent of the total allowable costs before bids are received and must be reduced to 10 percent after a construction contract has been awarded. NIH may maintain control up to 3% of the total contingency for unanticipated program specific changes during the course of the project.
- Filing fees for recording the NFI. See Real Property Management Standards—Notice of Federal Interest in this chapter.
- Force Account Labor. If the recipient's own construction and maintenance staffs are used in carrying out construction or modernization activities (i.e., force account), the associated costs are allowable provided the recipient can document that a force account is less expensive than if the project were competitively bid and can substantiate all costs with appropriate receipts for the purchase of materials and certified pay records for the labor involved. This requires prior approval by the NIH awarding IC.
- General conditions (e.g. moveable site trailers, port-a-johns, hard hats, temporary or limited duration signage, security costs during construction).
- Inspection and commissioning fees.
- Insurance. Costs of builders risk insurance, title insurance, physical destruction insurance, and liability insurance are generally allowable. Physical destruction, and liability insurance usually are treated as F&A costs but may be treated as direct costs in accordance with the established policy of the recipient, consistently applied regardless of the source of funds. Builder's risk insurance and title insurance may be charged to the grant in proportion to the amount of NIH participation in the property (see Real Property Management Standards—Insurance Requirements in this chapter).
- Legal fees. Legal fees related to obtaining a legal opinion regarding title to a site.
- Pre-award costs. Costs incurred before award for architect's fees, consultant's fees and environmental analysis necessary to the planning and design of the project are allowable if the project is subsequently approved and funded. Pre-award construction or modernization costs are generally unallowable unless NIH grants an exception.
- Profit/fee for contractors/subcontractors. Allowable as part of the overall cost/price of a contract consistent with commercial practice.
- Project management.
- Relocation expenses related to the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (49 CFR 24).
- Sidewalks necessary for use of facility.

- Site survey and soil investigation.
- Site clearance. Site clearance costs are allowable as long as they are reflected in the bid.
- Threat-risk assessment. Costs incurred for a site-specific or project-specific assessment of security risk by a qualified professional are allowable.
- NEPA and historic preservation analysis. Costs associated with evaluation of the environmental effects and historic preservation effects of proposed construction, modernization, or A&R activity and obtaining public input, producing the necessary studies, analysis, and resultant reports are allowable. Also see Pre-award costs above.

Unallowable costs and activities include the following:

- Bonus payments to contractors. Bonus payments other than earned incentive payments to contractors under formal incentive arrangements are unallowable. An incentive arrangement is used to motivate contractors to provide required supplies or services at lower costs and, in certain instances, with improved delivery or technical performance, by relating the amount of profit or fee payable under the contract to the contractor's performance.
- Construction of shell space designed for completion at a future date.
- Consultant fees not related to actual construction.
- Damage judgment suits.
- Equipment purchased through a conditional sales contract. A conditional sale is a type of agreement to sell under which the seller retains title to goods sold and delivered to a purchaser until full payment has been made.
- F&A costs.
- Fund-raising expenses.
- Interior and exterior decorating fees (e.g. purchase of artwork, sculpture, etc).
- Land acquisition.
- Landscaping and irrigation costs.
- Legal services not related to title certification.
- Movable equipment.
- Off-site improvements. Off-site improvements, such as parking lots, are not allowable.

10.8 ADMINISTRATIVE REQUIREMENTS

10.8.1 Prior Approval Requirements

Recipients must obtain written prior approval from the GMO for the following types of recipient-initiated project or budget changes:

- Any applicable change as specified in Administrative Requirements—Changes in Project and Budget in IIA.

- Revision that would result in a change in scope of the project, change in project site and/or location, including proposed modifications that would materially alter the costs of the project, space utilization, or financial outlay (including Federal/non-Federal cost share adjustments), resulting in changes in the previously approved procurement method or contract. Modifications that would materially alter the costs include the transfer of funds between construction and non-construction work.
- Deviations from design requirements.
- Alternate contracting methods.
- Revision that would increase the amount of Federal funds needed to complete the project.
- Extension of the project period with or without funds.
- Change in the use of the facility (see Real Property Standards—Use of Facility and Disposition in this chapter).
- Transfer of the remaining usage obligation to another facility.

The request for approval must include sufficient information to allow NIH review of the circumstance(s) and need for the proposed change. For changes affecting construction contracts, if the recipient receives written prior approval from the GMO, the recipient may make or authorize the approved modifications to the construction contract. Minor modifications to construction contracts may be made without NIH awarding IC prior approval. However, copies of all change orders to construction contracts must be retained as grant-related records (see Administrative Requirements—Monitoring—Record Retention and Access in IIA).

10.8.2 Alteration and Renovation Projects Under Non-construction Grants

Two copies of each of the following documents must be submitted with each request for approval of minor A&R costs greater than $300,000, but not more than $500,000 (whether proposed in the application or as a post-award rebudgeting request):

- Single-line drawing of the existing space and proposed alterations.
- Narrative description of the proposed functional utilization of the space and equipment requirements prepared by the program and administrative managers who will use and be responsible for the working space and, when appropriate, with input from architectural and engineering advisors. Final drawings and specifications will be based on this description. The description must include a detailed explanation of the need, character, and extent of the functions to be housed in the space proposed for A&R, using the following headings, as appropriate:
    - General information
    - Description of the functions to be performed in the space
    - Space schedule (detailed description of floor space)
    - List of fixed equipment proposed for the facility
    - Cost estimate (see sample format in Exhibit 8)
    - Special design problems
    - Description of the existing and proposed utility systems for the modified space
    - Description of plans to provide accessibility for the physically handicapped
    - Provisions for meeting the requirements of the Life Safety Code
    - Length of the property lease if the space is rented
    - Other information required by program legislation or regulations.

When the proposed alteration is to occur in a building that is under construction or in an incomplete structure, two copies of the following documentation also must be provided:

- Detailed justification for the need to perform the work before the building is completed
- Cost comparison between doing the work before and after the building is completed
- Description of other specific benefits to be gained by doing the work before the building is completed.

Applicants/recipients undertaking A&R projects that will require NIH funding of more than $500,000 are subject to the review, approval, and documentation requirements included or referenced in this chapter for construction grants.

10.9 CLOSEOUT

Immediately upon completion of construction, modernization, or alteration under a major A&R project the recipient should contact the awarding IC GMO. Under construction grants, the recipient will generally be required to submit the following documents within 120 days following the completion of the project as part of the closeout process:

- A final tabulation of net assignable space supported under the award for each program activity.
- The actual cost of construction per gross and net square foot/meter.
- The actual total allowable project costs after construction per gross and net square foot/meter.
- Actual date of beneficial occupancy of the facility.
- A simplified floor plan or space assignment drawing in electronic format clearly marked to identify the grant-supported space.

- Final record as-built construction documents.
- Electronic submission of the FFR reflecting both the Federal and non-Federal share of outlays when matching is required.
- A written assurance signed by the AOR stating that the recipient has the required insurance coverage and agrees to maintain the required insurance for the applicable duration of the Federal interest in the property or an indication that the recipient is self-insured against the risks involved and the source of funds.

10.10 PUBLIC POLICY REQUIREMENTS

In addition to the public policy requirements and objectives specified in IIA, grants for construction, modernization or major A&R projects are subject to the public policy requirements in this section. These requirements may be specified by statute, regulation, executive order, or policy, and apply regardless of the type of recipient. Exhibit 11 may be used as guidance; however, some of the requirements for construction or modernization grants or major A&R activities may not be applicable to your project or program. Specific questions about whether a particular requirement applies should be directed to the GMO of the awarding IC. Recipients of construction or modernization grants and funding for major A&R projects also must require contractors and subcontractors providing construction services to comply with certain Federal labor standards. These labor standards are discussed in Equal Employment Opportunity and Labor Standards in this chapter. Following are highlights of public policy requirements:

- ***Architectural Barriers Act of 1968, as amended (42 U.S.C. §§ 4151 et seq.).*** The Architectural Barriers Act of 1968, as amended, the Federal Property Management Regulations 101-19.6 (41 CFR 101-19.6), and the Uniform Federal Accessibility Standards issued by the General Services Administration (41 CFR 101-19.6, Appendix A) set forth requirements to make facilities accessible to, and usable by, the physically handicapped and include minimum design standards. All new facilities constructed with NIH grant support must comply with these requirements. These minimum standards must be included in the specifications for any NIH-funded new construction unless the recipient proposes to substitute standards that meet or exceed these standards. Where NIH assistance is provided for alteration or renovation (including modernization) of existing facilities, the altered facility (or part of the facility) must comply, including use of the minimum standards in the specifications. The recipient will be responsible for conducting inspections to ensure compliance with these standards by any contractor performing construction services under the grant.
- ***Clean Air Act (42 U.S.C. 7401 et seq.), and Federal Water Pollution Control Act (Clean Water Act), as amended (33 U.S.C. 1251 et seq.).*** Provide for the protection and enhancement of the quality of the nation's air resources to promote public health and welfare, and for restoring and maintaining the chemical, physical and biological integrity of the nation's waters; for contracts exceeding $100,000.
- ***Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.).*** Assurance of project consistency with the approved State management program developed under the Act.
- ***Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874).*** When required by statute.
- ***Davis-Bacon Act (40 U.S.C. §§276a to 276a-7).*** When required by statute.

- ***Earthquake Hazards Reduction Act of 1977, as amended (Public Law 95-124), and EO 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990).*** Apply to NIH-assisted construction located in the applicable geographic location. The EO requires that new federally assisted or regulated buildings be designed and constructed using appropriate seismic standards compliant with State, country, or local jurisdictional building ordinances. Where necessary, special structural and other features to protect life and minimize damage to facilities from tornadoes also may be required.
- ***Endangered Species Act of 1973, as amended (P.L. 93-205).*** For the protection of endangered species.
- ***Flood Disaster Protection Act of 1973 - Flood Insurance - The Flood Disaster Protection Act of 1973, as amended (Public Law 93-234).*** Provides that no Federal financial assistance to acquire, modernize, or construct property may be provided in identified flood-prone communities in the United States, unless the community participates in the National Flood Insurance Program and flood insurance is purchased within 1 year of the identification. Lists of flood-prone areas that are eligible for flood insurance are published in the Federal Register by FEMA.
- ***Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.).*** Prohibits the use of lead-based paint in construction or rehabilitation of residence structures.
- ***National Environmental Policy Act of 1969 - NEPA, as amended (Public Law 91-190).*** Establishes national policy goals and procedures to protect and enhance the environment, including protection against natural disasters. NEPA requires all Federal agencies to consider the reasonably foreseeable environmental consequences of any major Federal activity, including grant-supported activities. If NIH determines that NEPA applies to grant-supported activities, NIH will require that the environmental aspects of the activity be reviewed and evaluated by NIH technical staff before final action on the application. This determination also includes determinations concerning floodplain management pursuant to EO 11988, Floodplain Management (May 24, 1977) (42 FR 26951, 3 CFR, 1977 Comp., p. 117) and EO 11990, Protection of Wetlands (May 24, 1977) (42 FR 26961, 3 CFR, 1977 Comp., p. 121).

Because projects for construction, modernization, or major A&R activities have the potential to affect the environment, NIH requires that applicants for this type of support provide information on anticipated environmental impact as part of their just-in-time submission. Applicants may use the Review of Environmental and Other Impacts document that is available at http://d-pcpsi.nih.gov/orip/documents/environmental_analysis_form_3-2009.pdf to supply this information. An alternate format can be used as long as equivalent environmental and other impacts information is provided.

The NIH will review the Environmental and Other Impacts information contained in the application to assess the level of environmental impact of the proposed project. It is the responsibility of NIH to determine which of the following will apply to the proposed project:

- ***Environmental Impact Statement (EIS).*** A document required of federal agencies by the NEPA for major projects or legislative proposals significantly affecting the environment. A tool for decision making, it describes the positive and negative effects of the undertaking and considers alternatives.
- ***Environmental Assessment (EA).*** An environmental analysis prepared pursuant to the NEPA to determine whether a federal action would significantly affect the environment and thus require a more detailed environmental impact statement.
- No Further Action is Required.

If NIH determines that an EA or an EIS is required, the applicant (recipient) must conduct the appropriate environmental review and provide the necessary documentation to NIH for review, approval, and processing. NIH will provide advice and assistance to the applicant (recipient), as necessary, concerning review procedures; evaluate the results of the review; and make the final decision on environmental impact as required by NEPA.

Applicants also must (1) provide a current listing and copies, as applicable, of all relevant licenses, permits, and/or other approvals required including, but not limited to, the State and local air, water quality, and zoning board reports, and (2) indicate the State, local, and regional planning authorities contacted or consulted regarding the application and briefly discuss the proposed facility with respect to regional development plans.

Applicants are not required to incur costs for extensive consultant services at the application stage; therefore, hiring of consultants to develop detailed data and elaborate presentations is discouraged and such costs generally will not be allowable as pre-award costs.

- ***Public Disclosure - Section 102 of NEPA and EO 11514.*** Section 102 of NEPA and EO 11514 (March 5, 1970) provide for public comment and participation in the environmental impact review process. When there is an environmental impact (in accord with NEPA), the applicant must publicly disclose the project in a newspaper or other publicly available medium and to describe any environmental impacts that affect the protection and enhancement of environmental quality concurrent with notification to the SPOC (see Public Policy Requirements—Executive Orders—Intergovernmental Review of Programs under Executive Order 12372 in this chapter). An example of a sample disclosure statement follows:

  "Notice is hereby given that the Uptown Medical School proposes to construct additional space, partially utilizing Federal funds. The proposed construction project is the addition of 251 net square meters connected to the existing Allen Building, which is located at 5333 Main Street, Downtown, Ohio.

  The Medical School has evaluated the environmental and community impact of the proposed construction. There will be (appropriate text will describe impact). The Medical School anticipates that no significant permanent environmental impacts are foreseen, however, this determination is ultimately the responsibility of the awarding Federal agency. In accordance with Executive Order 11514 (March 5, 1970), which implements the National Environmental Policy Act of 1969, as amended, any individual or group may comment on, or request information concerning, the environmental implications of the proposed project. Communications should be addressed to the Office of Planning, Uptown Medical School, and must be received by (date). The Federal grant application may be reviewed at the Office of the Dean, School of Medicine, 5333 Main Street, during normal working hours."

- ***National Historic Preservation Act of 1966 and Archaeological and Historic Preservation Act of 1974.*** Under the provisions of the National Historic Preservation Act, as amended (16 U.S.C. 470 et seq.), and the Archaeological and Historic Preservation Act of 1974, as amended (16 U.S.C. 469a-1 et seq.), the Secretary of the Interior has compiled a National Register of Historic Places—sites and buildings of significant importance to U.S. history. These statutes require that, before approval of a grant related activity, NIH take into account the effect on these sites of the proposed activity. NIH is primarily responsible for determining whether activities will affect a property listed in the National Register or one that meets the eligibility criteria for inclusion, even if not included in the National Register at the time the application is submitted. The National Register of Historic Places may be obtained from the State Liaison Officers designated by their respective states to administer this program or from the Advisory Council on Historic

Preservation, http://www.achp.gov/. The National Trust for Historic Preservation is at http://www.nationaltrust.org/.

If an eligible or potentially eligible historic property will be affected, the applicant must obtain clearance from both the appropriate State Historic Preservation Office and Tribal Historic Preservation Office before submitting the application. Failure to obtain this clearance will delay NIH action on an application. The State Historic Preservation Liaison Officer or the National Trust for Historic Preservation may be contacted for additional details. Information on Tribal Preservation Officers and Offices is available at http://www.achp.gov/thpo.html.

- ***Rehabilitation Act of 1973.*** The HHS implementation of section 504 of the Rehabilitation Act of 1973 is found in 45 CFR 84, Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance. Section 504 is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance. Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by handicapped persons. Furthermore, each facility or part of a facility which is modernized or altered by, on behalf of, or for the use of a recipient in a manner that affects or could affect the usability of the facility or part of the facility shall, to the maximum extent feasible, be modernized or altered in such manner that the altered portion of the facility is readily accessible to and usable by handicapped persons. Design, construction, or alteration of buildings shall conform to the Federal Property Management Regulations at 41 CFR 102 subchapter C, Real Property, Part 102-76.
- ***Safe Drinking Water Act (Title XIV of the Public Health Service Act, as amended).*** For the protection of underground sources of drinking water.
- ***Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Uniform Relocation Act).*** HHS requirements for complying with the Uniform Relocation Act are set forth in 49 CFR 24. Uniform relocation assistance and real property acquisition for Federal and federally assisted programs. The Uniform Relocation Act, 42 U.S.C. 4601 et seq., applies to all programs or projects undertaken by Federal agencies or with Federal financial assistance that cause the displacement of any person. The HHS requirements for complying with the Uniform Relocation Act are set forth in 45 CFR 15, which references 49 CFR 24. Those regulations provide policies and procedures for the acquisition of real property, including acquisition by recipients, and require that displaced people be treated fairly and equitably. They encourage acquiring entities to negotiate promptly and amicably with property owners so property owners' interests are protected and litigation can be avoided.
- ***Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.).*** Related to protecting components or potential components of the national wild and scenic rivers system.

10.10.1 Executive Orders

- ***Intergovernmental Review of Federal Programs (July 14, 1982), as amended, under Executive Order 12372.*** EO 12372 requires consultation with State and local officials on certain proposed Federal assistance. For HHS, these requirements are implemented in 45 CFR 100, Intergovernmental Review of Department of Health and Human Services Programs and Activities. NIH construction and modernization grants are subject to these requirements. Applicants from states that have chosen to participate in the intergovernmental review process should contact their SPOC as early as possible to alert the SPOC to the planned application and to obtain neces-

sary instruction on the State process. Indian tribes (or "federally recognized Indian tribes") are not subject to these requirements.

SPOCs are given 60 days to review applications. To accommodate this time frame and the NIH review process, an applicant must provide a copy of the application to the SPOC no later than the time the application is submitted to NIH. SPOC comments must be submitted to NIH with the application, or the application must indicate the date on which the application was provided to the SPOC for review. If SPOC comments are not submitted with the application, the applicant must provide them upon receipt and may include its reaction to the comments, or it must notify NIH that it did not receive any SPOC response.

- ***Executive Order 11988, Floodplain Management (May 24, 1977) (42 FR 26951, 3 CFR, 1977 Comp., p. 117).*** Uneconomical, hazardous, or unnecessary use of flood plains for construction.
- ***Executive Order 11990, Protection of Wetlands (May 24, 1977).*** See 42 FR 26961, 3 CFR, 1977 Comp., p. 121.
- ***Executive Order 12185, Conservation of Petroleum and Natural Gas (Dec. 17, 1979).*** See 44 FR 75093, 3 CFR, 1979 Comp., p. 474.
- ***Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990).*** See 3 CFR, 1990 Comp., p. 269. See Earthquake Hazards Reduction Act bullet in the Construction—Public Policy Requirements section.
- ***Executive Order 12770 - Metric System.*** Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs. All construction, modernization, or A&R (major or minor) supported by NIH grant funds must be designed using the metric system.

Exhibit 11. Summary of Requirements Applicable to Construction, Modernization, and Major A&R Activities

Program Regulation

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
NIH Construction Grants Regulations (42 CFR 52b)	Applicable	Applicable	Applicable to major A&R under a research project grant; does not apply to minor A&R funded under an NIH Center grant.

Public Policy Requirements

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Architectural Barriers Act of 1968	Applicable	Applicable	Applicable
Clean Air and Clean Water Act	Applicable	Applicable	Applicable
Coastal Zone Management Act of 1972	Applicable	Applicable	Applicable
Copeland Act	As required by statute	As required by statute	As required by statute
Davis-Bacon Act	As required by statute	As required by statute	As required by statute
Earthquake Hazards Reduction Act of 1977	Applicable	N/A	N/A
Endangered Species Act of 1973	Applicable	Applicable	Applicable
Flood Disaster Protection Act of 1973	Applicable	N/A	N/A
Lead-Based Paint Poisoning Prevention Act	Applicable	Applicable	Applicable
National Environmental Policy Act (NEPA) of 1969	Applicable	Applicable	As specified by NIH
Public Disclosure - Section 102 of NEPA and EO 11514 (as applicable for the protection and enhancement of environmental quality)	Applicable when the project involves an environmental impact	Applicable when the project involves an environmental impact	Applicable when the project involves an environmental impact
Rehabilitation Act of 1973 (45 CFR 84)	Applicable	Applicable	Applicable
Safe Drinking Water Act	Applicable	Applicable	Applicable
Uniform Relocation Act (49 CFR 24)	Applicable	N/A	N/A
Wild and Scenic Rivers Act of 1968	Applicable	Applicable	Applicable

Executive Orders

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Executive Order 12372, Intergovernmental Review of Federal Programs	Applicable	Specified in the FOA	Applicable
Executive Order 11988, Floodplain Management	Applicable	Applicable	Applicable
Executive Order 11990, Protection of Wetlands	Applicable	Applicable	Applicable
Executive Order 12185, Conservation of Petroleum and Natural Gas	Applicable	Applicable	Applicable
Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction	Applicable	N/A	N/A
Executive Order 12770, Metric System	Applicable	Applicable	Applicable

Other Requirements

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Matching	Specified in the FOA and NoA	Specified in the FOA and NoA	N/A
NIH Design Requirements Manual	Applicable	Specified in the FOA	Applicable
Design Documentation Requirements	Applicable	Applicable	Applicable

Procurement Requirement

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Liquidated Damages	Applicable	Applicable	Applicable

Equal Employment Opportunity and Labor Standards

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Equal Employment Opportunity	Applicable	Applicable	Applicable
Nonsegregated Facilities	Contracts exceeding $10,000	Contracts exceeding $10,000	Contracts exceeding $10,000
Contract Work Hours and Safety Standards	Contracts exceeding $100,000	Contracts exceeding $100,000	Contracts exceeding $100,000
Disposition of Unclaimed Wages	Applicable	Applicable	Applicable

Real Property Standards

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Real Property Management Standards	Applicable	Applicable	Applicable
Notice of Federal Interest	Applicable	Applicable	Applicable
Title Insurance	Applicable unless waived	Applicable unless waived	Applicable unless waived
Physical Destruction Insurance	Applicable unless waived	Applicable unles waived	Applicable unless waived
Use of Facility and Disposition	Specified in the FOA and NoA	Specified in the FOA and NoA or 45 CFR 75.318	As specified by NIH in accordance with 45 CFR 75.318

Closeout

Requirement	Type of Activity: Construction Grant	Type of Activity: Modernization Grant	Type of Activity: Major A&R Project
Final Record As-built Construction Documents	Applicable	Applicable	N/A

11 RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS

11.1 GENERAL

This chapter includes general information about Kirschstein-NRSA individual fellowships and institutional research training grants. Separate but all inclusive sections are provided for each; therefore some information may appear duplicative but is provided separately so that nuances between individual fellowships and institutional training grants are covered. Many of the requirements of IIA also apply; this chapter of IIB includes appropriate cross-references to IIA when applicable.

11.1.1 Background

Section 487 of the PHS Act (42 U.S.C. 288) provides authority for NIH to award Kirschstein-NRSA individual fellowships to support predoctoral and postdoctoral training of individuals to undertake biomedical, behavioral, or clinical research at domestic and foreign, public and private institutions (profit and non-profit). Section 487(a)(1)(B) authorizes Kirschstein-NRSA institutional research training grants and limits institutional Kirschstein-NRSA support to training and research at domestic public and non-profit private entities. The legislation requires recipients to pay back to the Federal government their initial 12 months of Kirschstein-NRSA postdoctoral support by engaging in health-related biomedical, behavioral and/or clinical research, research training, health-related teaching, or any combination of these activities. (See Payback Requirements in this chapter.) The regulations at 42 CFR 66 apply to these awards.

11.1.2 Nondiscrimination

The Kirschstein-NRSA program is conducted in compliance with applicable laws that provide that no person shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program or activity) receiving Federal assistance. Applicant organizations are required to have appropriate Assurance of Compliance forms filed with HHS's OCR before a grant may be made to that institution. The NIH awarding IC should be contacted if there are any questions concerning compliance. (See Public Policy Requirements and Objectives—Civil Rights in IIA for detailed requirements.)

11.2 INDIVIDUAL FELLOWSHIPS

11.2.1 General

The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical, behavioral, and clinical research agenda. Fellowship activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH mission. Under this authority, NIH awards individual postdoctoral fellowships (F32) to promising applicants with the potential to become productive, independent investigators in fields related to the mission of the NIH ICs. Individual pre-doctoral fellowships for research doctoral dissertation training (F31), Individual pre-doctoral fellowships for MD/PhD and other dual clinical/research doctoral training (F30), and

Senior Fellowships (F33), are also provided under this authority. For individual pre-doctoral fellowships, NIH ICs have differing requirements; specific FOAs should be consulted for guidance.

Kirschstein-NRSA fellowships are awarded as a result of national competition for research training in specified health-related areas. All NIH ICs have authority to award Kirschstein-NRSA fellowships. FIC and NLM also have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

11.2.2 Eligibility

11.2.2.1 Research Areas

Kirschstein-NRSA fellowships may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians. The HHS Secretary is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of 2 consecutive years of biomedical, behavioral, or clinical research training. NIH recognizes the critical importance of training clinicians to become researchers and encourages them to apply. For those who have a doctoral-level health professional degree, the proposed training may be used to satisfy a portion of the degree requirements for a master's degree, a doctoral degree, or any other advanced research degree program.

11.2.2.2 Research Training Program

The Kirschstein-NRSA fellowship must be used to support a program of research training. It may not support studies leading to M.D., D.O., D.D.S., D.V.M., or other similar clinical, health professional degrees except when those studies are part of a formal combined research degree program such as the M.D./Ph.D. Similarly Kirschstein-NRSA fellowships may not support the clinical portion of residency training. Research fellows in clinical areas are expected to devote full time effort to the proposed research training and to confine clinical duties to those that are part of the research training.

11.2.2.3 Degree Requirements

Predoctoral Training. Individuals must have received, as of the activation date of their Kirschstein-NRSA pre-doctoral fellowship award, a baccalaureate degree and must be enrolled in and training at the postbaccalaureate level in a program leading to the award of a Ph.D. or equivalent research degree program (e.g., Eng.D., D.N.Sc., Dr.P.H., D.S.W., Pharm.D, Sc.D.), a formally combined MD/PhD, or other combined professional/clinical and research doctoral program (eg., D.O./Ph.D., D.D.S./Ph.D., D.V.M./Ph.D.) in the biomedical, behavioral, or clinical sciences.

Postdoctoral Training. Before a Kirschstein-NRSA postdoctoral fellowship award can be activated, individuals must have received a Ph.D., M.D., D.D.S, D.M.D., D.C., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D.P.T., Pharm.D., N.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign organization. Also acceptable is a statement by an AOR of the degree-granting institution that all degree requirements have been met. It is the responsibility of the sponsoring institution, not the NIH, to determine if a foreign degree is equivalent.

Senior Fellows. As of the beginning date of their award, senior fellows must have a doctoral degree (as specified in Postdoctoral training referenced above) and at least 7 subsequent years of relevant research and professional experience. The senior fellowship is awarded to provide opportunities for experienced scientists to make major changes in the direction of their research careers or to broaden their scientific backgrounds by acquiring new research capabilities. In addition, these awards will enable individuals who are beyond the new investigator stage to take time from regular professional responsibilities to

enhance their capabilities to engage in health-related research. Senior fellowships are made for full-time research training. Health professionals may use some of their time in clinical duties as part of their research training. More information on the senior fellowship program can be found in the NIH Kirschstein-NRSA Senior Fellows (F33) program announcement available on the NIH Website.

11.2.2.4 Citizenship

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence by the time of award. Noncitizen nationals are individuals, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the responsibility of the sponsoring institution to follow up and ensure that the individual receives the I-551 before the 6-month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the Kirschstein-NRSA individual fellowship program announcement may submit an application for a fellowship. The submission of documentation concerning permanent residency is not required as part of the initial application. Any fellowship applicant selected to receive an award must provide a notarized statement of admission for permanent residence prior to award.

Fellowship applicants who have been lawfully admitted for permanent residence, i.e., have a Permanent Resident Card or other legal verification of such status, should check the Permanent Resident box in the citizenship section on the PHS Fellowship Supplemental Form of the fellowship application. Fellowship applicants who have applied for and have not yet been granted admission as a permanent resident should check the box indicating Permanent Resident of U.S. Pending.

Individuals with a Conditional Permanent Residency Status may still apply for individual fellowships. However, in all cases when permanent residency status is involved, it is the responsibility of the sponsoring institution to assure the individual remains eligible for NRSA support for the period of time of any award.

Individuals with Asylum/Refugee status do not automatically hold a type of permanent residency status; they have the opportunity to apply for permanent residency status once they have been in the U.S. for a period of time. Therefore, individuals with Asylum/Refugee status should only submit an individual fellowship application once they have applied for permanent residency status.

When an application involving Permanent Residency is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the individual's valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.

Individuals on temporary or student visas are not eligible to apply for Kirschstein-NRSA individual fellowships unless they have begun the process for becoming a permanent resident and expect to be admitted as a permanent resident by the earliest possible award date.

11.2.2.5 Sponsorship

General. Before submitting a Kirschstein-NRSA individual fellowship application, the fellowship applicant must identify a sponsoring institution and an individual who will serve as a sponsor (also called mentor or supervisor) and supervise the training and research experience. The sponsoring institution may

be domestic or foreign, public or private (for-profit or non-profit), including the NIH intramural programs, other Federal laboratories, and units of State and local governments. The sponsoring institution is legally responsible for providing facilities for the applicant and financially responsible for the use and disposition of any funds awarded based on the application. The sponsor should be an active investigator in the area of the proposed research who will directly supervise the fellow's research. The sponsor must document in the application the training plan for the applicant as well as the availability of staff, research support, and facilities for high-quality research training. In most cases, postdoctoral fellowships support research training experiences in new settings in order to maximize acquisition of new skills and knowledge. Therefore, postdoctoral fellowship applicants proposing training at their doctoral institution must document thoroughly the opportunity for new training experiences designed to broaden their scientific backgrounds. In addition, the application should propose research experiences that will allow the fellow to acquire new knowledge and/or technical skills that will enhance his/her potential to become a productive, independent investigator.

Foreign Sponsorship. An individual may request support for training abroad. In such cases, the fellowship applicant is required to provide detailed justification for the foreign training, including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than training in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training may require additional administrative reviews and will be considered for funding only when the scientific advantages are clear.

11.2.2.6 NIH Employees & Other Federal Sponsorship (Federal Fellows)

Both civil service employees and PHS commissioned officers at NIH and other Federal laboratories are permitted to compete for predoctoral and postdoctoral fellowships. The proposed training should be primarily for career development rather than for the immediate research needs of NIH or the other Federal laboratory. When at an NIH laboratory, the employee's supervisor must disassociate himself/herself from the review and award process.

An individual at NIH or another Federal laboratory who is supported under an individual fellowship may not also hold an employee position with the Federal Government. Therefore, successful fellowship applicants for predoctoral or postdoctoral awards must either resign from NIH or the other Federal laboratory or take LWOP before activating the award. (There is no obligation or commitment by either the Federal agency or the fellow for future employment upon termination of the fellowship.)

Support provided for Federal fellows is similar to those at non-Federal sponsoring institutions; stipends, tuition (when applicable), and institutional allowance are provided. However, the administration and payment of these fellowships is unique. Specifics are noted in the applicable sections below.

11.2.2.7 Individuals on Active Military Duty

NIH does not restrict career military personnel from applying for Kirschstein-NRSA individual fellowship awards while on active military duty. At the time of application, the fellowship applicant's branch of the military service should submit a letter endorsing his/her application and indicating willingness to continue normal active duty pay and allowances during the period of the requested fellowship. If an award is made, the institutional allowance and necessary tuition and fees permitted on a postdoctoral program will be paid by NIH. However, stipends, health insurance, and travel allowances are not allowable charges to a Kirschstein-NRSA individual fellowship for career military personnel. Payment of concurrent benefits by NIH to active duty career military awardees is not allowed.

11.2.3 Application Requirements and Receipt Dates

11.2.3.1 Application

Each fellowship applicant must submit an application based on the application package provided as part of the FOA. Individual fellowship applications are submitted electronically through Grants.gov using an application package that combines form components from the SF424 (R&R) application with the PHS Fellowship Supplemental Form.

The major emphasis of the application should be the research training experience and broadening of scientific competence. The AOR of the sponsoring institution agrees to secure and retain, but need not submit to NIH, the assurance signatures of the fellowship applicant and sponsor. The assurance of the fellowship applicant includes certification that he or she has read the payback information and will meet any payback provisions required under the law as a condition for accepting the award.

Fellowship applicants and sponsoring institutions must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements; research misconduct; the humane care and use of live vertebrate animals; the inclusion of women, minorities and children in study populations; human embryonic stem cells; and recombinant DNA and human gene transfer research. (For a complete list of applicable requirements, see Exhibit 4, Public Policy Requirements, Objectives and Appropriation Mandates in IIA.)

11.2.3.2 eRA Commons Registration

All fellowship applicants and sponsoring institutions must be registered in the eRA Commons. The fellowship applicant must be assigned the "PI Role" in the eRA Commons. Only the PI Role will provide the fellowship applicant with the appropriate access in the eRA Commons to the application and review information. When a prospective fellowship applicant is submitting an application through a sponsoring institution that is different than their current institution, that individual must be affiliated with the sponsoring institution. Additional information on eRA Commons registration and affiliating individuals with different institutions can be found at https://-commons.era.nih.gov/commons/registration/registrationInstructions.jsp.

11.2.3.3 Letters of Reference

As part of an application submission, at least three (but no more than five) letters of reference on behalf the fellowship applicant also must be submitted. Electronic submission of the fellowship application incorporates a separate, yet simultaneous electronic submission process for reference letters through the eRA Commons. Reference letters are submitted directly by the referee through the eRA Commons and not as part of the electronic application submitted through Grant.gov. Reference letters will be joined with the electronic application within the eRA system once an application completes the submission process. Applications that are missing the required letters may be delayed in the review process or not accepted. Applicants must carefully follow the instructions provided in Part I, Section 5.4 of the Individual Fellowship Application Guide found at: http://grants.nih.gov/grants/funding/424/index.htm. The Application Guide includes specific instructions to be sent to prospective referees.

11.2.3.4 Responsible Conduct of Research

All fellowship applicants must include a plan to obtain instruction in the responsible conduct of research. This plan should document prior instruction in responsible conduct of research during the applicant's current career stage (including the dates of last occurrence) and propose a plan to receive instruction in responsible conduct of research. The plan must address the five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined and

explained below. The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the sponsor/mentor in responsible conduct of research instruction must be described. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process. Further, applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan. For additional instructions, see the specific FOA.

1. ***Format.*** Substantial face-to-face discussions between the fellow, other individuals in a similar training status and sponsors plus a combination of didactic and small-group discussions (e.g. case studies), are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable.
2. ***Subject Matter.*** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:
    a. conflict of interest – personal, professional, and financial
    b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
    c. sponsor/fellow responsibilities and relationships
    d. collaborative research including collaborations with industry
    e. peer review
    f. data acquisition and laboratory tools; data management, sharing and ownership
    g. research misconduct and policies for handling misconduct
    h. responsible authorship and publication
    i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

3. ***Faculty Participation.*** Sponsors and other appropriate faculty are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Sponsors may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors.
4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the fellow, sponsor and other appropriate faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Individual fellows are strongly encouraged to consider how to optimize instruction in responsible conduct of research for their particular career stage. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Senior fellows may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the award recipient is not actually supported by an NIH grant. This instruction must be documented in the submitted plan.

Information on the nature of the instruction in the responsible conduct of research and the extent of fellow and faculty participation also must be provided in the annual progress report submitted as a prerequisite to receiving non-competing continuation support.

11.2.3.5 Concurrent Applications

An individual may not have two or more competing Kirschstein-NRSA individual fellowship applications pending review concurrently. In addition, CSR will not accept for review any application that is essentially the same as one already reviewed.

11.2.3.6 Receipt Dates

Kirschstein-NRSA individual fellowship applications undergo a review process that takes 5 to 8 months. The annual schedule for application receipt, review, and award can be found in a specific Funding Opportunity Announcement and at http://grants.nih.gov/grants/funding/submissionschedule.htm.

11.2.4 Review

Each new and renewal application will be evaluated for scientific merit by an NIH SRG.

11.2.4.1 Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhance the fellowship applicant's potential for a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria (as applicable for the project proposed).

Individual Fellowship programs are training awards and not research awards. Major considerations in the review are the candidate's potential for a productive career, the candidate's need for the proposed training, and the degree to which the research training proposed, the sponsor, and the environment will satisfy those needs.

11.2.4.2 Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. The following review criteria are applicable primarily to F31 and F32 applications. For review criteria pertaining to other individual fellowship applications (e.g., F05, F30, F33), please refer to the specific FOA. The scored criteria are:

- Fellowship Applicant
- Sponsor(s), Collaborator(s), and Consultant(s)

- Research Training Plan
- Training Potential
- Institutional Environment and Commitment to Training

The FOA should be consulted for additional information describing each of the scored review criteria.

11.2.4.3 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Resubmission Applications
- Renewal Applications

The FOA should be consulted for additional information describing each of the relevant additional review criteria.

11.2.4.4 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Training in the Responsible Conduct of Research
- Select Agents Research
- Resource Sharing Plans
- Budget and Period Support
- Foreign Sponsoring Institutions

The FOA should be consulted for additional information describing each of the relevant additional review considerations.

11.2.4.5 Secondary Level of Review

Kirschstein-NRSA individual fellowship applications receive a secondary level of review by IC staff. Criteria used in making award decisions include the SRG's recommendation concerning the overall merit of the application, the relevance of the application to the IC's research training priorities and program balance, and the availability of funds.

11.2.5 Notification of Action

Shortly after the initial review meeting, each fellowship applicant receives an e-mail indicating that the SRG recommendation/impact score is available in the eRA Commons. The fellowship applicant is also notified via an e-mail when the summary statement is available in the eRA Commons.

The PO may notify the fellowship applicant about the final review recommendation. All questions about initial review recommendations and funding possibilities should be directed to the designated IC PO, not

to the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons. If the application is under consideration for funding, NIH will request any additional necessary information from the applicant. After all program and administrative issues have been resolved, the NoA will be issued for those selected for funding.

11.2.6 Period of Support

No individual may receive more than 5 years of aggregate Kirschstein-NRSA support at the predoctoral level and 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of Kirschstein-NRSA support from institutional research training grants and individual fellowships. For individual MD/PhD or other dual-doctoral degree fellowships (F30 only), individuals may receive up to 6 years of aggregate Kirchstein-NRSA support at the pre-doctoral level, including any combination of support from institutional research training grants and individual fellowships. Over the total duration of dual degree support, at least 50 percent of the award period must be devoted to graduate research training leading to the doctoral research degree. For F30 applications for dual-degree candidates other than DDS/PhD, DMD/PhD, and AuD/PhD candidates, applicants must have matriculated into a dual-degree program no more than 48 months prior to the due date of the initial (-01) application. For DDS/PhD, DMD/PhD, and AuD/PhD degree candidates to be eligible, an applicant must have matriculated into a dual-degree program and identified a dissertation research project and sponsor(s).

Any exception to the maximum period of support requires a waiver from the NIH awarding IC based on review of a justification from the individual and sponsoring institution. The AOR of the sponsoring institution must make the request in writing to the NIH awarding IC on behalf of the fellow, and must secure and retain, but need not submit to NIH, the fellow and sponsor's signatures. The request must specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their PO before submitting a waiver request.

Some generally recognized categories under which NIH may grant exceptions include the following:

- ***Physicians/Clinicians.*** Individuals requiring additional time to complete training, either as participants in a combined M.D./Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training. An exception is contingent upon an assurance of the recipient's good academic standing and justified.
- ***Interruptions (Break in Service).*** Requests for additional time also will be considered if an event unavoidably alters the planned course of the research training, if the interruption has significantly detracted from the nature or quality of the planned research training, and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation, which prevent a fellow from effectively pursuing research training for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the fellow an opportunity to use an exceptional training resource directly related to the approved research training program.

Requests for additional time that do not arise from either of the above-described circumstances will be considered only if they are accompanied by an exceptionally strong justification.

11.2.7 Full-Time and Part-Time Training

All fellows are required to pursue their research training full time. Full-time is generally defined as devoting at least 40 hours per week to research training activities or as specified by the sponsoring

institution in accordance with its own policies.

Part-Time Training. While NRSA fellows are required to pursue training full-time, under certain circumstances, a written request may be submitted to the NIH awarding IC to permit less than full-time training.

Written requests for part-time training will be considered on a case by case basis and must be approved by the NIH awarding IC in advance of each budget period. The circumstances requiring part-time training might include medical conditions, disability, or personal or family situations such as a child or elder care. Part-time training will not be approved to accommodate other sources of funding, job opportunities, clinical practice, clinical training, or responsibilities associated with the fellow's position at the sponsoring institution.

Each written request must be signed by the fellow, the AOR and the fellowship sponsor. The request for part-time training must provide a justification of the need for a reduced level of effort and the expected duration of the period of part-time training. The written request also must include an estimate of the expected duration of the period of part-time training and assurances that the fellow intends to return to full-time training when that becomes possible and intends to complete the proposed research training program. In no case will it be permissible for the fellow to be engaged in Kirschstein-NRSA support for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave of absence from Kirschstein-NRSA fellowship support.

NIH will issue a revised NoA with prorated stipend for the period of any approved part-time training. Part-time training may affect the rate of accrual or repayment of the service obligation for postdoctoral fellows.

11.2.8 Initiation of Support

11.2.8.1 Process

The NIH IC will notify the fellowship applicant of the intention to make an award and confirm the plans for the start of fellowship support. The individual may activate the fellowship on or after the Federal; award date of the NoA up to the latest activation date shown in the NoA (generally 6 months after the Federal award date). This timing allows the individual to make arrangements, such as the completion of degree requirements, coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The latest activation date may be extended in unusual circumstances. Written requests for extensions should be submitted to the NIH awarding IC, by the AOR of the sponsoring institution. The sponsoring institution must secure and retain, but need not submit to NIH, signatures of the fellowship applicant and sponsor before the request is submitted to NIH.

The Activation Notice must be submitted to the NIH awarding IC as of the day the individual begins training. A Payback Agreement also must be completed and submitted but only by postdoctoral fellows in their first 12 months of Kirschstein-NRSA postdoctoral support. See Reporting Requirements—Activation Notice and Reporting Requirements—Payback Agreement in this chapter. A stipend may not be paid until the forms are submitted and the fellow begins training. If necessary for payroll purposes, the Activation Notice and Payback Agreement may be submitted up to 30 days before the start date. However, any change in the planned activation start date must be reported immediately to the sponsoring institution's business office and to the NIH awarding IC. If an award is conditioned upon completion of degree requirements, the fellow must submit, with the Activation Notice, proof of completion by the degree-granting institution.

Generally, individual fellowship support is approved for consecutive years of training. The initial award budget period is usually for 12 months. Subsequent periods of approved fellowship training are

consecutive with the first year of support and are usually in 12-month increments (budget periods). Awards for less than 12 months will be prorated accordingly. If a fellow decides not to activate the award, or to terminate early, he or she must notify the institution's business office, the sponsor, and the NIH awarding IC immediately, in writing. NIH will make any necessary adjustments in the stipend and other costs, including the institutional allowance.

11.2.8.2 Payment

Domestic. Non-Federal sponsoring institutions receive an award for the stipend, institutional allowance, and tuition and fees (when applicable). The institution directly pays the fellow and disburses all other awarded costs.

Federal Laboratories. Fellows training at Federal laboratories are paid stipends directly by the NIH awarding IC through NIH's OFM for awards made prior to October 1, 2013. For awards issued after that date, payment is through PMS. Reimbursement to the fellow for appropriate expenditures from the institutional allowance also is coordinated by the NIH awarding IC and paid through OFM for awards made prior to October 1, 2013. For awards issued after that date, reimbursement for appropriate expenditures is still coordinated by the NIH awarding IC; however, payment is through PMS. Note, if a fellow is training at a facility that is Government-owned but Contract operated, this is not considered a Federal laboratory. As with other grants to these types of facilities, the sponsoring institution would be the contractor.

Foreign. Fellows training at foreign sites receive stipends directly from NIH's OFM for awards made prior to October 1, 2013. For awards issued after that date, payment is through PMS. However, the institutional allowance is awarded to and disbursed by the sponsoring institution.

11.2.9 Allowable and Unallowable Costs

11.2.9.1 Pre-award Costs

Pre-award costs to an individual fellowship are limited. Stipends and tuition and fees may not be charged to a fellowship award until a fellow has actually activated and the appropriate paperwork submitted to the NIH. Therefore, these costs may never be charged as pre-award to an individual fellowship. There are rare occasions when costs associated with the institutional allowance may be allowable as pre-award costs. Sponsoring institutions should consult with the NIH awarding IC when considering a pre-award cost.

11.2.9.2 Stipends

A stipend is provided as a subsistence allowance for Kirschstein-NRSA fellows to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal government or the sponsoring institution. Stipends must be paid in accordance with stipend levels established by NIH, which are based on a 12-month full-time training appointment. In the event of early termination, the stipend will be prorated according to the amount of time spent in training. The sponsoring institution will submit a Termination Notice reflecting the early termination and the NIH awarding IC will issue a revised NoA to decrease approved funding. The sponsoring institution must base its calculations on the applicable stipend level provided by the NIH.

11.2.9.3 Stipend Levels

Stipend levels are updated periodically in conjunction with an NIH annual appropriation. When increases are approved, they are published in the *NIH Guide for Grants and Contracts*. Current levels are posted at http://grants.nih.gov/training/nrsa.htm. The NIH awarding IC will adjust fellowship awards on their anniversary dates to include the currently applicable stipend amount.

General information related to stipends follows:

- ***Predoctoral.*** One stipend level is used for all pre-doctoral candidates, regardless of the level of experience.
- ***Postdoctoral.*** The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the fellow must be paid at that level for the entire grant year. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.
- ***Senior Fellows.*** The amount of the Kirschstein-NRSA stipend to be paid must be commensurate with the base salary or remuneration that the individual receiving the award would have been paid by the institution with which he or she has permanent affiliation on the Federal award date of the fellowship award. In no case shall the stipend award exceed the current Kirschstein-NRSA stipend limit set by NIH. The level of Kirschstein-NRSA support will take into account concurrent salary support provided by the institution and the policy of the sponsoring institution. NIH support does not provide fringe benefits for senior fellows.

11.2.9.4 Institutional Allowance

NIH awards an institutional allowance to help support the costs of training. The specific levels of allowance for predoctoral and postdoctoral support, including those for individuals training at Federal laboratories, for-profit organizations, or foreign organizations, are published in the *NIH Guide for Grants and Contracts*. They also are available on the NIH Web site at http://-grants.nih.gov/training/nrsa.htm#fellowships.

The institutional allowance is a fixed amount. Expenditures under institutional allowances are not subject to NIH prior approval requirements, and the institution is not required to account for these expenditures on an actual cost basis. Allowable uses of the Institutional Allowance are described below.

Except for fellows at Federal training sites, consistent with NIH policy governing the type of expenditures appropriate for the institutional allowance, the sponsoring institution authorizes the expenditure of the institutional allowance on behalf of the fellow according to the institution's policy. The institution is entitled to expend up to the full institutional allowance upon official activation of the award. However, if an individual fellow is not in a training status for more than 6 months of the award year, only one-half of that year's institutional allowance may be charged to the grant. The NoA will be revised and the stipend and institutional allowance balances must be refunded to NIH.

For fellows at Federal training sites, the NIH awarding IC authorizes the expenditure of the allowance. Payment is made through NIH's OFM for awards made prior to October 1, 2013 and through PMS for awards issued after that date.

The type of sponsoring institution dictates what costs may be charged to this category and how the funds are to be administered:

- ***Non-Federal Public and Private Non-Profit Institutions (Domestic and Foreign).*** The allowance is intended to defray expenses for the individual fellow such as research supplies, equipment, travel to scientific meetings, and health insurance and to otherwise offset, insofar as possible, appropriate administrative costs of training. Funds are paid directly to and administered by the sponsoring institution.

- ***Federal Laboratories.*** The allowance is intended to cover the costs of scientific meeting travel, health insurance, and books. Funds are administered by the NIH awarding IC and disbursed through PMS.
- ***For-Profit Institutions.*** The allowance is intended to cover the costs of scientific meeting travel, health insurance, and books. Funds are paid directly to the sponsoring institution for disbursement to the fellow.

The following are guidelines for the use of the institutional allowance:

- ***Travel.*** Payment for travel to scientific meetings is appropriate when it is necessary for the individual's training and when the costs are incurred within the period of grant-supported training.

  For fellows at Federal laboratories, reimbursement of travel costs must be in accordance with applicable Federal travel regulations.

  Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training institution, except that the sponsoring institution may authorize the cost of a one-way travel allowance in an individual case of extreme hardship.

- ***Health Insurance.*** A fellow's health insurance is an allowable cost only if applied consistently to all individuals in a similar training status regardless of the source of support. Family health insurance is an allowable cost for fellows who have families and are eligible for family health insurance coverage at the sponsoring institution. Self-only health insurance is an allowable cost for fellows without families. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy. Historically predoctoral fellowships included health insurance as part of the tuition and fees category. This is no longer the policy. For any fellowship (predoctoral and postdoctoral) that competed and was awarded in FY2007 and beyond, health insurance is awarded as part of the Institutional Allowance. Any fellowship that competed and was awarded prior to FY2007, health insurance will continue to be awarded as part of the Tuition and Fees category.
- ***Medical Liability and Other Special Insurance.*** Medical liability (malpractice) insurance or other special insurance is an allowable cost to NRSA grants only if nature of the research training requires such special insurance. For instance, medical liability would be allowable if the research training experience involves direct contact with patients or human subjects. In all cases, for the cost to be charged to the NRSA grant, it must be consistently required for all in a similar training status, regardless of the source of support. Special insurances that are routinely offered as optional employee benefits (such as disability insurance, life insurance, or workman's compensation insurance), are not normally allowable charges (see separate section on Employee Benefits) unless the nature of the research training requires such special insurance.
- ***Extraordinary Costs.*** Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution in the application or as part of a special written request.

11.2.9.5 Tuition and Fees

Tuition and fees are provided under the following policy:

- For individual predoctoral fellowships (**F30 and F31**), an amount equal to 60% of the level requested by the sponsoring institution, up to $16,000 per year, will be provided. If the program supports formally combined dual-degree training (e.g., M.D.-Ph.D., D.D.S.-Ph.D.), the amount provided will be up to $21,000 per year. Note the new policy moves health insurance into the Institutional Allowance budget category for predoctoral fellowships. This is now consistent with the treatment of this cost for postdoctoral fellowships
- For individual postdoctoral fellowships (**F32**) and individual senior fellowships (**F33**), an amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year, will be provided. If the program supports postdoctoral individuals in formal degree-granting training, the amount provided will be up to $16,000 per year. For postdoctoral fellows, costs associated with tuition and fees are allowable only if they are required for specific courses in support of the research training. Health insurance is not included in this budget item because costs for it are to be charged as institutional allowance.

11.2.9.6 Travel to Foreign Training Sites

For fellows at foreign training sites, in addition to the institutional allowance, awards may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference. Any funds awarded for travel to/from foreign training sites must be reported on the Termination Notice as part of the "Amount of Stipend" column. For additional information regarding foreign travel, see Cost Considerations—Allowability of Costs/Activities-Selected Items of Cost-Travel/Employees in IIA.

11.2.9.7 Employee Benefits

Since Kirschstein-NRSA fellowships are not provided as a condition of employment with either the Federal government or the sponsoring institution, institutions may not seek funds, or charge individual fellowship awards, for costs that normally would be associated with employee benefits (for example, FICA, workman's compensation, life insurance, union dues, and unemployment insurance). Concerning union dues or other similar costs otherwise paid personally by the fellow; if a fellow requests the institution deduct such a cost from the stipend amount, the institution can provide the fellow such a service. However, in no case can such a deduction from the stipend be made automatically without the approval of the fellow.

11.2.9.8 Rebudgeting of Funds

Individual fellowship awards are formula based, generally restricted for the specific budget category of the award, and cannot be rebudgeted without prior written approval from the NIH awarding IC.

- Stipends must be expended using the stipend level provided in the award; no funds can be rebudgeted into the stipend category to accommodate a stipend level different from the established NIH level. When a fellowship terminates early, any unexpended stipends must be returned and cannot be rebudgeted into any other budget category.
- Institutional allowance is a fixed amount of money with a number of allowable costs. In the rare case where institutional allowance may be unexpended, it can only be rebudgeted into the tuition and fees category when tuition and fees have been awarded.
- When tuition and fees is awarded, it is generally restricted and cannot be rebudgeted without prior written approval from the NIH awarding IC.

11.2.10 Supplementation of Stipends, Compensation, and Other Income

11.2.10.1 Stipend Supplementation

Kirschstein-NRSA fellows receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation is without any additional obligation for the fellow. An institution can determine the amount of stipend supplementation, if any, it will provide according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may PHS funds be used for supplementation.

An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in Other Income: Educational Loans or GI Bill in this chapter.

11.2.10.2 Compensation

NIH recognizes that Kirschstein-NRSA fellows may seek part-time employment incidental to their training program to offset further their expenses. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part time research, teaching, or clinical employment, so long as those activities do not interfere with, or lengthen, the duration of their NRSA training. Funds characterized as compensation may be paid to fellows only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions for compensation of students as detailed in Cost Considerations—Selected Items of Cost—Fringe Benefits / IHE Tuition/Tuition Remission in IIA. In addition, compensation must be in accordance with organizational policies applied consistently to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, NIH expects that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the fellow's planned training experience as approved in the Kirschstein-NRSA individual fellowship application.

Stipend Supplementation & Compensation. Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved Kirschstein-NRSA training program. Fellowship sponsors must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

11.2.10.3 Other Income: Concurrent Benefits

A Kirschstein-NRSA individual fellowship may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA.

11.2.10.4 Other Income: Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation.

11.2.10.5 Other Income: NIH Loan Repayment Program

Postdoctoral fellows may also be eligible to participate in the NIH Loan Repayment Program. Information on this program is available at http://www.lrp.nih.gov/.

11.2.10.6 Taxability of Stipends

Section 117 of the Internal Revenue Code (26 U.S.C. 117) applies to the tax treatment of scholarships and fellowships. In general, degree candidates may exclude from gross income (for tax purposes) any amount used for qualified tuition and related expenses such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are required to report as gross income any monies paid on their behalf for stipends or any course tuition and fees required for attendance.

The IRS and Treasury Department released regulations in January 2005 (Revenue Procedures 2005-11) clarifying the student exception to the FICA (Social Security and Medicare) taxes for students employed by a school, college, or university where the student is pursuing a course of study. NIH's understanding is that these final regulations do **not** apply to or impact Kirschstein-NRSA programs or awards.

The taxability of stipends in no way alters the relationship between Kirschstein-NRSA fellows and sponsoring institutions. Kirschstein-NRSA stipends are not considered salaries. In addition, recipients of Kirschstein-NRSA individual fellowships are not considered to be in an employee-employer relationship with NIH or the sponsoring institution solely as a result of the Kirschstein-NRSA award. The interpretation and implementation of the tax laws are the domain of the IRS and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

11.2.10.7 Form 1099

Although stipends are not considered salaries, these funds are subject to Federal and, sometimes, State income tax. Such income may be reported by the sponsoring institution on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the sponsoring institution will be responsible for annually preparing and issuing IRS Form 1099 for fellows paid through the institution (fellows at domestic non-Federal institutions). Sponsoring institutions are not required to issue a Form 1099, but it is a useful form of documentation of funds received and it serves as a reminder to the fellow that some tax liability may exist. Fellows are reminded that, even if the sponsoring institution does not issue a Form 1099, they still are required to report Kirschstein-NRSA stipends. NIH will issue a Form 1099 for each fellow training at a Federal or foreign laboratory and receiving a stipend check from the NIH for awards made prior to October 1, 2013. For awards issued after that date, PMS will issue the Form 1099.

11.2.11 Reporting Requirements

The submission of the forms described in this subsection is critical to establishing and paying stipends and other costs and determining possible payback service. All of these forms are available in PDF-fillable and Word formats at http://grants.nih.gov/grants/forms.htm. The NIH awarding IC may provide copies of applicable forms with the NoA or reference this Web site in the NoA.

11.2.11.1 Activation Notice

The individual may activate the fellowship on or after the issue date of the NoA up to the latest activation date shown in the NoA (generally 6 months after the award issue date).Immediately upon the initiation of training, the individual must complete and sign the Ruth L. Kirschstein Individual Fellowship

Activation Notice (Form PHS 416-5), obtain the signature of the AOR, and forward the notice along with the Payback Agreement (required only for postdoctoral fellows in their first 12 months of Kirschstein-NRSA support) to the NIH awarding IC.

For Kirschstein-NRSA fellows paid directly by PMS (i.e., those sponsored by foreign or federal institutions, the Activation Notice is required for the initial year only and should be submitted immediately prior to the initiation of training. For all other Kirschstein-NRSA fellows the form should not be submitted before the fellow actually begins training. Stipend checks are issued when both the Activation Notice and the Payback Agreement (required only for postdoctoral fellows in their first 12 months of Kirschstein-NRSA support) are received by the NIH awarding IC.

The Activation Notice is required for the initial year only. The Activation Notice may be submitted up to 30 days before the individual begins training if necessary for payroll purposes. However, the institution must not release any funds until the individual has started training. Furthermore, if the individual does not begin research training on the day indicated, the institution must notify the NIH awarding IC immediately. Competing continuation awards must be activated on the day following the end of the last budget period of the previous award.

11.2.11.2 Payback Agreement

A Ruth L. Kirschstein National Research Service Award Payback Agreement (Form PHS 6031) that covers the initial 12 months of Kirschstein-NRSA postdoctoral support must be signed by each person who is to receive an individual postdoctoral fellowship. This form is not required if the individual has already received 12 months of postdoctoral Kirschstein-NRSA support under any Kirschstein-NRSA institutional research training grant or fellowship award. For details on Kirschstein-NRSA payback, see Payback Reporting Requirements in this chapter.

No Payback Agreement is required for predoctoral fellows.

11.2.11.3 Termination Notice

The Ruth L. Kirschstein National Research Service Award Termination Notice (Form PHS 416-7) (along with the Activation Notice and the NoA) is the basis for validating the total period of Kirschstein-NRSA support and establishing the amount of payback obligation for each Kirschstein-NRSA fellow. For individual fellowships, a reminder of this reporting requirement may be sent to the fellow by the NIH awarding IC before the scheduled termination date. For early terminations, the completed form will be required immediately upon receipt of notification from the fellow or an AOR.

For individual fellowships training at Foreign training sites, any funds awarded for travel to/from foreign training sites must be reported on the Termination Notice as part of the “Amount of Stipend” column. For individual fellowships training at Federal laboratories, this column should include all monies paid directly to them through PMS (stipend, travel, etc. as awarded).

The termination notice must be submitted within 30 days of the termination date even if the fellow is not available for signature. In all cases, the information on the form must be verified by the sponsor and an institutional business official. The lack of timely and accurate information on this form could adversely affect data collected associated with aggregate NRSA support and the payback process. For additional information on early termination, see Changes in the Project below. All Termination Notices for individual fellowships are required to be submitted electronically using the eRA Commons xTrain application.

11.2.11.4 Consecutive Support

If a fellow switches from one Kirschstein-NRSA grant mechanism to another (e.g., from an institutional research training grant to an individual fellowship or from one NIH IC to another), the requirement for payback service incurred is deferred until the total period of Kirschstein-NRSA support is completed. All fellowship applications are reviewed to determine if previous Kirschstein-NRSA support has been provided.

11.2.11.5 Progress Reports

Annual progress reports must be submitted for non-competing continuation support. The Research Performance Progress Report (RPPR), which is required for fellowship awards, can be accessed from the eRA Commons. The IDP requirement described in Non-Competing Continuation Progress Reports applies to individual fellowships. Inadequate or incomplete progress reports may result in a delay of continued support. For Kirschstein-NRSA individual fellowship awards, the final progress report information is required as part of the Termination Notice.

11.2.11.6 Financial Reporting

An annual or final FFR to report expenditure information is not required for Kirschstein-NRSA individual fellowship awards. However, sponsoring institutions must still complete the quarterly reporting of Federal cash transactions using the FFR and submit that information directly to PMS.

11.2.12 Changes in the Project

Individual fellowship awards are made for training at a specific institution under the guidance of a particular sponsor. The approval of the NIH awarding IC is required for a transfer of the award to another institution, a change in sponsor, or a project change. As part of the approval process, if a fellow sponsored by a domestic non-Federal institution requests a transfer to another domestic non-Federal institution before the end of the current award year, the institutions are responsible for negotiating which will pay the stipend until the end of the current year. Disposition of the institutional allowance is also negotiable between the two sponsoring institutions. No Activation Notice is required from the new sponsoring institution.

Transfers involving Federal or foreign sponsoring institutions require unique administrative procedures and approvals. Because each transfer varies depending on individual circumstances, the sponsoring institution should contact the NIH awarding IC for specific guidance.

Any proposed change in the individual's specified area of research training must be reviewed and approved in writing by the NIH awarding IC to ensure that the training continues to be within the scientific scope of the original peer-reviewed application.

When the sponsor plans to be absent for a continuous period of more than 3 months, an interim sponsor must be named by the institution and approved in writing by the NIH awarding IC.

11.2.13 Other Terms and Conditions

11.2.13.1 Leave

Vacations and Holidays. Kirschstein-NRSA fellows may receive the same vacations and holidays available to individuals in comparable training positions at the sponsoring institution. Fellows shall continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters generally is considered an active part of the training period and is not considered to be a vacation or holiday.

Sick leave and Other Leave. Kirschstein-NRSA fellows may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for medical conditions related to pregnancy and childbirth.

Parental Leave. Kirschstein-NRSA fellows may receive stipends for up to *60 calendar days* (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of each child. NRSA trainees and fellows must provide advanced notification to the grantee institution prior to taking parental leave. Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds. Either parent is eligible for parental leave. The use of parental leave requires approval by the sponsor.

Terminal Leave. A period of terminal leave is not permitted, and payment may not be made from grant funds for leave not taken.

Unpaid Leave. Individuals requiring extended periods of time away from their research training experience, that is, more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding IC for an unpaid leave of absence. A request letter signed by the fellow and fellowship sponsor must be submitted by the AOR, and must advise the NIH awarding IC of the dates of the leave of absence. Upon approval of the request, the NIH awarding IC will issue a revised NoA extending the ending date of the current budget/project period by the appropriate number of days or months of unpaid leave time. Recipients are precluded from spending award funds during the leave of absence; although continued coverage of health insurance would be allowable if in accordance with policy of the sponsoring institution.

During a leave of absence, documentation to suspend the award and/or the accrual of service for calculating the payback obligation must be completed and retained by the sponsoring institution. When the fellowship is eventually terminated, the leave of absence must be clearly documented on the Termination Notice.

11.2.13.2 Termination

NIH may terminate a Kirschstein-NRSA individual fellowship before its scheduled completion date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. If an award is terminated for cause, NIH will notify the fellow in writing of the determination, the reasons for the determination, the effective date, and the right to appeal the decision.

NIH also may terminate an award at the request of the sponsoring institution or the individual fellow. The NIH awarding IC must be notified immediately if a sponsoring institution wants to terminate an individual fellow or the fellow decides to terminate training before the scheduled completion date.

If a fellow receives another NIH award, e.g., as a PD/PI on an R03, then the fellow is no longer eligible for the fellowship and the sponsoring institution should contact the awarding IC concerning early termination.

If a Kirschstein-NRSA fellowship is terminated early, the stipend must be prorated according to the amount of time spent in training, and the NoA will be revised downward. In addition, if the length of the final budget period was 6 months or less, the balance of any institutional allowance (at least one-half) must be refunded.

11.2.13.3 Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, recipients of Kirschstein-NRSA fellowships should make the results and accomplishments of their activities

available to the research community and to the public at large. The sponsoring institution should assist the fellow in such activities, including the further development of discoveries and inventions for furthering research and benefiting the public. No restrictions should be placed on the publication of results.

Kirschstein-NRSA fellows are encouraged to submit reports of their findings to the journals of their choice for publication. Responsibility for direction of the project should not be ascribed to NIH. However, NIH awarding IC support must be acknowledged by a footnote in language similar to the following: "This research was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award (number) from the (name of NIH IC)." In addition, Federal funding must be acknowledged as provided in Appropriation Mandates—Acknowledgment of Federal Funding in IIA.

The Public Access Policy requirements described in Administrative Requirements—Availability of Research Results—NIH Public Access Policy in IIA apply to articles that are authored or co-authored by NRSA fellows and arose from NIH Support. Information on publications is included as part of the annual progress report.

11.2.13.4 Copyright

Except as otherwise provided in the conditions of the award, when a publication or similar copyrightable material is developed from work supported by NIH, the author is free to arrange for copyright without approval of the NIH awarding IC. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce, translate, publish, and use and dispose of such materials, and to authorize others to do so for Federal government purposes.

11.2.13.5 Inventions and Patents

Fellowships funded primarily for educational purposes are not subject to invention reporting requirements nor does NIH have any rights to inventions under those awards (as specified in 37 CFR 401.1(b)). Kirschstein-NRSA fellows training at NIH represent an exception to this policy. Those fellows are subject to the provisions of EO 10096 and NIH determines the disposition of rights to any invention conceived or first actually reduced to practice during the period of the fellowship.

11.2.13.6 Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award must be assigned to the sponsoring institution for disposition in accordance with established organizational policy. The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations, which, if permitted by organizational policy, may be retained by the fellow.

11.2.13.7 Public Policy Requirements and Objectives

All Public Policy Requirements, Objectives, and Other Appropriation Mandates discussed in IIA apply to Individual Kirschstein-NRSA fellowships when appropriate. Applicants must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements and inclusion policies for women, minorities and children; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant DNA and human gene transfer research. See IIA for a complete list of applicable requirements.

It is the sponsoring institution's responsibility to ensure that a fellow has received the proper training/education and is properly supervised particularly in the areas of human subjects research, vertebrate animal research, and occupational safety programs.

Additional information and any application requirements can be found in the Individual Fellowship Application Guide available at: http://grants.nih.gov/grants/funding/424/index.htm.

Information provided below is in addition to that provided in IIA where unique circumstances might exist for individual fellowships.

11.2.13.7.1 Human Subjects

Indefinite Involvement. If the sponsoring institution has an approved FWA on file with OHRP but, at the time of application, plans for the involvement of human subjects are indefinite, the assurance number should be provided in the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

If the applicant organization does not have a FWA registered with the OHRP, that registration process must be completed prior to IRB approval.

11.2.13.7.2 Vertebrate Animals

Indefinite Involvement. If the sponsoring institution has an approved Animal Welfare Assurance on file with OLAW but, at the time of application, its plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, the institution should indicate "Yes," to the involvement of Vertebrate Animals, include the Animal Welfare Assurance number, and indicate "Indefinite." If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding IC.

If the applicant organization does not have an approved Animal Welfare Assurance on file with OLAW or for additional information on vertebrate animals, refer to the Individual Fellowship Application Guide or contact OLAW (see Part III).

11.2.13.8 Applicability of NIH Standard Terms of Award

Individual Fellowships are awarded under the NIH Standard Terms of Award however the provisions to extend the final budget period of a project period without additional funds and carryover of unobligated balances do not apply.

11.3 INSTITUTIONAL RESEARCH TRAINING GRANTS

11.3.1 General

NIH will award Kirschstein-NRSA institutional research training grants (T32, TL2, T34, and T35) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical, behavioral, and clinical research. The purpose of the Kirschstein-NRSA program is to help ensure that a diverse and highly trained workforce is available in adequate numbers and in the appropriate research areas and fields to carry out the nation's biomedical, behavioral, and clinical research agenda. Training activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH Mission. The Kirschstein-NRSA program supports predoctoral, postdoctoral, and short-term research training as well as limited specialized support at the pre-baccalaureate level. All NIH ICs except FIC and NLM award Kirschstein-NRSA institutional research training grants. FIC and NLM have unique funding authorities for training grants that are separate from the Kirschstein-NRSA authority.

11.3.2 Eligibility

11.3.2.1 Applicant Eligibility

A domestic, non-profit public or private organization may apply for a grant to support a research training program in a specified area(s) of research. Support for predoctoral, postdoctoral, or a combination of trainees may be requested. (Specific program announcements should be consulted for IC guidelines.) Support for short-term training positions for students in health-professional degree programs also may be requested as indicated in Short-Term Research Training in this subsection. Each applicant institution must submit an application using the research training forms and instructions (see Application Requirements and Receipt Dates in this subsection).

11.3.2.2 Research Areas

Kirschstein-NRSA institutional research training grants may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians. The HHS Secretary is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of 2 consecutive years of biomedical, behavioral, or clinical research training.

The applicant institution must have a strong research program in the areas proposed for research training and must have the staff and facilities required to carry out the proposed program.

Trainees appointed to the training program must have the opportunity to carry out supervised biomedical, behavioral, or clinical research with the primary objective of developing or extending their research skills and knowledge in preparation for a research career.

11.3.2.3 Training Program Director/Principal Investigator(s)

The Training PD/PI must be an individual with the skills, knowledge, and resources necessary to organize and implement a high-quality research training program at the recipient organization. The Training PD/PI at the recipient organization will be responsible for the selection and appointment of trainees to the Kirschstein-NRSA research training grant and for the overall direction, management, and administration of the training program, including program evaluation, and submission of all required forms in a timely manner. In selecting trainees, the PD/PI must make certain that individuals receiving support meet the eligibility requirements set forth in this subsection.

More than one Training PD/PI (or multiple PD/PIs), may be designated on the application for training programs that require a team approach and therefore, clearly do not fit the single-PD/PI model (e.g., interdisciplinary of multidisciplinary training). The decision to apply for a single PD/PI or multiple PD/PIs is the responsibility of the investigators and applicant organizations, and should be determined and justified by the goals of the training program. Applications for grants with multiple PD/PIs require additional information, including the structure and governance of the PD/PI leadership team. In addition, the knowledge, skills and experience of the individual PD/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PD/PIs on a program share the authority and responsibility for leading and directing the training program, intellectually and logistically. Each PD/PI is responsible and accountable to the recipient organization for the proper conduct of the program, including the submission of required reports.

Applications reflecting multiple PD/PIs must provide a Leadership Plan. The emphasis in the Leadership Plan should be on how it will benefit the research training program and the trainees.

A single Contact PD/PI must be designated for the purpose of communicating with the NIH, although other individuals may contact the NIH on behalf of the Contact PD/PI when necessary. Because training programs are intended to be coherent, NIH will not allocate the budget or training positions between multiple PD/PIs. Only a single award will be issued. Multiple PD/PI training programs should include reasonable numbers of PD/PIs and each should individual should be included for a specific purpose. Multiple-PD/PI applications should not include all mentors of the training grant as PD/PIs, except in unusual cases.

11.3.2.4 Research Training Program

A Kirschstein-NRSA institutional research training grant must be used to support a program of research training. It may not support studies leading to the M.D., D.D.S., D.V.M., or other clinical, health professional training except when those studies are a part of a formal combined research degree program, such as the M.D./Ph.D. Similarly, trainees may not accept Kirschstein-NRSA support for clinical training that is part of residency training leading to clinical certification in a medical or dental specialty or subspecialty. However, clinicians are permitted and encouraged to engage in Kirschstein-NRSA-supported full-time, postdoctoral research training even when that experience is creditable toward certification by a clinical specialty or subspecialty board.

Research trainees are expected to devote full time to the proposed research training. Full-time is generally defined as devoting at least 40 hours per week to the program or as specified by the sponsoring institution in accordance with its own policies. In order to fulfill the full-time requirement, trainees who also are training as clinicians must confine clinical duties to those that are an integral part of the research training experience.

11.3.2.5 Degree Requirements

11.3.2.5.1 Predoctoral Training

Predoctoral research training is for individuals who have a baccalaureate degree and are enrolled in a doctoral program leading to either a Ph.D., a comparable research doctoral degree, or a combined clinical degree and Ph.D., such as M.D./Ph.D. Students enrolled in health-professional programs that are not part of a formal, combined program (i.e., M.D./Ph.D.), and who wish to postpone their professional studies to gain research experience, also may be appointed to a Kirschstein-NRSA institutional research training grant. Predoctoral research training must emphasize fundamental training in areas of basic biomedical, behavioral, and clinical sciences.

11.3.2.5.2 Postdoctoral Training

Postdoctoral research training is for individuals who have received a Ph.D., M.D., D.D.S., D.M.D., D.C., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D.P.T., Pharm.D., N.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign organization. It is the responsibility of the recipient institution, not the NIH, to determine if a foreign degree is equivalent. Research training at the postdoctoral level must emphasize specialized training to meet national research priorities in the biomedical, behavioral, or clinical sciences.

Kirschstein-NRSA institutional research training grants are a desirable mechanism for the postdoctoral training of physicians and other health professionals who may have had extensive clinical training but limited research experience. For such individuals, the training may be a part of a research degree program. In all cases, health-professional postdoctoral trainees are to engage in at least 2 years of research, research training, or comparable experiences beginning at the time of appointment, since the duration of training has been shown to be strongly correlated with post-training research activity.

11.3.2.5.3 Short-Term Research Training

Short-term research training includes the following:

- ***Students in Health Professional Schools.*** NIH offers two short-term training programs: those that are part of a traditional institutional research training grant (T32) and those that exclusively support short-term trainees (T35). Short-term research training experiences of 2 to 3 months are available to students in health-professional schools under both mechanisms. All short-term training must be full time. Unless otherwise stated, the requirements that apply to institutional research training grants also apply to short-term research training. Current stipend levels are published in NIH Guide for Grants and Contracts.
- ***T32.*** T32 (Kirschstein NRSA-Institutional Research Training Grant) applications may include a request for short-term positions reserved specifically to provide full-time health-related research training experiences during the summer or other "off-quarter" periods. Such positions are limited to medical students, dental students, students in other health-professional programs, and graduate students in the physical or quantitative sciences. Short-term appointments under institutional research training grants are intended to provide health-professional students with opportunities to participate in biomedical, behavioral, or clinical research in an effort to attract these individuals into research careers.

To be eligible for short-term predoctoral research training positions, students must be enrolled and in good standing and must have completed at least one quarter or semester in a program leading to a clinical doctorate or doctorate degree in a quantitative science, such as physics, mathematics, or engineering, before participating in the program. Individuals already matriculated in a formal research degree program in the health sciences, holding a research doctorate or master's degree, or a combined professional and research doctorate normally are not eligible for short-term training positions. In schools of pharmacy, only candidates for the Pharm. D. degree are eligible for short-term positions.

Short-term positions should be requested in the application. Short-term research training positions should last at least 8, but no more than 12, weeks. Health-professional students and students in the quantitative sciences selected for appointment should be encouraged to obtain multiple periods of short-term, health-related research training during the years leading to their degrees. Such appointments may be consecutive or may be reserved for summers or other "off-quarter" periods.

Since some NIH ICs do not support short-term research training positions under the T32 or support them on a limited basis only, applicants are urged to contact the appropriate NIH IC before requesting short-term research training positions as part of a T32 application.

T35. Several NIH ICs provide short-term research using a separate training grant mechanism (T35). The program intent and student eligibility requirements are similar to those indicated for the T32. However, since this Kirschstein-NRSA funding mechanism is used by only a few NIH ICs; interested applicants are encouraged to contact specific ICs for details.

11.3.2.5.4 Pre-baccalaureate Training

NIH offers two distinct programs for pre-baccalaureate training under the auspices of the Kirschstein-NRSA undergraduate support mechanism (T34). Both programs are designed to support undergraduate students from institutions with a substantial minority enrollment.

NIGMS administers the MARC U*STAR program. This program is designed to support selected junior/senior undergraduate honors students at baccalaureate colleges and universities.

NIGMS recognizes that there are differences in organizational environments and missions. Therefore, the emphasis of this program is on the specific objectives and measurable goals that the applicant institution sets.

Information about the program is available in the applicable FOA.

11.3.2.6 Citizenship

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Noncitizen nationals are individuals who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the recipient's responsibility to follow up and ensure that the individual received the I-551 prior to the 6-month expiration date.

A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271). Individuals with a Conditional Permanent Resident status may be supported on Kirschstein-NRSA training grants; however, as with all types of Permanent Resident status it is the recipient's responsibility to assure the individual remains eligible for NRSA support for the period of time of any appointment. Individuals with Asylum/Refugee status do not automatically hold a form of permanent residency status; they have the opportunity to apply for permanent residency status once they have been in the U.S. for a period of time. Therefore, individuals with Asylum/Refugee status may not be appointed to a Kirschstein-NRSA training grant until they have also secured permanent residency status. Individuals on temporary or student visas are not eligible for Kirschstein-NRSA support.

11.3.3 Application Requirements and Receipt Dates

11.3.3.1 Application

All applications for Kirschstein-NRSA institutional research training grants are submitted electronically through Grants.gov and use an application package that combines form components from the SF424 (R&R) application along with the PHS398 components. Application forms and instructions are provided as part of each FOA. Applicants should pay particular attention to the special instructions for institutional research training grants found in the SF424(R&R) Application Guide.

11.3.3.2 Receipt Dates

Several NIH ICs receive training grant applications three times each year; however, many ICs use only one or two receipt dates. Information on IC-specific receipt dates is available in the *NIH Guide for Grants and Contracts* in the NIH-wide T32 and T35 FOAs and FOAs issued by the individual NIH ICs or by contacting the appropriate NIH IC program official. For a list of the standard receipt dates and review cycle, see the http://grants.nih.gov/grants/funding/submissionschedule.htm. (Also see http://grants.nih.gov/training/nrsa.htm#inst.)

Applicants are encouraged to contact the appropriate NIH staff before preparing and submitting an application. Applications requesting funding of $500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within the specific NIH ICs who has agreed to accept assignment of the application. This requirement is in place for all NIH ICs except those assigned to NIGMS, NICHD, NEI, NIDCR, or NINR; these ICs automatically accept all T32 applications

regardless of the dollar amount, thus prior approval is not required. NIA waives this requirement for renewal and resubmission applications only. Applicants are strongly encouraged to contact the NIH IC if there are questions about the applicability of this policy

11.3.3.3 Special Program Considerations

The primary objective of the Kirschstein-NRSA program is to support graduate and postdoctoral research training to help ensure that a diverse and highly trained workforce is available to assume leadership roles related to the Nation's biomedical, behavioral and clinical research agenda.

NIH also considers the duration of training and the transition of trainees to other support mechanisms. Studies have shown that the length of the research training grant appointment of postdoctoral trainees with health-professional degrees strongly correlates to subsequent application for and success in receiving independent NIH research support. Therefore, Training PD/PIs should appoint only those individuals who are committed to a career in research and plan to remain on the training grant or in a non-Kirschstein-NRSA research experience for a minimum of 2 years in the aggregate. It also has been shown that transition to independent support is related to career success. Therefore, Training PD/PIs also should encourage and provide training in the skills necessary for postdoctoral trainees to apply for subsequent support through individual postdoctoral fellowships, mentored career development awards (K programs), or independent research project grants. When reviewing Kirschstein-NRSA institutional research training grant applications, peer reviewers will examine the training record to determine the average duration of training appointments for health-professional postdoctoral trainees and whether there is a history of transition to individual support mechanisms.

Studies also have shown that health professional trainees that train in combined programs with postdoctoral researchers with intensive research experience are more likely to apply for and receive research grant support. Programs located in clinical departments that focus on research training for individuals with the M.D. or other health-professional degrees should consider developing ties to basic science departments, or, if consistent with the goals of the program, modifying the program to include individuals with research doctorates. In these cases, applications should describe the basic science department's contribution to the research training experience and also indicate whether both health professional trainees and trainees with research doctorates will be included in the training program.

Training PD/PIs also must develop methods for ongoing evaluation of the quality and effectiveness of the training program. This should include plans to obtain feedback from current and former trainees to help identify weaknesses in the program and provide suggestions for program improvements as well as plans for assessing trainee's career development and progression, including publications, degree completion, and post-training positions. Evaluation results are to be included in competing continuation (renewal) applications and as part of the Final RPPR.

Within the framework of the program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting trainees from racial or ethnic groups underrepresented in the biomedical, behavioral and clinical sciences, individuals with disabilities, and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research. Institutions are encouraged to identify candidates who will enhance diversity on a national or institutional basis. NIH's requirements for diversity recruitment and retention are described below.

11.3.3.4 Recruitment Plan to Enhance Diversity

Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation–requires superior intellect, creativity and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in

scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the researchers, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust.

Underrepresented Populations in the U.S. Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise

In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. NIH encourages institutions to diversify their student and faculty populations to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral and social sciences, such as:

A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27, and the report Women, Minorities, and Persons with Disabilities in Science and Engineering). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the grantee institution should be encouraged to participate in this program. For more information on racial and ethnic categories and definitions, see NOT-OD-15-089.

B. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended. See NSF data at, https://www.nsf.gov/statistics/2017/nsf17310/static/data/tab7-5.pdf.

C. Individuals from disadvantaged backgrounds, defined as:

    1. Individuals who come from a family with an annual income below established low-income thresholds. These thresholds are based on family size, published by the U.S. Bureau of the Census; adjusted annually for changes in the Consumer Price Index; and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels at http://aspe.hhs.gov/poverty/index.shtml.

    2. Individuals who come from an educational environment such as that found in certain rural or inner-city environments that has demonstrably and directly inhibited the individual from obtaining the knowledge, skills, and abilities necessary to develop and participate in a research career.

The disadvantaged background category (C1 and C2) refers to the financial and educational background of individuals, particularly before graduating from high school, while residing in the United States.

Literature shows that women from the above backgrounds (categories A, B, and C) face particular challenges at the graduate level and beyond in scientific fields. (See, e.g., Inside the Double Bind, A Synthesis of Empirical Research on Undergraduate and Graduate Women of Color in Science, Technology, Engineering, and Mathematics.)

Women have been shown to be underrepresented in doctorate-granting research institutions at senior faculty levels in most biomedical-relevant disciplines, and may also be underrepresented at other faculty levels in some scientific disciplines (See data from the National Science Foundation National Center for Science and Engineering Statistics: Women, Minorities, and Persons with Disabilities in Science and Engineering, special report available at https://www.nsf.gov/statistics/2017/nsf17310/, especially Table 9-23, describing science, engineering, and health doctorate holders employed in universities and 4-year colleges, by broad occupation, sex, years since doctorate, and faculty rank).

Upon review of NSF data, and scientific discipline or field related data, NIH encourages institutions to consider women for faculty-level, diversity-targeted programs to address faculty recruitment, appointment, retention or advancement.

Training Program Requirements

NRSA training programs require all applicants to submit a recruitment plan to enhance diversity. New applications must include such a plan and may wish to include data in support of past accomplishments. Renewal applications also must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous the funding period. Information must be included on successful and unsuccessful recruitment strategies including aggregate information on the distribution of:

- Students or postdoctorates who applied for admission or positions within the department(s)/-program(s) relative to the research training grant;
- Students or postdoctorates who were offered admission to or a position within the department(s)/-program(s);
- Students actually enrolled in the academic program relevant to the research training grant;
- Students or postdoctorates who were appointed to the research training grant.

For those trainees who were enrolled in the academic program, the application should include information about the duration of research training and whether those trainees finished their training in good standing.

Application without a diversity recruitment plan to enhance diversity will be considered incomplete and will not be reviewed.

The review panel's evaluation will be included in an administrative note in the summary statement. If the recruitment plan to enhance diversity is judged to be unacceptable, funding will be withheld until a revised plan (and report) that addresses the deficiencies is received. Staff within the NIH IC, with guidance from its National Advisory Council or Board, will determine whether amended plans and reports submitted after the initial review are acceptable.

A detailed account of experiences in recruiting individuals from underrepresented groups during the previous budget period also must be provided in the non-competing progress report submitted as a prerequisite to receiving non-competing continuation support.

11.3.3.5 Training in the Responsible Conduct of Research

Every trainee supported by an NRSA training grant must receive instruction in the responsible conduct of research. All applications must include a plan to provide such instruction. The plan must address the five components listed below. Renewal (Type 2) applications must, in addition, describe changes in formal instruction over the past project period and plans for the future to address any weaknesses in the current instructional plan. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed

in the review process. Plans and past record will be rated as acceptable or unacceptable. Applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan. For additional instructions, see the specific FOA.

1. ***Format.*** Substantial face-to-face discussions among the participating trainees; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs, or unusual and well-justified circumstances.

2. ***Subject Matter.*** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

a. conflict of interest – personal, professional, and financial
b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
c. mentor/trainee responsibilities and relationships
d. collaborative research including collaborations with industry
e. peer review
f. data acquisition and laboratory tools; management, sharing and ownership
g. research misconduct and policies for handling misconduct
h. responsible authorship and publication
i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

3. ***Faculty Participation.*** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the trainees and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must

be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level must receive instruction in responsible conduct of research at least once during this career stage. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the trainee is not actually supported by an NIH grant. This instruction must be documented in the submitted plan.

Information on the nature of the instruction in the responsible conduct of research and the extent of trainee and faculty participation also must be provided in the annual progress report submitted as a prerequisite to receiving non-competing continuation support.

11.3.4 Review

11.3.4.1 Overall

Each initial and competing continuation application will be evaluated for scientific merit by an NIH peer review group. Kirschstein-NRSA institutional research training grant applications also must be reviewed by the National Advisory Council or Board of the IC whose activities relate to the proposed research training.

11.3.4.2 Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the research training program to exert a sustained, powerful influence on the research field(s) involved. The scored review criteria and additional review criteria (as applicable for the research training program proposed) will be considered when determining the overall impact.

11.3.4.3 Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific merit.

- Training Program and Environment
- Training Program Director/Principal Investigator
- Preceptor/Mentors
- Trainees
- Training Record

The FOA should be consulted for additional information describing each of the scored review criteria. Individual Institutes and Centers may have additional specialized review criteria appropriate for their special initiatives and mission.

11.3.4.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals

- Biohazards
- Resubmission Applications
- Renewal Applications
- Revision Applications

The FOA should be consulted for additional information describing each of the relevant addition review criteria.

11.3.4.5 Additional Review Considerations

As applicable for the training program proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing the overall impact score:

- Recruitment Plan to Enhance Diversity
- Training in the Responsible Conduct of Research
- Select Agents Research
- Budget and Period of Support

The FOA should be consulted for additional information describing each of the relevant addition review considerations.

11.3.4.6 National Advisory Council Review

Following initial peer review, applications undergo a second-level review by the appropriate NIH IC's National Advisory Council or Board. In addition to the assessment of the scientific and educational merit of the research training grant application, these advisory groups will consider the initial peer review group's comments on the plan for recruitment to enhance diversity and the plan for instruction in the responsible conduct of research.

11.3.5 Notification of Action

Shortly after the initial peer review meeting, the PD/PI will be sent an e-mail indicating that the SRG recommendation/impact score is available in the eRA Commons. The PD/PI is also notified via an e-mail when the summary statement is available in the eRA Commons. The PD/PI may be notified by the PO of the final review recommendation. Once all administrative and programmatic issues have been resolved, the NoA will be issued for applications selected for funding. Any questions concerning initial review recommendations and funding possibilities should be directed to the named PO, not to the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons.

11.3.6 Period of Support

11.3.6.1 Training Grants

Kirschstein-NRSA institutional research training grants may be made for competitive segments of up to 5 years and are renewable. Awards within an approved competitive segment normally are made in 12-month increments, referred to as budget periods; support for additional non-competitive years depends on satisfactory progress, submission of all required trainee-related documents, and availability of funds.

11.3.6.2 Trainees

Trainees under Kirschstein-NRSA institutional research training grants generally are appointed for full-time 12-month continuous periods. An appointment or reappointment period may begin any time during a particular budget period but may not begin before the budget period start date of the grant year. An appointment or reappointment may not exceed 12 months without prior approval by the NIH awarding IC. All trainees are required to pursue their research training on a full-time basis. Full-time is generally defined as devoting at least 40 hours per week to the program or as specified by the recipient in accordance with its own policies. Unless the NIH awarding IC furnishes other instructions, the amount of the stipend, tuition, and fees for each full period of appointment must be obligated by the recipient from funds available when the individual begins training.

With the exception of specifically designated short-term research training positions, no trainee may be appointed under a regular Kirschstein-NRSA institutional research training grant for less than 9 months except with the prior written approval of the NIH awarding IC and then usually only to complete an ongoing program of training. An initial appointment of less than 9 months may be allowed as long as an assurance is included that the individual will be immediately reappointed in the subsequent year so that the cumulative continuous training period is at least 9 months.

Part-Time Training. While Kirschstein-NRSA trainees are required to pursue research training on a full-time basis, under certain circumstances, a written request may be submitted to the NIH awarding IC to change a trainee appointment to less than full time. All such requests must be signed by the trainee, the AOR and the training grant PD/PI. The request for part-time training must provide a justification of the need for a reduced level of effort and the expected duration of the period of part-time training. Such requests will be considered case-by-case and must be approved by the awarding IC before the applicable budget period. The circumstances requiring the part-time training might include medical conditions, disability, or personal or family situations such as a child or elder care. Part-time training will not be approved to accommodate use of other sources of funding, job opportunities, clinical practice, clinical training, or for other responsibilities associated with the trainee's position at the organization. In each case, the written request must be signed by an AOR and must include documentation supporting the need for part-time training. Countersignatures of the trainee and program director must be secured and retained by the recipient, but need not be submitted to NIH prior to submission to NIH. The written request also must include an estimate of the expected duration of the period of part-time training and assurances that the trainee intends to return to full-time training when that becomes possible and intends to complete the research training program.

The stipend may be prorated in the grant award during the period of any approved part-time training. Part-time training also may affect the rate of accrual or repayment of the service obligation for postdoctoral trainees. In no case will it be permissible for the trainee to be engaged in Kirschstein-NRSA-supported research for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave-of-absence from a Kirschstein-NRSA training grant.

11.3.6.3 Kirschstein-NRSA Limitations

No individual trainee may receive more than 5 years of aggregate Kirschstein-NRSA support at the predoctoral level and 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from Kirschstein-NRSA institutional research training grants and individual fellowships.

Any exception to the maximum period of support requires a waiver from the NIH awarding IC based on review of a justification from the individual and the recipient organization. The AOR must make the request in writing to the NIH awarding IC on behalf of the trainee. The endorsement of the trainee's

PD/PI certifying the need for additional support is retained by the recipient institution. The request must specify the amount and length of additional support for which approval is sought.

Some generally recognized categories under which NIH may grant exceptions include the following:

- ***Physicians/Clinicians.*** Individuals requiring additional time to complete training, either as participants in a combined M.D./Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training, may anticipate favorable consideration of a request for waiver of the time limitation. This action is contingent upon an assurance of the trainee's good academic standing and justified need for the exception to this policy.
- ***Interruptions (Break in Service).*** Requests for additional time also will be considered if an event unavoidably has altered the planned course of the research training, if the interruption has significantly detracted from the nature or quality of the planned research training, and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation that prevents a trainee from effectively pursuing research training for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the trainee an opportunity to use an exceptional training resource directly related to the approved research training program.

Requests that arise from circumstances other than those described above will be considered only if they are accompanied by an exceptionally strong justification.

11.3.7 Initiation of Support

The NoA is issued to the recipient organization, generally for a budget period of 12 months. A trainee may be appointed any time during the budget period for an appointment period of 9 to 12 months, without prior approval by the NIH awarding IC. A trainee appointment may not begin before the budget period start date.

At the time of the initial appointment and subsequent reappointment of trainees, the Training PD/PI must submit a Statement of Appointment for each trainee to the NIH awarding IC. In addition, a signed Payback Agreement must be submitted for each postdoctoral trainee who is in his/her first 12 months of Kirschstein-NRSA postdoctoral support. See Reporting Requirements—Statement of Appointment (Form PHS 2271) and Reporting Requirements—Payback Agreement (Form PHS 6031) in this chapter for specific information on required forms. The Statement of Appointment includes biographical data on the trainee and the stipend level for the period of appointment. The stipend is paid by the recipient organization directly to the trainee.

11.3.8 Allowable and Unallowable Costs

Policies included in the applicable cost principles in 45 CFR 75, Subpart E and the NIHGPS govern the expenditure of all training grant funds, unless otherwise indicated in the NoA.

11.3.8.1 Pre-Award Costs

While some pre-award costs are allowable to a training grant, recipients should note that stipends and tuition and fees may not be charged to a grant until a trainee has been officially appointed and the appropriate paperwork submitted to the NIH. Therefore, these costs may not be charged as pre-award to an institutional training grant. There are rare occasions when costs associated with training related

expenses and/or trainee travel may be allowable as pre-award costs. Recipient institutions should consult with the NIH awarding IC when considering a pre-award cost.

11.3.8.2 Stipends

Trainees generally are supported for 12-month full-time training appointments for which they receive a stipend as a subsistence allowance to help defray living expenses during the research training experience. The stipend is not "salary" and is not provided as a condition of employment with either the Federal government or the recipient organization. Stipends must be paid in accordance with established stipend levels. No departure from the standard stipend provided by NIH under the grant may be negotiated by the recipient organization with the trainee. NIH stipend amounts may be adjusted only at the time of appointment or reappointment. For appointments of less than 12 months, the stipend will be prorated.

Stipend levels are updated almost every fiscal year. When increases are approved, they are published in *NIH Guide for Grants and Contracts*. Current levels also are posted at http://-grants.nih.gov/training/nrsa.htm.

Stipend levels are as follows:

- ***Prebaccalaureate.*** Two separate levels are provided for trainees: freshman/sophomore or junior/senior.
- ***Predoctoral.*** One stipend level is used for all predoctoral trainees, regardless of the level of experience.
- ***Postdoctoral.*** The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience at the time of appointment. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the trainee must be paid at that level for the entire period of appointment. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.

11.3.8.3 Trainee Tuition and Fees

Tuition and fees are allowable trainee costs only if such charges are applied consistently to all individuals in a similar training status at the organization, without regard to their source of support.

Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program and requires NIH awarding IC prior approval.

Tuition and fees are provided under the following policy:

- ***For Predoctoral Trainees.*** An amount equal to 60% of the level requested by the sponsoring institution, up to $16,000 per year, will be provided. If the program supports formally combined dual-degree training (e.g., M.D.-Ph.D, D.D.S.-Ph.D.), the amount provided will be up to $21,000 per year.
- ***For Postdoctoral Trainees.*** An amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year, will be provided. If the program supports postdoctoral individuals in formal degree-granting training, the amount provided will be up to $16,000 per year.

Tuition and fees are awarded as a lump sum that can be allocated (without the prior approval of the NIH awarding IC) based on recipient needs.

11.3.8.4 Training-Related Expenses

Funds are provided to defray costs such as staff salaries, consultant costs, equipment, research supplies, staff travel, trainee health insurance (self-only or family as applicable), and other expenses directly related to the training program. Funds are requested and awarded as a lump sum on the basis of the predetermined amount per predoctoral and postdoctoral trainee approved for support. Levels are published in the *NIH Guide for Grants and Contracts*. Interested applicants should consult the program announcement regarding the specific level for programs such as the short-term training program, the MARC U*STAR program, or the COR program. Many of the costs allowable under Training-Related Expenses may cover global costs for an institutional training program where the Kirschstein-NRSA support covers only some of the participating trainees. For these types of global costs, institutions should allocate the appropriate portion of such costs to the training grant. Institutions are reminded that this budget category is a finite amount of money available to cover a variety of allowable costs. Institutions should be particularly mindful to apply core cost principles of allocation and consistent treatment.

Health Insurance. Health Insurance (self-only or family) are allowable trainee related expenses only if such charges are applied consistently to all individuals in a similar training status at the organization, without regard to their source of support. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy. Historically health insurance was awarded as part of the tuition and fees category. This is no longer the policy. For any training grant that competed and was awarded in FY2006 and beyond, health insurance is awarded as part of the Training Related Expenses category.

Medical Liability and Other Special Insurance. Medical liability (malpractice) insurance or other special insurance is an allowable cost to NRSA grants only if nature of the research training requires such special insurance. For instance, medical liability would be allowable if the research training experience involves direct contact with patients or human subjects. In all cases, for the cost to be charged to the NRSA grant, it must be consistently required for all in a similar training status, regardless of the source of support. Special insurances that are routinely offered as optional employee benefits (such as disability insurance, life insurance, or workman's compensation insurance), are not normally allowable charges (see separate section on Employee Benefits) unless the nature of the research training requires such special insurance.

Staff Salaries. Institutions are reminded that applicable cost principles apply. Training programs may qualify as a "major project" where administrative salaries are allowable as a training-related expense.

Speaker Fees. When speakers are part of program required for NSRA-supported trainees, a portion of such a cost could be charged as Training-related expenses.

Meals. As stated in IIA, the cost of meals may be allowable if they are provided in conjunction with a meeting considered an ancillary activity to the training grant. A portion of such a cost could be charged as Training-related expenses. See Cost Considerations—The Cost Principles in IIA for specific guidance on the need institutional policies on consistent treatment and reasonableness.

Extraordinary Costs. Under exceptional circumstances, which can include accommodating the disabilities of a trainee, it is possible to request organizational costs above the standard level. Requests for additional costs must be explained in detail and justified in the application. Consultation with NIH program staff in advance of such requests is strongly advised.

11.3.8.5 Trainee Travel Costs

If requested by the recipient, the NIH awarding IC may provide grant funds to cover the costs of trainee travel, including attendance at scientific meetings, which the organization determines is necessary to the individual's training. Trainees must be appointed to the training grants at time of the actual travel for this

to be an allowable cost. Funds may not be expended to cover the costs of travel between the trainee's place of residence and the training institution, except that the recipient organization may authorize a one-way travel allowance in an individual case of extreme hardship.

In addition, support for travel to a research training experience away from the recipient organization may be permitted. Research training experiences away from the parent organization must be justified on the basis of the type of opportunities for training available, the opportunities offered that are different from those at the parent organization, and the relationship of the proposed experience to the trainee's career stage and career goals. This type of research training requires prior approval of the NIH awarding IC. Letters requesting such training may be submitted to the NIH awarding IC at any time during the appointment period.

11.3.8.6 Short-Term Training Costs

The recipient may receive up to one-twelfth of the annual amount designated for training-related expenses each month to offset the costs of tuition, fees, travel, supplies, and other expenses for each short-term, health-professional research training position.

11.3.8.7 Employee Benefits

Because Kirschstein-NRSA awards are not provided as a condition of employment with either the Federal government or the recipient, it is inappropriate and unallowable for organizations to seek funds, or to charge Kirschstein-NRSA institutional research training grants, for costs that normally would be associated with employee benefits (for example, FICA, workers compensation, life insurance, union dues, and unemployment insurance). Concerning union dues or other similar costs otherwise paid personally by the trainee, if a trainee requests the institution deduct such a cost from the stipend amount, the institution can provide the trainee such a service. However, in no case can such a deduction from the stipend be made automatically without the approval of the trainee.

11.3.8.8 Facilities and Administrative Costs

Recipients, other than State, local, or Indian tribes (or ''federally recognized Indian tribes"), will receive F&A costs at 8 percent of modified total direct costs (exclusive of tuition and fees, consortiums in excess of $25, 000, and expenditures for equipment) rather than on the basis of a negotiated rate agreement. State, local, and Indian tribe (or ''federally recognized Indian tribes") are eligible for full F&A cost reimbursement. For this policy, State universities or hospitals are not considered governmental agencies.

11.3.9 Rebudgeting of Funds

Funds may be rebudgeted only as follows:

- ***Trainee-Related Expenses.*** Rebudgeting of funds awarded in a lump sum for trainee-related expenses does not require NIH awarding IC prior approval.
- ***Trainee Costs.*** For rebudgeting purposes, trainee costs include funds awarded in the stipends or tuition/fees budget categories. These costs may not be used for other purposes except under unusual circumstances and then only with the prior approval of the NIH awarding IC. Unless otherwise restricted, rebudgeting into or within the stipends and tuition/fees is allowable without prior approval of the NIH awarding IC.
- ***Trainee Travel.*** For rebudgeting purposes, trainee travel is not considered a trainee cost and, therefore, may be rebudgeted into any other budget category without prior approval of the NIH awarding IC.

11.3.10 Stipend Supplementation, Compensation, and Other Income

11.3.10.1 Stipend Supplementation

Recipients may supplement stipends from non-Federal funds provided the supplementation is without any additional obligation for the trainee. An organization can determine what amount of stipend supplementation, if any, will be provided according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar training status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in Educational Loans or GI Bill below. Under no circumstances may PHS funds be used for supplementation.

11.3.10.2 Compensation

NIH recognizes that student or postdoctoral trainees may seek part-time employment coincidental to their training program to further offset their expenses. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part time research, teaching, or clinical employment, so long as those activities do not interfere with, or lengthen, the duration of their NRSA training. Funds characterized as compensation may be paid to trainees only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions of the compensation of students as detailed in Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Fringe Benefits / IHE Tuition/Tuition Remission in IIA. In addition, compensation must be in accordance with organizational policies consistently applied to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching, laboratory assistance, or clinical duties are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, NIH expects that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the trainee's planned training experience as approved in the Kirschstein-NRSA institutional research training grant application.

Stipend Supplementation & Compensation. Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the trainee's approved Kirschstein-NRSA training program. Training PD/PIs must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

11.3.10.3 Other Income: Concurrent Benefits

An individual may not receive support under a Kirschstein-NRSA institutional research training grant concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA award.

11.3.10.4 Other Income: Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation. In the case of the MARC-U*STAR program, funds from a Pell grant may be accepted as well.

11.3.10.5 Other Income: NIH Loan Repayment Program

Postdoctoral trainees also may be eligible to participate in the NIH Loan Repayment Program. Information about this program is available at http://www.lrp.nih.gov/.

11.3.10.6 Taxability of Stipends

Section 117 of the Internal Revenue Code (26 U.S.C. 117) applies to the tax treatment of scholarships and fellowships. Degree candidates may exclude from gross income (for tax purposes) any amount used for qualified tuition and related expenses, such as fees, books, supplies, and equipment, required for courses of instruction at a qualified educational organization. Nondegree candidates are required to report as gross income any monies paid on their behalf for stipends or any course tuition and fees required for attendance.

The IRS and Treasury Department released regulations in January 2005 (Revenue Procedures 2005-11) clarifying the student exception to the FICA (Social Security and Medicare) taxes for students employed by a school, college, or university where the student is pursuing a course of study. NIH's understanding is that these final regulations do **not** apply to or impact Kirschstein-NRSA programs or awards.

The taxability of stipends in no way alters the relationship between Kirschstein-NRSA trainees and recipient organizations. Kirschstein-NRSA stipends are not considered salaries. In addition, trainees supported under Kirschstein-NRSA institutional research training grants are not considered to be in an employee-employer relationship with NIH or the recipient organization solely as a result of the Kirschstein-NRSA support. Interpretation and implementation of the tax laws are the domain of the IRS and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

11.3.10.7 Form 1099

Although stipends are not considered salaries, the funds are subject to Federal and, sometimes, State taxes. The recipient organization may report such funds on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the recipient organization will be responsible for annually preparing and issuing the IRS Form 1099 for trainees. Recipient organizations are not required to issue the Form 1099, but it is a useful form of documentation of funding received and it serves as a reminder to the trainee that some tax liability may exist. Even if the recipient organization does not issue the Form 1099, trainees are required to report Kirschstein-NRSA stipends as income.

11.3.11 Carryover Authority

The NIH Standard Terms of Award apply to Kirschstein-NRSA institutional research training grants; however, in most cases, recipients must obtain awarding IC prior approval to carry over funds. Some NIH awarding ICs have also waived this prior approval requirement for training grants. The NoA for a Kirschstein-NRSA institutional research training grant will specify whether or not the recipient must obtain the prior approval of the awarding IC to carry over funds.

11.3.12 Program Income

Applicants for NIH research grants, including Kirschstein-NRSA institutional research training grants, are required to include in their grant applications an estimate of the amount and source of program income expected to be generated as a result of the project for which support is being sought. See Administrative Requirements—Management Systems and Procedures—Program Income in IIA for policies that govern the disposition and reporting of program income.

11.3.13 Reporting Requirements

The submission of the forms described in this subsection is critical to establishing the payment of stipends and other costs and determining possible payback service. Failure to submit the required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation funding. All of these forms are available in PDF-fillable and MS Word formats at http://grants.nih.gov/grants/forms.htm.

11.3.13.1 Statement of Appointment (Form PHS 2271)

The recipient must submit a PHS 2271 to the NIH awarding IC before or at the start of each trainee's appointment or reappointment. No 2271s can be submitted until after the NoA for the respective budget period has been issued. Effective with any PHS2271 submitted January 1, 2011 and beyond, recipients are required to submit the PHS 2271 data electronically using the eRA Commons xTrain application. More information on xTrain is available at http://era.nih.gov/services_for_applicants/other/xTrain.cfm.

No stipend or other allowance may be paid until the appointment form has been submitted. If the support covers the individual's initial 12 months of postdoctoral support, a signed Payback Agreement also must be submitted. The information on the Statement of Appointment (and the Termination Notice as discussed below) is the basis for determining the length or amount of an individual's payback requirement. A complete Social Security Number must be included on the Payback Agreement. The PD/PI and the organizations' financial officials should coordinate the information reported on the Statement of Appointment. It should be treated as a financial document for obligating funds (stipends), which later are reflected on the Termination Notice and as part of the total costs in the FFR.

Interim Revisions. Any changes or corrections involving a trainee appointment under a Kirschstein-NRSA institutional research training grant, such as name, permanent mailing address, period of training, or stipend support, must be reported by the Training PD/PI to the NIH awarding IC on an amended PHS 2271 at the time of the change. Interim revisions for any appointment initially processed via xTrain, must also be submitted through xTrain.

Consecutive Support. If a trainee switches from one Kirschstein-NRSA mechanism to another (e.g., from an individual fellowship to a training grant) or from one NIH awarding IC to another, the requirement for payback service incurred is deferred until the total period of Kirschstein-NRSA support is completed. All Statement of Appointment forms are reviewed to determine if previous Kirschstein-NRSA support has been provided.

11.3.13.2 Payback Agreement (Form PHS 6031)

A Payback Agreement that covers the initial 12 months of Kirschstein-NRSA postdoctoral support must be signed by each postdoctoral trainee. If the individual has already received 12 months of postdoctoral support under any Kirschstein-NRSA training grant or fellowship award, this form is not required. For details on Kirschstein-NRSA payback, see Payback Requirements in this chapter.

No Payback Agreement is required for predoctoral or prebaccalaureate trainees.

11.3.13.3 Termination Notice (Form PHS 416-7)

The Termination Notice (along with the PHS 2271 Statement of Appointment form) is the basis for validating the total period of Kirschstein-NRSA support and establishing the amount of payback obligation, if any, for each Kirschstein-NRSA trainee. The PD/PI is responsible for submitting a Termination Notice for each trainee within 30 days of the end of the total period of support even if the trainee is not available for signature. In all cases, the information on the form must be verified by the program director and an institutional business official. The lack of timely and accurate information on this form could adversely affect data collected associated with aggregate NRSA support and the payback process.

Recipients are required to submit the PHS 416-7 data electronically using the xTrain application. More information on xTrain is available at http://era.nih.gov/services_for_applicants/other/xTrain.cfm.

No Termination Notice is required for prebaccalaureate (T34) trainees.

11.3.13.4 Research Performance Progress Reports

RPPRs must be submitted for non-competing continuation support in accordance with the RPPR instructions. Report forms and instructions are available from the NIH Web site at http://-grants.nih.gov/grants/forms.htm. Guidance for training grants can be found in section 7.4 of the RPPR Instructions. Following completion or termination of a project period, the recipient must submit a Final RPPR to the NIH awarding IC within 120 days after the end of grant support.

The IDP provision described in Non-Competing Continuation Progress Reports applies to all trainees reported on a Statement of Appointment Form (PHS2271). This information should be provided using the instructions in Non-Competing Continuation Progress Reports.

11.3.13.5 Federal Financial Report (FFR)

An annual FFR is required for all Kirschstein-NRSA institutional research training grant awards no later than 90 days after the end of the calendar quarter in which the budget period ended. This report will document the financial status of the grant according to the official accounting records of the recipient organization. Trainee stipends and tuition are obligated for the full 12-month appointment from the budget period in which the appointment is initiated. Portions of stipends, tuition, and applicable F&A that extend beyond the budget period are reported as unliquidated obligations. The same principal may apply to trainee health insurance when an institution cannot truly obligate the full amount of health insurance at the start of the appointment.

If the report covers the final budget period of the project period, it must have no unliquidated obligations, must indicate the exact balance of unobligated funds, and is due within 120 days of the period of performance end date (see Administrative Requirements—Monitoring—Reporting—Financial Reports and Administrative Requirements—Closeout—Final Reports in IIA).

11.3.14 Closeout

The Closeout requirements included in IIA apply (see Administrative Requirements—Closeout—Final Reports). In addition, Termination Notices for all trainees are required.

11.3.15 Changes in the Project

Changes in the program objectives as they relate to the area of research training for which the grant was approved require prior approval of the NIH awarding IC.

If the PD/PI is expected to be absent more than 3 months, plans for the conduct of the program during his or her absence must be approved in writing by the NIH awarding IC. Any proposed change of PD/PI must be requested by the recipient organization and be approved in writing by the NIH awarding IC following review of the nominee's qualifications and re-evaluation of the project in light of the proposed change.

Kirschstein-NRSA institutional research training grants may not be transferred from one domestic organization to another except under the most unusual circumstances. Such a change generally will be approved by the NIH awarding IC only if all of the major benefits attributable to the original grant can be transferred and there is no negative impact on trainees active in the program.

11.3.16 Other Terms and Conditions

11.3.16.1 Leave

Note: The leave durations stated below apply to full-time trainees. Short-term trainee leave must be proportionally adjusted based depending on the duration of appointment.

In general, trainees may receive stipends during the normal periods of vacation and holidays observed by individuals in comparable training positions at the sponsoring institution. For the purpose of these awards, however, the period between the spring and fall semesters is considered to be an active time of research and research training and is not considered to be a vacation or holiday. Trainees may receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for the medical conditions related to pregnancy and childbirth. Trainees may receive stipends for up to *60 calendar days (equivalent to 8 work weeks)* of parental leave per year for the adoption or the birth of each child. Either parent is eligible for parental leave. Kirschstein-NRSA trainees and fellows must provide advanced notification to the grantee institution prior to taking parental leave. Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds. A period of terminal leave is not permitted, and payment may not be made from traineeship funds for leave not taken. Trainees requiring periods of time away from their research training experience longer than specified here, i.e., more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding component for an unpaid leave of absence. Approval for a leave of absence must be requested in advance by an AOR on behalf of the trainee. Trainees supported by academic institutions should refer to the NIH Institutional NRSA training grant guidelines in the NIH Grants Policy Statement for further guidance regarding vacations and requested leave.

Vacations and Holidays. Trainees may receive the same vacations and holidays available to individuals in comparable training positions at the recipient organization. Trainees will continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters generally is considered an active part of the training period and is not considered to be a vacation or holiday.

Sick Leave and Other Leave. Trainees may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for the medical conditions related to pregnancy and childbirth.

Parental Leave. Trainees may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of each child. Either parent is eligible for parental leave. Kirschstein-NRSA trainees and fellows must provide advanced notification to the grantee institution prior to taking parental leave. Notification of supervisors and others about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds.

Terminal Leave. A period of terminal leave is not permitted, and payment may not be made from grant funds for leave not taken.

Unpaid Leave. Individuals requiring extended periods of time away from their research training experience, that is, more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding IC for an unpaid leave of absence. A request letter must be submitted by the AOR, signed by the trainee as well as the training grant PD/PI.

During a leave of absence, documentation to suspend the period of appointment must be completed by submitting an amended Statement of Appointment and a Termination Notice. These forms should be submitted to the NIH awarding IC at the beginning of the leave. Upon resumption of Kirschstein-NRSA support, the reappointment must be documented on another Statement of Appointment form.

11.3.16.2 Termination

NIH may terminate a Kirschstein-NRSA institutional research training grant before its normal completion date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which the award was made. If an award is terminated for cause, NIH will notify the recipient organization in writing of this determination, the reasons for the determination, the effective date, and the right to appeal the decision. NIH also may terminate an award at the request of the recipient.

An organization that wants to terminate a training grant before the scheduled termination date must notify the NIH awarding IC immediately. In such cases, NIH will issue a revised NoA to specify the changed period of support and to show prorated trainee stipends, depending on the amount of time spent in training.

11.3.16.3 Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, PD/PIs and trainees should make the results and accomplishments of their Kirschstein-NRSA institutional training grant activities available to the research community and to the public at large. The recipient organization should assist trainees in these activities, including further development of discoveries and inventions for furthering research and benefiting the public. No restrictions should be placed on the publication of results.

Trainees are encouraged to submit reports of their findings for publication to the journals of their choice. Responsibility for direction of the project should not be ascribed to NIH. However, NIH IC support must be acknowledged by a footnote in language similar to the following: “This investigation was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award (number) from the (name of NIH IC).” In addition, Federal funding must be acknowledged as provided in Appropriation Mandates—Acknowledgment of Federal Funding in IIA.

The Public Access Policy requirements described in Administrative Requirements—Availability of Research Results—NIH Public Access Policy in IIA apply to articles that are authored or co-authored by NRSA trainees and arose from NIH Support. Information on trainee publications is included as part of the annual progress report.

11.3.16.4 Copyright

Except as otherwise provided in the NoA, when a publication or similar copyrightable material is developed from work supported by NIH, the author is free to arrange for copyright without the approval of the NIH awarding IC. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce, translate, publish, and use and dispose of such materials, and to authorize others to do so for Federal government purposes.

11.3.16.5 Inventions and Patents

All Kirschstein-NRSA institutional research training grants and other funding agreements awarded primarily for educational purposes are not subject to invention reporting requirements nor does NIH have any rights to inventions under those grants and agreements (as specified in 45 CFR 75.322 and in 37 CFR 401.1(b)).

11.3.16.6 Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award may not be retained by the trainee. Such fees must be assigned to the recipient organization for disposition in accordance with NIH policy on program income (see Administrative Requirements—Management Systems and Procedures—Program Income in IIA). The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations. If permitted by organizational policy, these fees may be retained by the trainee.

11.3.16.7 Public Policy Requirements and Objectives

All Public Policy Requirements, Objectives, and Other Appropriation Mandates discussed in IIA apply to Kirschstein-NRSA Institutional programs when appropriate. Applicants must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements and inclusion policies for women, minorities and children; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant DNA and human gene transfer research. See IIA for a complete list of applicable requirements.

Additional information and any application requirements can be found in the SF424 (R&R), Section 8. Supplemental Instructions for Preparing Institutional Ruth L. Kirschstein-NRSA Applications.

Information provided below is in addition to that provided in IIA where unique circumstances might exist for institutional training programs.

11.3.16.7.1 Human Subjects

Indefinite Involvement. If the applicant organization has an approved FWA or other applicable assurance on file with OHRP but, at the time of application, plans for the involvement of human subjects are indefinite, the assurance number should be provided in the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

In many instances, trainees supported by Kirschstein-NRSA institutional research training grants will be participating in research supported by research project grants for which the IRB review is already completed or an exemption is already designated. This review or exemption designation is sufficient, provided the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. The recipient institution must ensure that trainees have received the proper training/education in human subjects research.

11.3.16.7.2 Vertebrate Animals

Indefinite Involvement. If the applicant organization has an approved Animal Welfare Assurance on file with OLAW but, at the time of application, its plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, the organization should indicate "Yes," to the involvement of Vertebrate Animals and include the Animal Welfare Assurance number. If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding IC.

In many instances, trainees supported by institutional research training grants will be participating in research supported by research project grants for which the IACUC review already is completed. This review is sufficient, provided the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates. The institution

must ensure that trainees are enrolled in the institution's animal welfare training and occupational health and safety programs for personnel who have contact with animals, as appropriate. It is also the institution's responsibility to ensure that trainees are properly supervised when working with live vertebrate animals.

If the applicant organization does not have an approved Animal Welfare Assurance on file with OLAW or for additional information on vertebrate animals, refer to the Application Guide or contact OLAW (see Part III).

11.4 PAYBACK REQUIREMENTS

11.4.1 General

The Kirschstein-NRSA legislation requires some recipients of support (post-doctoral fellows and trainees) to pay back the Federal government by engaging in health-related research, research training, health-related teaching, and/or other relevant health-related activities. See Payback—Service Payback—Definitions in this subsection for complete coverage of requirements.

11.4.2 Implementation

The incurrence of a payback obligation for an NRSA recipient is solely dependent upon when NRSA support was received. This section reflects current Payback requirements for individuals supported on/after June 10, 1993. Payback requirements for individuals supported before June 10, 1993 are found on the Payback Service Center Home Page.

Predoctoral Recipients. For predoctoral trainees no payback obligation is incurred. Thus a Payback Agreement Form (PHS 6031) is not required.

Postdoctoral Recipients. For individuals receiving postdoctoral support under individual fellowships or institutional research training grants, a payback obligation is incurred for the first 12 months of Kirschstein-NRSA support. However, the 13th and subsequent months of postdoctoral NRSA supported research training serves to pay back this obligation month by month. A Payback Agreement (PHS 6031) is required but only for the initial 12-month postdoctoral support period.

Short-Term Training. Any individual receiving support for predoctoral short-term training does not incur a payback obligation; however, postdoctoral short-term training does incur a payback obligation. Support for short-term training accrues, along with any subsequent NRSA postdoctoral support, until the first 12 months is established. At that point, the 13th and subsequent months of support serve to offset the obligation month by month. If subsequent postdoctoral support is not received, the individual has an obligation to pay back in the traditional manner.

11.4.3 Payback

Once a Termination Notice has been submitted and accepted, the NIH awarding IC determines if a payback obligation exists. When a trainee or fellow must pay back, the Termination Notice and related documents are forwarded to the NIH Kirschstein-NRSA Payback Service Center (PSC). PSC personnel are NIH's experts in Kirschstein-NRSA payback requirements. The PSC administers the payback activities of all of the NIH ICs. The authorities related to payback normally delegated to the IC are delegated to the Chief, Kirschstein-NRSA PSC. The PSC retains all records until an obligation is satisfied, and then transfers closed records to the Federal Records Center.

Most Kirschstein-NRSA recipients eventually fulfill their payback obligation by engaging in activities that are determined to be acceptable service. Some recipients fulfill their obligation via financial payback. On rare occasions, the payback obligation is waived.

As indicated in Payback Reporting Requirements—Implementation in this subsection, the amount of a payback obligation incurred is solely dependent on the total period of support and the laws in effect when the Kirschstein-NRSA support was received.

11.4.3.1 Service Payback

11.4.3.1.1 Definitions

For fulfilling the Kirschstein-NRSA service payback obligation, the following definitions apply:

- ***Research.*** Research is defined as an activity that involves designing experiments, developing protocols, and collecting and interpreting data. In addition, review of original research or administration of original research that includes providing scientific direction and guidance to research may be acceptable if a doctoral degree and relevant research experience is required for individuals filling such positions. Such research can be conducted in an academic, government, commercial, or other environment in either a foreign or domestic setting. In addition, when consistent with the cumulative amount, type, and frequency of research or research training experiences, functions that involve analytic or other technical activities conducted in direct support of research, as defined above, will also satisfy the service payback obligation.
- ***Teaching.*** Teaching is an instructional activity that takes place in an organized educational or other instructional environment. Activities classified as teaching are generally carried out in a formal didactic setting, but other activities will be considered if they are consistent with the certifying institution's policy on the definition of teaching responsibilities. Such teaching can be conducted at universities, professional schools, research institutes, teaching hospitals, primary schools, secondary schools, or colleges. When calculating hours of teaching per week, it is permissible to include 3 hours of preparation time for each hour of direct instruction. Acceptable teaching activities must have a biomedical or health-related relevance.
- ***Health-Related Activities.*** This incorporates a broad range of activities related to the description, diagnosis, prevention, or treatment of disease from the most basic biomedical or behavioral research to the most applied or clinical research. Activities in fields other than those usually considered to be directly related to human disease, such as agriculture, environmental sciences, biotechnology, and bioengineering, also will be considered health-related.

11.4.3.1.2 Time Commitment

All acceptable activities must be undertaken for periods that average at least 20 hours per week. Total employment in such activities averaging less than 20 hours per week cannot be counted toward fulfilling the obligation except in cases of disability or other pressing personal or family circumstances, such as child care or elder care responsibilities. It is not permissible for individuals otherwise engaged in full-time employment to engage in service payback activities at effort levels below 20 hours per week.

If less than 20 hours commitment per week is permitted, the total period of service obligation will be prorated. For example, an individual who owes 12 months of service and can devote only 10 hours per week to service payback activities due to a disability will be required to engage in such service for 24 months. These exceptions are rare and must receive prior approval from the PSC.

11.4.3.1.3 Initiation of Payback Service

Service payback obligations for postdoctoral recipients may be discharged by

- receiving an equal number of months of postdoctoral Kirschstein-NRSA support beginning in the 13th month of such postdoctoral Kirschstein-NRSA support, or
- engaging in an equal number of months of health-related research, training, or teaching averaging more than 20 hours per week.

11.4.3.1.4 Source of Funding

There is no restriction on the source of funds supporting an individual's service payback activity. An individual could be supported by a PHS grant or any non-Kirschstein-NRSA Federal or non-Federal source. Unpaid service also is permitted.

11.4.3.1.5 Timing of Service Obligation

An individual must begin to undertake the payback service requirement within 2 years after the termination date of the individual's Kirschstein-NRSA support unless an extension of time to begin payback has been approved by the PSC (see Payback—Extensions of Payback—Extensions of the 2-Year Period to Initiate Payback below).

11.4.3.2 Financial Payback

11.4.3.2.1 Policy and Principal Calculation

If an individual does not perform payback service, the Federal government shall be entitled to recover certain costs. The amount the United States is entitled to recover depends on when support was received. Calculation formulas take into account the total amount paid the individual (see Interest and Interest Rate Calculation below), less any obligation already fulfilled through service or legislative allowance when applicable. The total paid an individual under an institutional research training grant or individual fellowship award at a domestic, non-Federal sponsoring institution is considered to be the stipend only. The total paid an individual under a fellowship award at a foreign sponsoring institution includes the payment for the round-trip travel costs. The total paid an individual under a fellowship award at a Federal sponsoring institution includes any money expended from the institutional allowance provided for such purposes as health insurance, travel, tuition, and fees.

11.4.3.2.2 Interest and Interest Rate Calculation

NIH computes interest on the principal amount beginning on the date the United States became entitled to recover stipends. The interest rate is the rate fixed by the Secretary of the Treasury after considering prevailing consumer rates of interest. Accordingly, interest may accrue on any Kirschstein-NRSA obligation if the 2-year grace period has passed, if deferment has expired, or if service has terminated before completion of the payback obligation. The Department of the Treasury certifies Kirschstein-NRSA interest rates quarterly. Interest is computed on a 360 day-a-year basis and is applied through the date of receipt. Any outstanding amount will continue to bear interest at the initial rate set by the Secretary of the Treasury until financial payback is complete.

The date that sets the applicable rate of interest depends on the type of Kirschstein-NRSA account received for collection. If financial payback is voluntary, the signature date of the notification of voluntary payback is the date that determines the interest rate as well as the initiation of the 3-year repayment period. If financial payback is involuntary, the date that sets the interest rate and the 3-year repayment period is the date of expiration of the 2-year period following the completion date or

termination of Kirschstein-NRSA support. For example, if during June 2007, OFM received an account reflecting January 31, 2005, as the termination date of NRSA support, the Federal government, lacking any documentation to the contrary, becomes entitled to financial payback effective February 1, 2005. The rate of interest applicable is determined based on the February 1, 2005, date, and the total NRSA obligation is required to be fulfilled by January 31, 2008.

The amount to be recovered financially, as determined from the Termination Notice plus applicable interest, shall be paid to the United States within the 3-year period following such date.

11.4.3.3 Extensions of Payback

The authorizing legislation and the implementing regulations (42 CFR 66) permit exceptions to certain requirements under the Act.

11.4.3.3.1 Extensions of the 2-Year Period to Initiate Payback

An extension of the 2-year period to initiate payback may be requested in the Annual Payback Activities Certification form. Indication of valid plans to initiate payback soon after the 2-year grace period may be good reason to grant an extension.

11.4.3.3.2 Basis for Extensions or Break in Service

The PSC may extend the period for undertaking payback service or permit breaks in continuous service. These determinations are based on the following criteria:

- An extension or break in service is necessary so the individual may complete his or her research or clinical training.
- An extension or break in service is necessary so the individual may participate in the NIH Loan Repayment Program.
- The individual is unable to complete the requirements within the specified period because of a temporary disability.
- Completion by the individual of the requirement within the specified period would involve substantial hardship to the individual, and failure to extend the period would be against equity and good conscience.

Reasons for an extension or break in service include, for example, completing residency training where clinical teaching or research are not an integral part of the training, or seeking employment that would fulfill the payback requirements.

Requests must be made in writing (separate letter or APAC) to the PSC, specifying the need for additional time and the length of the requested extension.

11.4.3.4 Waiver

11.4.3.4.1 Policy

The authorizing legislation and the implementing regulation (42 CFR 66) permit exceptions to certain requirements under the Act. NIH may waive, in whole or in part, the payback obligation, upon determination that compliance by the individual is impossible or would involve substantial hardship, and enforcement of the individual's obligation would be against equity and good conscience.

11.4.3.4.2 Waiver Criteria

Requests for waivers should be made in writing to the PSC and should include an explanation of the need for the waiver according to the following criteria:

- Compliance by an individual will be deemed impossible if the individual is permanently, and totally disabled.
- In determining whether compliance would involve substantial hardship to the individual and would be inequitable, the PSC will consider the individual's
  - financial resources and obligations at the time of request for a waiver and
  - estimated future financial resources and obligations.
- In rare cases, the following also may be considered:
  - Reasons for the individual's failure to complete the requirements within the prescribed period, such as personal problems;
  - Extent to which the individual has engaged in payback activities;
  - Sufficiency of training to qualify the individual to perform such activities;
  - Lack of employment opportunities appropriate to the individual's education and training;
  - Any other extenuating circumstances.

Any obligation of any individual toward payback will be canceled upon death of the individual.

11.4.4 Certification of Payback Activities

11.4.4.1 Annual Payback Activities Certification (Form PHS 6031-1)

11.4.4.2 Annual Certification

Payback service is certified through the use of the Kirschstein-NRSA APAC (PHS 6031-1). Individuals with an outstanding payback obligation must complete an APAC annually until their payback obligation is fulfilled.

If an individual has a payback obligation, an APAC is sent by the PSC approximately one year after the completion of Kirschstein-NRSA support. Payback service may be initiated within the first 12 months of termination even though trainees and fellows have up to 24 months to initiate payback. There is no penalty to those individuals who do not initiate payback within the first 12 months; however, it is critical that they complete an APAC form to ensure contact is maintained and addresses are current.

The individual will report on the APAC the activity in which he or she was engaged for the preceding 12 months, within the specified reporting period. These forms are to be returned within 30 days of the reporting period end date to the address specified on the mailing label included with the form.

The PSC reviews the forms, determines acceptability of reported activities, and then informs the former trainee or fellow of his or her status. This process will continue annually until the individual's total payback obligation is satisfied.

11.4.4.3 Change of Address

Any change in the mailing address of a Kirschstein-NRSA recipient must be reported promptly to the PSC until the service obligation is fully discharged. Notification of changes can be made by letter, telephone, fax, or e-mail to NRSAPaybackCenter@mail.nih.gov.

11.4.4.4 Breaks in Kirschstein-NRSA Support

Sometimes a trainee/fellow will have a period of non-Kirschstein-NRSA support between two Kirschstein-NRSA awards. An appropriate activity performed during this period of time may count for payback purposes toward the first Kirschstein-NRSA award. If the nonsupport period is 6 months or longer, the individual receives an APAC form through the regular mechanism. However, if the break is less than 6 months, an APAC will not be mailed automatically. If acceptable payback service was performed during the break, the individual may complete an APAC, which can be obtained from the NIH Web site at http://grants.nih.gov/grants/forms.htm.

11.4.4.5 National Health Service Corps

A Kirschstein-NRSA recipient may have also been a National Health Service Corps (NHSC) scholar. Legislative changes effective October 26, 2002, eliminated the previously existing concurrent payback option. As a result, Kirschstein-NRSA recipients that also are NHSC scholars now are required to fulfill their NHSC service commitment through direct clinical service to the underserved in accordance with NHSC policy. Any Kirschstein-NRSA payback must be fulfilled separately through acceptable Kirschstein-NRSA payback service.

12 RESEARCH CAREER DEVELOPMENT ("K") AWARDS

12.1 GENERAL

This chapter includes general information about research career development awards (CDAs), also known as “K” awards. It supplements the general information found in IIA that applies to all NIH awards.

The objective of the NIH career development programs is to help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation’s biomedical, behavioral, and clinical research needs. Among NIH ICs, a variety of programs are available for scientists who require additional mentored or independent experience in a productive scientific environment in order to further develop their careers in independent biomedical, behavioral and clinical research.

For mentored programs, support is provided to cover protected time for supervised career development experiences with a goal of leading to research independence. Independent (non-mentored) programs foster the development of outstanding scientists and enable them to expand their potential to make significant contributions to a field of research.

12.1.1 Background

The research CDA program was established in 1961 to enable investigators who have demonstrated research potential to develop further their research careers. The program is authorized by sections 301, 402 and 405 of the PHS Act, 42 U.S.C. 241, 282 and 284. In general, CDAs provide up to five years of salary support and guarantee substantial protected time to engage in research and related activities. The award is available to persons who have demonstrated independent research accomplishments but need additional experience to establish or sustain an independent research program.

12.2 TYPES OF CAREER DEVELOPMENT AWARDS

12.2.1 General

NIH offers a wide variety of CDAs: mentored awards to individuals, including unique career transition programs; non-mentored awards to individuals (mid-career and senior stages), and institutional programs that provide mentored experiences for multiple individuals who are selected by the institution. Some CDAs are linked to other types of NIH awards. Applicants are encouraged to review the FOA for information about IC-specific utilization of the wide variety of CDAs. Specific questions may be directed to the appropriate NIH scientific/research staff or grants management staff named in the FOA.

Further information about specific NIH CDAs is found at the K Kiosk http://-grants.nih.gov/training/careerdevelopmentawards.htm.

12.2.2 Individual Mentored Career Development Awards

Individual mentored CDAs (e.g. K01, K07 (developmental), K08, K22, K23, K25, K99/R00) provide support for a sustained period of “protected time” (generally three, four, or five years) for intensive research career development under the guidance of an experienced mentor or sponsor in the biomedical, behavioral, or clinical sciences. Through the sustained period of research career development and

training provided by mentored CDAs, recipients are expected to gain the skills and experience necessary for independent and productive research careers. Mentored CDAs are not renewable, nor are they transferable from one individual to another. No-cost extensions in time are permitted; however, all terms and conditions, including appointment and minimum effort requirements, remain during the extension period.

Generally, mentored CDA programs are covered by NIH-wide Parent FOAs. In addition, some ICs may issue IC-specific FOAs for specialized programs. Specific program requirements for each mentored CDA program are found in the FOAs. Some programmatic information is provided below for programs with unique policies.

12.2.2.1 Mentor

Individual mentored CDA applications require the candidate to identify a mentor (sometimes referred to as a sponsor) with extensive and appropriate research experience. The candidate must name a primary mentor/sponsor, who, together with the candidate is responsible for the planning, direction, and execution of the program. The mentor should be recognized as an accomplished investigator in the proposed research area; have a track record of success in training independent investigators; and should have sufficient independent research support to cover any costs of the proposed research project in excess of the allowable costs of the CDA award. Candidates may have co-mentors/sponsors as appropriate to the goals of the program. Whenever possible and appropriate, women, individuals from diverse racial and ethnic groups, and individuals with disabilities are encouraged to be involved as mentors to serve as role models.

12.2.3 Career Transition Awards

In general, the career transition award programs (K22 and K99/R00) provides protected time through salary and research support to facilitate the transition of postdoctoral individuals or junior faculty in mentored positions to research independence.

12.2.3.1 K22

In general, the K22 program supports two phases of research: 1) a mentored phase (2 years); and, 2) an independent phase (up to 3 years), for a total of up to 5 years of combined support. Some programs, however, support only the newly-independent phase of an investigator's research career development. Applicants for K22 programs need not be affiliated with an applicant institution, e.g., NIH intramural scientists. Planning, direction, and execution of the proposed K22 award are the responsibility of the candidate. Only a few ICs support K22 programs and each has specific eligibility criteria and award provisions. There is no parent FOA.

When the applicant is an intramural scientist, NIH issues a provisional award letter and the actual NoA is issued after identifying a suitable position at an extramural research institution. The position may include continuation of a postdoctoral segment.

12.2.3.2 Pathway to Independence Award (K99/R00)

The objective of the Pathway to Independence Award (K99/R00) is to assist postdoctoral investigators in transitioning to a stable independent research position with independent research funding. The K99/R00 program offers a two-phase award, generally providing up to a total of 5 years of support. Phase I (K99) provides support for up to 2 years of intensive, mentored research career development; Phase II (R00) provides support for up to 3 years of independent research, contingent on securing an independent research position. Phase II is also contingent upon an administrative review and approval by the awarding IC of a transition application.

12.2.3.2.1 Eligibility

The K99/R00 program has several unique eligibility criteria that are not generally applicable to other CDA programs.

- U.S. citizens and non-U.S. citizens with the skills, knowledge and resources necessary to carry out the proposed research and career development activities are eligible to apply.
- K99/R00 applicants must not have more than 4 years of postdoctoral research training as of the relevant application due date regardless of whether it is a new or resubmission application.
- NIH intramural scientists are eligible to apply. If selected for funding, the K99 phase is supported by the NIH IC intramural laboratory in which the candidate conducts research. The R00 phase is supported via an extramural award once an acceptable position at an extramural organization is secured.
- It is expected that K99 awardees will benefit from no less than 12 months of mentored research training and career development before transitioning to the R00 phase.
- If an applicant achieves independence prior to initiating the K99 phase, neither the K99 nor the R00 phase will be awarded.

12.2.3.2.2 K99 Phase

Generally the K99 phase is for 2 years; however, award recipients may transition earlier than 2 years when the recipient has been offered an acceptable position. It is expected that K99 awardees will receive at least 12 months of career development support from the award before transitioning to the R00 phase. If an applicant achieves independence prior to initiating the K99 phase, neither the K99 nor the R00 phase will be awarded. Recipients are advised to contact the awarding IC if early transition is being considered. In all cases, early transition is considered a prior approval request and therefore subject to the approval of the NIH in accordance with Requests for Prior Approval.

Since the K99 and R00 phases are awarded independently, a no-cost extension may be allowed should additional time be needed to complete the goals of the K99 phase. However, no-cost extensions for K99 awards are not automatic and require prior approval by the NIH. All terms and conditions of the K99/R00 award (including minimum effort requirements) remain in effect when the grant is in a no-cost extension. In requesting a no-cost extension, K99 awardees wishing to continue to seek a tenure-track or equivalent position should submit a plan for continued career development and a timely transition to an independent position. If an application for the R00 Phase with a suitable position is not submitted within the one-year period of the no-cost extension, the R00 will not be awarded. Those not continuing to seek to transition to the R00 will be permitted to extend without additional funds, in order to permit an orderly phase-out of the project.

Carryover of Funds: Carryover from the K99 phase to the R00 phase may be allowed provided the K99 phase was funded by extramural support. The K99 recipient should consult with the awarding IC as to its practices regarding carryover.

12.2.3.2.3 Transition to the R00 Phase

The K99 award recipient is required to secure a tenure track, full-time assistant professor position or equivalent in order to transition to the R00 independent phase. Transition to the R00 phase is not guaranteed. The transition application for the R00 phase is administratively reviewed by NIH staff and is not peer reviewed by a study section. There should not be any delay between the K99 phase and the R00

phase. R00 award recipients will be expected to compete successfully for independent R01 support from the NIH during the R00 phase of the award.

Additional information on the K99/R00 and the FOA are found on the New Investigators Program web page under Pathway to Independence Award: http://grants.nih.gov/grants/new_investigators/#indaward.

12.2.4 Individual Non-mentored (Independent) Career Development Awards

Independent (non-mentored) CDAs (e.g. K02, K05, K07 leadership, K24) provide protected time for scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers. Independent CDAs are intended to foster the development of outstanding scientists and to enable them to expand their potential to make significant contributions to their field of research. Some Independent CDAs also require the candidates to serve as research mentors for junior researchers.

Candidates for independent CDAs must have a doctoral degree and independent, peer-reviewed support at the time the award is made. Some of the participating NIH ICs require candidates to have an NIH research grant from their IC at the time of application. Other NIH ICs will accept candidates with peer-reviewed, independent research support from other sources.

Planning, direction, and execution of the proposed career development program and research project are the responsibility of the applicant and sponsoring institution. Independent CDAs are not transferable from one PD/PI to another. Non-mentored awards are sometimes renewable.

12.2.5 Institutional Scientist Development Programs

The institutional mentored research scientist development program (K12 and KL2) provides support to an institution for the development of independent basic or clinical scientists. The goal is to enhance research career development for individuals (known as ‘scholars’) selected by the institution who are training for careers in specified research areas. A specified number of scholar positions are awarded in a K12. The K12 is solicited only by IC-specific FOAs. Although the K12 is subject to NIH Standard Terms of Award, the carryover of unobligated balances from one budget period to the next generally requires prior written approval. K12 awards are generally not transferable to another institution. When institutional mentored research development programs are incorporated as part of a Clinical and Translational Science Award Consortium the KL2 activity code is used.

The Clinical Research Curriculum Award (K30) is awarded to an institution to stimulate the inclusion of high-quality, multidisciplinary, didactic training as part of the career development of clinical investigators. It supports the development and/or improvement of core courses designed as in-depth instruction in the fundamental skills, methodologies, and theories necessary for the well-trained, independent, clinical researcher.

12.3 ELIGIBILITY

Eligibility can vary depending on the type of award and may even vary by NIH IC within a particular program. However, there are some eligibility criteria which are consistent across all CDA programs and these criteria are discussed in this section. Candidates are always strongly encouraged to carefully review the eligibility criteria in a specific FOA and to contact the scientific/research and/or grants management contacts in the relevant IC prior to preparing an application to discuss issues of eligibility. These contacts are listed in the individual FOA for each CDA.

12.3.1 Eligible Institutions

Applications for CDAs may be submitted on behalf of the candidate by any domestic for-profit or non-profit public or private institution/organization such as universities, colleges, hospitals, and laboratories to support a research program in a specified area(s) of research. Foreign organizations are not eligible to apply for CDAs, but foreign components may apply.

12.3.2 Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the candidate (called the PD/PI) is invited to work with his/her organization to develop an application for a CDA program. Individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are always encouraged to apply for NIH programs. Multiple PD/PI applications are not accepted for individual CDAs; institutional CDAs should check the FOA for the allowability of Multiple PD/PIs.

For mentored CDA programs, candidates who are well-established in their fields are considered ineligible. Some indications of having achieved this status are tenure or the equivalent, a substantial publication record or considerable research support that already requires commitment of a major part of the candidate's time. Applicants who meet one or more of these criteria must provide justification in the application that they are not already established in their field.

12.3.3 Degree Requirements

Degree requirements for CDAs are outlined in the specific FOA. Applicants are generally required to hold a research or health-professional doctoral degree or its equivalent; eligibility for some CDAs is limited to only applicants with health professional doctoral degrees.

12.3.4 Citizenship

For CDA programs other than the K99/R00 program, only U.S. citizens, non-citizen nationals or individuals lawfully admitted for permanent residence at the time an offer of an award is made, are eligible for this award. Individuals on temporary or student visas are not eligible to apply for a CDA unless they have begun the process for becoming a permanent resident and expect to be admitted as a permanent resident by the earliest possible award date. In an application package, on the PHS398 Career Development Award Supplemental Form, the option of selecting “Non-citizen with temporary visa” is applicable to K99/R00 candidates only.

Noncitizen nationals are individuals who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the applicant organization’s responsibility to follow up and ensure that the candidate receives the I-551 before the 6-month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the career award FOA may submit an application recognizing that no award will be made until legal verification of permanent resident status is provided to the NIH. The submission of documentation concerning permanent residency is not required as part of the initial application.

Applicants who have been lawfully admitted for permanent residence, i.e., have a Permanent Resident Card or other legal verification of such status, should check the Permanent Resident of U.S. box in Section 3. Citizenship of the PHS398 Career Development Award Supplemental Form. Applicants who have applied for and have not yet been granted admission as a permanent resident or have been granted Conditional Permanent Residency Status should also check the same box.

If a candidate's citizenship status changes after submission of an application, the new status should be reported in the candidate's Personal Profile in the eRA Commons.

In all cases involving any type of Permanent Residency status, when an application is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the candidate's valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. In all cases where Permanent Residency status is involved, it is the responsibility of the recipient institution to assure the individual remains eligible for the project period of the award.

12.3.5 Type of Appointment

By the time of award, all CDA recipients must have a full-time appointment at the applicant institution. With prior approval from the NIH, award recipients may hold part-time appointments for limited periods during the course of their awards (see Temporary Adjustments to the Full-Time Institutional Appointment Requirement below). Full-time or part-time is as defined by applicant institutional policy.

Candidates who hold additional appointments with an independent clinical practice plan, the VA or other organizations should contact the scientific/research and/or grants management contact in the relevant IC prior to preparing an application to discuss their eligibility. Responsibilities outside of the applicant organization appointment are not restricted; however, these types of additional appointments cannot be used to meet the full-time appointment requirement nor the effort requirement discussed below. If a candidate has a dual appointment, they must also have a full-time appointment at the applicant institution in order to qualify for a CDA.

12.3.5.1 Temporary Adjustments to the Full-Time Institutional Appointment Requirement

In January 2009 a new policy was adopted allowing a temporary adjustment of the full-time requirement for awarded CDAs under certain circumstances. At the time of the award, the candidate must meet the full-time appointment requirement (as well as any minimum effort requirement); however, awardees may request a temporary reduction in their appointment to less than full-time (but not less than three-quarter time) for a period not to exceed 12 continuous months during the CDA award project period. Circumstances requiring such a change in appointment status might include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. Permission to change appointment status will not be approved to accommodate job opportunities, clinical practice, clinical training, or joint appointments.

When requesting approval to change to a part-time appointment status, the awardee must continue to commit at least 75% effort (of the part-time appointment) to research and career development activities. The awardee is encouraged to consider increasing his/her percent effort to greater than 75% (e.g., 85%) to compensate for the anticipated effect of the part-time appointment on the awardee's career progress.

On behalf of the K awardee, the recipient institution must submit a request and documentation to the NIH awarding IC supporting the need for a reduced faculty appointment and assuring the institution's continuing commitment to the scientific and research career development of the awardee. The request should justify reducing the appointment to less than full-time status and must describe the anticipated

impact of the requested change on his/her career progress during the remainder of the award period. In addition, the awardee must submit assurance of his/her intention to return to a full-time faculty appointment as soon as possible. The mentor must provide a revised mentoring plan and specifically describe updated milestones for the awardee's progression to independence. Lastly, a revised statement of institutional commitment to the awardee must ensure continued "protected time" and describe additional support that will assist the awardee to continue to make progress toward his/her goals during the requested period of the reduced appointment. During the period of reduced appointment, the salary and other costs supported by the award will be reduced accordingly. Requests must be submitted by the recipient institution to the awarding Institute or Center (IC) where they will be considered on a case-by-case basis.

For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of the award, a request for reduction in the appointment must address the impact of this action on the awardee's ability to make sufficient progress to meet the goals of the program. For example, a K99 awardee must describe how the request will affect the awardee's ability to transition to the R00 phase of the award.

This policy also allows awardees to temporarily reduce the level of effort devoted to the CDA award; that policy is described below in Level of Effort. While these 2 policies are similar in overall goals, an awardee may not simultaneously request a reduction in appointment status from full-time to part-time AND a reduction in percent effort to less than 75%.

12.3.6 Level of Effort

In addition to the full-time appointment requirement described above, mentored and non-mentored CDA recipients are required to devote and maintain a minimum level of effort to the award. During a no-cost extension, the recipient is required to maintain any effort minimum and can only reduce his/her effort with prior approval of the awarding IC.

CDA recipients who hold additional appointments with an independent clinical practice plan, the VA or other organizations may not use these additional appointments to meet the minimum effort requirement. Responsibilities outside of the applicant organization appointment are not restricted; however, they also cannot be used to meet any minimum effort requirement. If a CDA recipient has a dual appointment, they must also have a full-time appointment at the applicant institution and be able to meet the minimum effort requirement as part of that full-time appointment in order to qualify for a CDA. Candidates are strongly encouraged to contact the scientific/research and/or grants management contact in the relevant IC prior to preparing an application to discuss their eligibility.

12.3.6.1 Mentored CDAs

Mentored CDA recipients are required to devote a minimum commitment equivalent of 9 calendar person months (75% of their full-time appointment at the applicant institution) to the career development and research objectives of the program specified in each FOA. The remaining 3 person months (25% effort), if applicable, can be divided among other research, clinical, and teaching activities only if these activities are consistent with the goals of the mentored CDA, i.e., the recipient's development into an independent investigator. Some NIH ICs allow less than 75% (but not lower than 50%) effort for certain clinical specialties. Applicants must consult the FOA and also IC Program staff for this exception.

Mentored K awardees are encouraged to apply for additional research grants during the tenure of their K award (see Concurrent Support below). Mentored CDA recipients are allowed to devote complementary effort without salary support on other research grants that include related research between the CDA and the research grant. In such cases where there is scientific overlap, the percent effort on the research grant is subsumed within the required effort of the CDA. However, there should not be significant duplic-

ation of the scope of the research supported by the CDA. Further, the related research must be consistent with the goals and objectives of the CDA.

12.3.6.2 Concurrent Support

Provided they remain in a mentored status, mentored CDA recipients in the final two years of their support period are permitted to reduce the level of effort required for the CDA when they have competed successfully for peer-reviewed research awards from NIH or any Federal agency, if programmatic policy of the other Federal agency allows such an arrangement. Recipients are encouraged to obtain funding from NIH or other Federal sources either as a PD/PI on a competing research grant award or cooperative agreement or as a project leader on a competing multi-project award.

Budgets for a competing research grant or a subproject on a multi-project grant should request appropriate amounts for the salary and associated costs for the CDA recipient's effort. At the time the research grant is awarded the effort required on the CDA may be reduced to no less than 6 person months (50% full-time professional effort at the recipient organization) and replaced by effort and corresponding salary from the research award so that the total level of research commitment remains at 9 person months (75% full-time professional effort) or more for the duration of the mentored CDA. This policy applies to the following mentored CDA activity codes: K01, K07 (developmental), K08, K22, K23, and K25, as well as individuals mentored through institutional K12 or KL2 awards. To be eligible for salary support from peer-reviewed research awards from any Federal agency:

- The CDA recipient must be one of the named PD/PIs on a competing NIH research grant application (R01, R03, R15, R21, R34, or equivalent application from another Federal agency) or a sub-project director on a competing multi-component research or center grant or cooperative agreement application (P01, P50, U01, etc. or an equivalent application from another Federal agency).
- The CDA must be active when the competing research grant application is submitted.
- The CDA must be in its final two years before the reduction in effort to 6 person months (50% full-time professional effort) is permitted.

For submissions to NIH, a letter must accompany the research grant application from the chair of the mentored award recipient's department or other responsible institutional official providing: (1) evidence that the recipient will continue to focus on the development of his/her research career; (2) will continue to have access to his/her mentor; and (3) that the recipient's total level of research effort will be maintained and protected at a minimum of 9 person months (75% full-time professional effort). For submissions to other Federal agencies, this type of institutional commitment letter is strongly encouraged; however, applicants should check with that agency for guidance on the allowability of such a letter.

When a mentored CDA recipient obtains independent support, as described above, the NIH awarding IC supporting the CDA will adjust the level of effort committed to the CDA to no less than 6 person months (50% effort) consistent with maintaining total research effort at 9 person months or 75% or more of the full-time appointment. NIH will adjust the total salary support committed to the K award consistent with the adjusted level of effort. If necessary, the K award may also be adjusted to avoid any additional budget overlap.

12.3.6.3 Non-mentored CDAs

Established investigators on independent (non-mentored) CDAs are generally required to devote a minimum of 3-6 person months (25-50% effort) conducting research and research career development related activities during the period of the award. Some independent CDAs allow and may require more

than 6 person months (50% effort). For example, K02 recipients are required to devote 9 person months (75% effort) to research.

Generally, an independent or leadership awardee may receive additional salary support from other NIH/PHS grants for effort not committed to the CDA and there are no limitations to receiving other salary support. Where applicable, specific policies are noted in the FOA. The candidate must be able to demonstrate that the requested period of salary support and protected time will foster his/her career and capacity to contribute to the specified field.

12.3.6.4 Temporary Adjustments to the Percent Effort Requirement

At the time of the CDA award, the candidate must still meet the applicable effort requirement (as well as the full-time appointment requirement); however, under certain circumstances, awardees may request a temporary reduction in their effort for a period not to exceed 12 continuous months during the award project period. For programs that require a 75% effort minimum (equivalent to 9 person months), an awardee can request a reduction to no less than 50%. Circumstances requiring such a change in effort might include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. Permission to temporarily reduce effort will not be approved to accommodate job opportunities, clinical practice, clinical training, or joint appointments.

On behalf of the K awardee, the recipient institution must submit a request and documentation to the NIH awarding IC supporting the need for reduced effort and assuring the institution's continuing commitment to the scientific and research career development of the awardee. The request should justify reducing effort and must describe the anticipated impact of the requested change on his/her career progress during the remainder of the award period. In addition, the awardee must submit assurance of his/her intention to return to 75% effort as soon as possible. The mentor must provide a revised mentoring plan and specifically describe updated milestones for the awardee's progression to independence. Lastly, a revised statement of institutional commitment to the awardee must ensure continued "protected time" and describe additional support that will assist the awardee to continue to make progress toward his/her goals during the requested period of the reduced appointment. During the period of reduced effort, NIH will adjust the total salary amount committed to the K award consistent with the adjusted level of effort. However, NIH will continue to provide full research costs in other budget categories as indicated on the original Notice of Award. In addition, the K awardee may request to extend the duration of the award to account for the reduced effort. Requests must be submitted by the recipient institution to the awarding Institute or Center (IC) where they will be considered on a case-by-case basis.

This option is not available for Independent CDAs that require only 25-50% effort; e.g., K07 leadership, K05, and K24.

While this temporary adjustment in effort policy is similar to the policy described above allowing a temporary adjustment in the full-time appointment requirement, awardee may not simultaneously request a reduction in appointment status from full-time to part-time AND a reduction in percent effort to less than 75%.

12.3.7 Prior Research Support

Applicants who have previously served as the PD/PI on a NIH R03 or R21 grant or non-PHS equivalent at the time of application may apply for a mentored CDA (except for the K99/R00 program).

In general, for mentored CDAs, individuals are NOT eligible if they:

- have a pending application for:1) any other PHS career award that duplicates the provisions of the proposed NIH program; 2) an NIH institute-specific K22, or a Pathway to Independence

Award (K99/R00); and/or

- have been or are currently a PD/PI on an independent NIH research grant (such as R01) or a sub-project leader on a Program Project (P01) or Center Grant (P50), or a non-PHS equivalent to these grants.

Most independent (non-mentored) CDAs require that the applicant have independent, peer-reviewed support at the time the award is made. Some of the participating NIH ICs require the candidate to have an NIH research grant at the time of application and that the support be from their IC. Other NIH ICs will accept candidates with peer-reviewed, independent research support from other sources. Applicants must check the FOA for specific eligibility requirements.

12.4 APPLICATION REQUIREMENTS AND SUBMISSION DATES

12.4.1 Application

Before applying for a CDA, applicants should carefully review the guidelines in the FOA for the specific career award(s) of interest, noting especially the eligibility requirements, award provisions, requirements for a mentor, and review criteria. The participating ICs may have distinctive guidelines, requirements, and funding amounts for each FOA in order to accommodate the career needs of researchers working in fields related to their specific research missions. Candidates are therefore strongly encouraged to contact the staff person in the relevant IC listed in the FOA prior to preparing an application to discuss any specific provisions of the award.

All CDA applications have transitioned to electronic submission through Grants.gov. The specific FOA provides links to the application forms package as well as the appropriate application instruction guide. As with all NIH programs using electronic submission, a CDA application uses a combination of SF424 (R&R) and PHS398 forms. A separate section (Section I.7) of the SF424(R&R) Application Guide is included that provides supplemental instructions for preparing a CDA application. Further assistance is available from GrantsInfo.

Applications must contain Candidate Information, Statements of Support, Environment and Institutional Commitment to the Candidate, as well as a Research Plan. The Candidate Information section includes required information about the candidate and must justify the need for the requested period of support, be tailored to the prior research experience and career development needs of the candidate, and for mentored CDAs be designed to move the candidate from a mentored phase to an independent status. The research plan must have intrinsic research importance as well as serve as a suitable vehicle for learning the methodology, theories, and skills necessary for a well-trained independent researcher. For mentored award programs, the research plan must also include a description of the relationship between the mentor's research and the candidate's proposed research plan.

Other than the K22 application from an unaffiliated candidate, all applications require documents describing the Environmental and Institutional commitment to the candidate.

For mentored award programs the career development application also must include Statement by Mentor(s), Co-Mentor(s), Consultant(s) and Contributor(s) as well as a statement describing the institution's commitment to the candidate's development.

12.4.1.1 Letters of Reference

At least three (but no more than five) letters of reference are required for all new and resubmission mentored CDA applications. The letters should be from individuals not directly involved in the application,

but who are familiar with the candidate's qualifications, training, and interests and include advisory committee members (if applicable). However, the candidate's mentor(s) of the application must not submit a separate letter of reference because a mentor's statement is required as part of the application. The letters of reference should address the candidate's competence and potential to develop into an independent biomedical, behavioral, or clinical investigator.

Electronic submission of CDA applications requires electronic submission of reference letters as well. However, reference letters are submitted directly by the referee through the eRA Commons and not as part of the electronic application that goes through Grants.gov. Reference letters will be joined with the electronic application within the eRA system once an application completes the submission process. Applications that are missing the required letters may be delayed in the review process or not accepted at all. Complete instructions for candidates and referees are found in Part I, Section 7.3 of the SF424 (R&R) Application Guide for Adobe Applications.

12.4.1.2 Concurrent Applications

NIH will not accept any application in response to an FOA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial resubmission of an application already reviewed, but such applications must include an Introduction addressing the previous critique.

12.4.1.3 Environment and Institutional Commitment to the Candidate

The applicant organization must define and document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with staff capable of productive collaboration with the candidate. The institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of the award. The institution should indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in the application. The applicant should describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

The institution should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development. The document should include the institution's agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

Because of the diverse types of CDAs, applicants should contact the appropriate awarding IC scientific/research contact named in the specific FOA to determine the level of commitment required for the application. Institutional commitment to the candidate may not be contingent upon the receipt of the CDA.

Off-Site Training Experience. A candidate may propose a career award experience that involves sites beyond the applicant organization, provided that the goals of the total experience are encompassed and supported under the appointment with the applicant organization.

12.4.1.4 Training in the Responsible Conduct of Research

All CDA applicants (mentored and non-mentored) must include a description of the formal and informal activities related to instruction in the responsible conduct of research planned for the proposed research

program. Specifically, applicants must include a description of a plan for instruction in responsible conduct of research. This description should document prior instruction in or the nature of the applicant's participation in responsible conduct of research instruction (lecturer, discussion leader, etc.) during the applicant's current career stage (including the dates of last occurrence) and propose plans to receive or participate in instruction in responsible conduct of research. Such plans must address the five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined below. Applications lacking a plan for instruction or participation in responsible conduct of research will be considered incomplete and may be delayed in the review process. Plans and past record will be rated as **acceptable** or **unacceptable** and the summary statement will provide the consensus rating of the review committee. Applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan. For additional information see the specific FOA.

1. ***Format.*** Substantial face-to-face discussions among the career recipient/scholars, other individuals in a similar training status, and mentors along with a combination of didactic and small-group discussions (e.g. case studies) are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term career development programs (see below), or unusual and well-justified circumstances.

2. ***Subject Matter.*** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

(a) conflict of interest – personal, professional, and financial

(b) policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

(c) mentor/mentee responsibilities and relationships

(d) collaborative research including collaborations with industry

(e) peer review

(f) data acquisition and laboratory tools; management, sharing and ownership

(g) research misconduct and policies for handling misconduct

(h) responsible authorship and publication

(i) the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

3. ***Faculty Participation.*** Mentors and other appropriate faculty are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. For institutional Career Awards, training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

4. ***Duration of Instruction.*** Instruction should involve substantive contact hours between the career recipient/scholars, mentors and other appropriate faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. ***Frequency of Instruction.*** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Non-mentored career award recipients may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the career award recipient/scholar is not actually supported by an NIH grant. This instruction must be documented in the submitted plan.

12.4.1.5 Budget

CDAs provide limited costs, generally covering only applicable salary and fringe benefits for the candidates, as well as a fixed amount for research development support. Costs requested and awarded for CDA programs must be consistent with applicable Federal cost principles. Salary amounts as well as the research development costs can vary by CDA program and then within a particular program even by each participating NIH IC. Applicants are advised to consult the relevant FOA for guidelines on allowable costs and budget limitations.

The transition to electronic submission included a change in business process with respect to budget information. Detailed budget information is now required as part of the initial application; however it is limited to the senior/key person information for only the candidate and then the total amount of requested research development support in budget section F.1. Other Direct Costs/Materials and Supplies. A budget justification is also required and should be used to provide a detailed description for the specific research development support costs. Instructions are provided in the applicable Application Guide and specific FOAs.

As with all NIH training programs, Facilities and Administrative costs for CDAs are provided at a rate of 8% of modified total direct costs.

12.4.1.6 Submission Dates

For all parent CDA FOAs, NIH receives applications three times each year using standard submission dates. For a list of the standard submission dates and review cycle, see http://grants.nih.gov/grants/funding/submissionschedule.htm. IC-specific FOAs may use special submission dates instead of the standards dates, but the FOA will clearly indicate if standard or special submission dates are used.

12.5 REVIEW

All CDA applications will undergo peer review as noted in The Peer Review Process in Part I; however, the actual review criteria and other review considerations are different as described herein.

12.5.1 Overall Impact

Reviewers should provide their assessment of the likelihood for the candidate to develop and/or maintain a strong research program, taking into consideration the criteria below in determining the overall impact score.

12.5.2 Scored Review Criteria

For CDA applications, reviewers will consider each of the five review criteria below in the determination of the scientific and technical merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have a major scientific impact. The scored criteria are:

- Candidate
- Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- Research Plan
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s); and for non-Mentors the Mentoring Plan
- Environment and Institutional Commitment to the Candidate

These criteria are listed in logical order and not in order of priority. Since the specifics for each of these criteria can vary for the various CDA programs, the review criteria are described in detail in the FOA. Note that different ICs may employ additional review criteria.

12.5.3 Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- Protection of Human Subjects
- Inclusion of Women, Minorities and Children
- Vertebrate Animals
- Biohazards
- Resubmission Applications
- Renewal Applications
- Revision Applications

The FOA should be consulted for further information describing each of the relevant additional review criteria.

12.5.4 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

- Training in the Responsible Conduct of Research
- Select Agents

- Resource Sharing Plans
- Budget and Period of Support

Candidates should carefully review the applicable FOA for complete information associated with the peer review process including further information describing each of the relevant additional review considerations.

12.6 NOTIFICATION OF ACTION

Shortly after the initial peer review meeting, candidates receive an e-mail indicating that the SRG recommendation/impact score is available in the eRA Commons. The candidate is also notified via an e-mail when the summary statement (written critique) is available in the eRA Commons.

The PO may notify the applicant about the final review recommendation. The applicant should direct any questions about initial review recommendations and funding possibilities to the designated IC PO, not the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons. If the application is under consideration for funding, NIH will request additional information. After all program and administrative issues have been resolved, the NoA will be issued for those applications selected for funding.

12.7 PERIOD OF SUPPORT

The NIH awarding IC will notify the individual of the intention to make an award and confirm the plans for the start of support. An award is for a period of 3 to 5 years and provides support for salary and research-development support costs. Support beyond the first year shall be based on an assessment by NIH staff of the effectiveness of the development opportunity and continued opportunity for growth, as reflected in the recipient's annual progress report. Continuation of awards is contingent upon future Federal appropriations.

Mentored CDAs are not renewable. Non-mentored CDAs may be renewable; awards may be competitively renewed at the discretion of the participating NIH ICs. Only a few of the NIH ICs permit competitive renewals.

Note the period of support for the K99/R00 program is awarded in 2 distinct phases. Phase I covers only the K99 period; phase II is the R00 portion and is contingent upon meeting certain criteria, including the submission and acceptance of a R00 application by the NIH IC.

Some K22 programs also have 2 distinct funding phases where specific criteria must be met before funding is provided for the second phase.

Note, the K99/R00 and some K22 programs allow NIH intramural scientist to apply. For those selected for funding, the period of support on any award issued will only reflect the period funded by NIH extramural funds. Any period of support supported by NIH intramural funds will not be evident in the NoA.

12.8 ALLOWABLE AND UNALLOWABLE COSTS

Policies included in the applicable cost principles in 45 CFR 75, Subpart E and the NIHGPS govern the expenditure of all CDA funds, unless otherwise indicated in the NoA.

12.8.1 Salaries and Fringe Benefits

Requested salary and fringe benefit amounts must be in accordance with institutional policies applied consistently to individuals in like circumstances and must be supported by acceptable accounting

principles. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. Salary amounts requested on CDA grants must be based on the investigator's institutional base salary (IBS) prorated for their commitment on the project. While requested salary and fringe benefit information is provided in the initial application, confirmation of these costs may be required prior to the issuance of an award.

The amount funded as salary for a CDA is not uniform throughout the NIH participating ICs. Salary limits vary by IC and are noted in the FOA. Note the limit is on salary only; applicable fringe benefits are provided in addition to the salary. The candidate is strongly advised to contact the relevant awarding IC for any distinct guidelines, requirements, and allowable funds. Salary costs charged cannot exceed the applicable legislative salary cap (http://grants.nih.gov/grants/policy/salcap_summary.htm).

The recipient institution may supplement the NIH salary contribution on the CDA up to a level that is consistent with the institution's salary scale. For effort directly committed to the CDA, salary supplementation is allowable, but must be from non-Federal sources (including institutional sources). In no case may PHS funds be used for such salary supplementation. Non-federal or institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the goals of the CDA. For effort not directly committed to the CDA, CDA recipients may devote effort, with compensation, on Federal or non-Federal grants as the Program Director/Principal Investigator (PD/PI) or in another role (e.g., co-Investigator), as long as the specific aims of the other supporting grant(s) differ from those of the CDA.

NIH IC limitations on awarded salary levels do not limit the recipient's rebudgeting authority. Institutions may rebudget the total costs awarded to cover additional salary charges, provided they are within the approved scope of the project and consistent with the institution's salary scale as long as the cost charged is within the applicable legislative salary cap.

Salary support for ancillary personnel (e.g. administrative assistance or secretarial support) on CDAs is not allowable.

Salary support for mentors is not allowable on individual mentored CDAs.

Salary support for research technicians or study coordinators for clinical studies are generally allowable but are budgeted as part of the Research Development Support Costs described below.

12.8.2 Research Development Support Costs

CDAs may include a fixed amount for research development support costs. This amount may vary by IC and is commonly used for supplies, equipment, technical personnel, travel to research meetings or training, tuition/fees for courses and computational services.

12.8.3 Proposal Preparation Costs

Mentored CDA programs provide support with a goal of leading to research independence for an individual. Since research independence is achieved through applying for other research support, consistent with these objectives, it is allowable for effort devoted to proposal preparation costs for subsequent research support to be charged to a mentored CDA award. This can be considered part of the awarded effort commitment of the mentored CDA or an increase to that commitment with the allowable salary provided as applicable.

12.8.4 Facilities and Administrative Costs

For career awards other than the R00 phase of the K99/R00 and other than State, local, or Indian tribe (or "federally recognized Indian tribes"), recipients will receive F&A costs at 8 percent of modified total direct costs. State and local agencies, and Indian tribes (or "federally recognized Indian tribes") are eligible for full F&A cost reimbursement. For this policy, State universities or hospitals are not considered governmental agencies.

12.9 REBUDGETING OF FUNDS

Funds awarded on CDAs may typically be rebudgeted within direct cost categories without prior approval; however restrictions on rebudgeting may be noted in the NoA.

Rebudgeting of salary funds in an NIH-supported research grant for the salaries or fringe benefits of individuals which are freed as a result of a career award, may not be rebudgeted without the prior approval of the NIH awarding IC.

12.10 CARRYOVER AUTHORITY

Unless otherwise noted by a specific term of award, Individual CDAs have automatic carryover authority. However, for most Institutional CDAs, carryover requires prior approval. The NoA will specify whether or not the recipient must obtain prior approval to carry over funds.

For the two-phased K99/R00 program, carryover from the K99 phase to the R00 phase may be allowed provided the K99 phase was funded by extramural support. The K99 recipient should consult with the awarding IC as to its practices regarding carryover.

12.11 REPORTING REQUIREMENTS

Failure to comply with reporting requirements and to submit the required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation funding.

12.11.1 Progress Reports

Most individual CDA awards (mentored and non-mentored) are awarded under SNAP authorities. Progress reports for SNAP awards must be submitted using the Research Performance Project Report (RPPR). The RPPR must be submitted electronically using the RPPR module in the eRA Commons. For progress reports submitted using the RPPR, the IDP requirement described in Non-Competing Continuation Progress Reports will apply. Progress reports for non-SNAP awards should be submitted in accordance with the PHS 2590 instructions, including Section 4, Additional Instructions for Preparing Continuation Career Development Award (CDA) Progress Reports. PHS 2590 progress report forms and instructions are available from the NIH Web site at http://grants.nih.gov/grants/forms.htm.

Following completion or termination of a project period, the recipient must submit a Final RPPR to the NIH awarding IC within 120 days after the end of grant support as part of the Closeout documents described below.

12.11.2 Federal Financial Report

For individual CDAs awarded under the SNAP authorities, an annual electronic FFR is not required. Only a final FFR is required at the end of the project period (see Administrative Requirements—Mon-

itoring—Reporting—Financial Reports and Administrative Requirements—Closeout—Final Reports in IIA).

12.11.3 Closeout

The Closeout requirements included in IIA (see Administrative Requirements—Closeout—Final Reports) apply to all Individual CDAs (mentored and non-mentored). For Institutional Scientist Development Programs the closeout requirements apply with the exception of the Final Invention Statement; invention reporting is not applicable to K12s & KL2s thus a final invention statement is not required as part of the closeout process.

12.11.4 Post Closeout Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of CDA programs. Accordingly, CDA awardees may be contacted after the completion of any CDA award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

12.12 CHANGES IN THE PROJECT

The approval of the NIH awarding IC is required for a transfer of the CDA to another institution, or a project change. Note, individual mentored and non-mentored CDAs may not be transferred to another PD/PI.

The Change of Recipient Organization policies described in IIA apply to Individual CDAs as long as the transfer is between domestic institutions. For mentored CDAs, the recipient must have a mentor at the new institution. If the transfer also involves a change in mentor, supporting documentation from the new mentor will be required. Consultation with the applicable NIH program staff and/or grants management staff is strongly encouraged when a change of institution is being considered.

CDAs are awarded under the NIH Standard Terms of Award and as such recipients have the authority to extend the final budget period of a project period without additional funds for up to 12 months. Recipients are reminded that all terms and conditions and programmatic requirements apply during the extension period. For instance, the full-time appointment and minimum effort requirements must continue for the entire extension period. Recipients should be mindful of these requirements when deciding how much additional time is needed.

12.12.1 Temporary Off-Site Training Experience

A temporary career development experience at another institution, including a foreign laboratory, may be permitted if the proposed experience is directly related to the overall goals and purpose of the K award. Only local institutional approval is required if such an arrangement does not exceed 3 months. For longer periods (not to exceed 12 months), prior written approval from the NIH awarding IC is required. The written request must document the approval of the recipient organization and the adequacy of arrangements for off-site training. Support from the career award will continue during such an off-site experience. For some CDAs additional information is required as part of any prior approval request:

- For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of each of these awards, a request for approval of an off-site training experience lasting more than 3 months must address the impact of such action on the awardee's ability to make

sufficient progress to meet the goals of the award. For example, for a K99 phase awardee, the request must describe how the off-site experience will affect the awardee's ability to transition to the R00 phase.

- For K05, K07 leadership, and K24 awardees, the request must include a letter assuring that arrangements have been made to continue to commit the appropriate effort to the research and to provide mentoring.
- For K12 and KL2 Scholar appointees, because of the short duration of the mentored phase of each of these awards, a request for approval of an off-site training experience lasting more than 3 months must address the impact of such action on the scholar's ability to make sufficient progress to meet the goals of the program.

12.13 OTHER TERMS AND CONDITIONS

Except as otherwise noted below, the provisions of IIA apply to all CDA programs. This includes all Public Policy Requirements, Objectives, and Other Appropriation Mandates such as civil rights; the protection of human subjects, including data and safety monitoring requirements; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant DNA and human gene transfer research. See Subpart IIA for a complete list of applicable requirements.

In addition, all Administrative Requirements described in IIA also apply to CDA program unless an exception is noted below. These include requirements such as prior approvals; availability of research results, publications, NIH Public Access policy, invention reporting, and program income. See IIA for a complete list of applicable administrative requirements.

12.13.1 Leave

Since CDA awardees are employees of the institution, applicable institutional leave policies for leave such as vacation, sick, parental, etc. apply to individuals supported by NIH CDAs.

CDAs are expected to be for continuous support of an individual; however, in certain circumstances, candidates will be permitted to take a leave of absence. Circumstances include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. A leave of absence or sabbatical greater than three months must be requested and approved in writing by the NIH awarding IC. A leave of absence less than 3 months only requires institutional prior approval.

For some CDAs additional information is required as part of any prior approval request:

- For transition CDAs (K22 and K99/R00), because of the relatively short duration of the mentored phase of each of these awards, a request for approval of a leave of absence lasting more than 3 months must address the impact of such action on the awardee's ability to make sufficient progress to meet the goals of the award. For example, a K99 phase awardee must describe how the leave will affect the awardee's ability to transition to the R00 phase.
- For K05, K07 leadership, and K24 awardees, the request for a leave of absence lasting more than 3 months must include a letter assuring that arrangements have been made to continue to commit the appropriate effort to the research and to provide mentoring.
- For K12 and KL2 Scholar appointees, because of the short duration of the mentored phase of each of these awards, a request for a leave of absence lasting more than 3 months must address the impact of such action on the scholar's ability to make sufficient progress to meet the goals of the program.

12.13.1.1 Unpaid Leave

Leave without award support may not exceed 12 months. Such leave requires prior written approval of the awarding component and will be granted only with justification. When approved, the K award will be placed in a no-cost extension for the duration of the unpaid leave and no charges to the grant will be allowed during that period, although continued coverage of health insurance would be allowable if in accordance with institutional policy. Such leave does not reduce the total number of months of program support for which an individual is eligible.

12.13.2 Statement of Appointment—Institutional CDAs Only

At the time of the initial appointment of K12 or KL2 scholars, the Program Director may submit a Statement of Appointment (Form PHS 2271) for each scholar to the NIH awarding IC to document the appointment of scholars to institutional CDAs. This policy varies with ICs. Contact the CGMO of the awarding IC to confirm their policy on submitting a PHS 2271. When 2271s are required, this information must be submitted using the xTrain feature in the eRA Commons.

12.13.3 Early Termination

Consultation with the applicable NIH program staff and/or grants management staff is strongly encouraged when a termination is being considered before the scheduled project end date. When an institution plans to terminate an award, the awarding IC must be notified in writing at the earliest possible time, so that appropriate instructions can be given for termination. NIH will issue a revised NoA to specify the changed period of support.

NIH may terminate a CDA before its normal completion date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. If an award is terminated for cause, NIH will notify the recipient in writing of the determination, the reasons for the determination, the effective date, and the right to appeal the decision.

The NIH awarding IC should be notified immediately if a sponsoring institution wants to terminate a K12 scholar, or if the scholar decides to terminate the appointment before the scheduled completion date.

12.13.4 Other Income: Generation and Disposition of Professional Fees

CDA awardees may retain royalties and fees from activities such as scholarly writing, service on an advisory group, honoraria from other institutions for lectures or seminars, fees resulting from clinical practice, professional consultation, or other comparable activities, provided these activities remain incidental, are not required by the research and research-related activities of the CDA, and provided that the retention of such pay is consistent with the policies and practices of the recipient institution. No other income or fees may be retained by the CDA recipient and must be assigned to the recipient institution for disposition by any of the following methods:

- The funds may be expended by the recipient institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the recipient institution.
- The funds may be used for health-related research purposes.

- The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services and forwarded to the Director, Office of Financial Management, NIH, Bethesda, MD 20892. Checks must identify the relevant award account and reason for payment.

Adequate records regarding the source, receipt and disposition of fees and other income are to be maintained by the institution for the time period(s) specified in 45 CFR 75.307.

13 MODULAR APPLICATIONS AND AWARDS

13.1 GENERAL

Modular applications and awards employ a simplified process for developing and reviewing application budgets, documenting approved budgets, and making post-award budgetary changes.

13.2 APPLICABILITY

Modular procedures are required to be used for new, renewal, and resubmission applications as well as for revisions for the following grants and their cooperative agreement equivalents that request up to a total of $250,000 of direct costs per year (excluding consortium F&A costs), regardless of whether the application is an investigator-initiated application or is one submitted in response to a PA/RFA: Research Project Grants Program (R01/U01), Small Grant Program (R03), Exploratory/Development Research Grant Award (R21/UH2), Clinical Trial Planning Grant Program (R34/U34) and Academic Research Enhancement Awards (R15/UA5). Modular procedures do not apply to SBIR and STTR Phase I grants (R43 and R41), and do not apply to foreign (non-U.S.) organizations.

Instructions for specific grant mechanisms other than the R01 and guidelines for IC programs may indicate a particular number or range of modules allowed.

Modular applications and awards may also be subject to other simplified procedures, specifically Just-in-Time requirements and SNAP.

13.3 APPLICATION REQUIREMENTS

Modular applications must be submitted on the SF424 (R&R) forms. Paper-based applications that include modular budgets will no longer be accepted.

13.3.1 Budget

Modular applications request direct cost funding in modules of $25,000, for up to $250,000 each year for covered activity codes. F&A costs for subcontracts are not included in determining the direct cost modular amount or the total cost amount requested. The modules should be a reasonable estimate of allowable, allocable, and reasonable costs for the proposed project. In addition, F&A costs at the negotiated rate for the applicant institution are also allowable.

Since only limited budget information is required for submission of a modular application, the PHS 398 Modular Budget Component, which is included as part of the electronic SF424 (R&R) form set, must be submitted to NIH through Grants.gov. Sample modular application budget pages are available at http://grants.nih.gov/grants/funding/modular/modular.htm. The standard SF 424 Research and Related Budget Component is not used for application using modular budgets.

The PHS 398 Modular Budget Component includes information on direct costs modules as well as F&A costs; budget justifications for all personnel by position, role, and level of effort (measured in person months); consultants; and 'to be appointed' positions. No individual salary information should be provided. Applicants must use the current legislatively imposed salary limitation when determining the number of modules to request (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages in IIA). Given the authority to rebudget and carry forward unobligated balances, funds generally should be available to cover modest increases in any statutorily imposed salary cap. NIH also limits the compensation for graduate students. Compensation includes salary or

wages, fringe benefits, and tuition remission. These limits should be used when estimating the number of modules. See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages in IIA for more information on compensation of graduate students.

When applicable, a separate budget justification must address consortium/contractual costs (including applicable F&A costs) rounded to the nearest $1,000. The narrative should list the individuals and organizations with whom consortium or contractual arrangements have been (or will be) made, the level of effort of senior/key personnel (measured in person months) and their role on the project, and indicate whether the collaborating organization is foreign or domestic.

A typical modular application will request the same number of modules for each year. However, well-justified modular increments (up to the $250,000 modular ceiling) or decrements in the total direct costs for any year of the project that reflect substantial changes in expected future activities may be requested at the outset. For example, a major equipment purchase in the first year may justify a higher overall budget in that year, but not necessarily in succeeding years. There is no provision for escalation in future years. NIH requires additional narrative budget justification if there is a variation in the number of modules requested from year to year. Further, when the pre-award review warrants such a request, NIH ICs may request a detailed budget as part of the Just-in-Time process.

13.4 APPLICATION REVIEW AND AWARD

SRGs evaluate the budget on the basis of a general, expert estimate of the total effort and resources required to carry out the proposed research. If the SRG recommends an adjustment in the project budget, the recommended adjustment will be in terms of an entire module.

Following peer review, for applications being considered for award, the IC will request information about “Other Support” and, as applicable, the use of human subjects or vertebrate animals, and education in the protection of human research participants. Additional budget information will be requested before award only under special circumstances.

NIH will attempt to make awards at or close to the level of total direct costs recommended by the SRG, taking other support into account. An IC may need to reduce the award amount to accommodate the IC’s cost management plan.

The award budget will be a noncategorical budget specifying approved total direct costs and F&A costs, if applicable.

13.5 POST-AWARD ADMINISTRATION

Recipients have discretion in determining how to allocate and account for costs related to modular awards within their organizational accounting system. However, institutions are still required to ensure that all costs charged to modular awards are in accordance with applicable costs principles, the NIH GPS, and any legislatively imposed restrictions.

Modular awards are subject to the standard NIH Terms of Award and may be awarded under the SNAP authorities. However, since the award is issued without direct cost budget categories, the significant rebudgeting provision described as a potential change of scope indicator does not apply to modular grants.

Recipients may submit requests for administrative supplements to the CGMO of the NIH awarding IC, but must provide a detailed (non-modular) budget.

Competing Revisions should be submitted to the NIH using the modular budget component.

14 SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS)

14.1 GENERAL

NIH supports scientific meetings, conferences, and workshops (hereafter "conferences") that are relevant to its scientific mission and to public health under the R13 and U13 activity codes. NIH's support of conferences is contingent on the interests and priorities of the individual ICs. Most ICs provide conference support although their budget guidelines may vary. Prior approval (advance permission) is required before submission of an application for conference support. Advance permission to submit an application must be requested early in the process and no later than 6 weeks before the application submission date. Permission to submit a conference grant application does not assure funding or funding at the level requested. The letter from the NIH IC conference grant contact person (http://grants.nih.gov/grants/guide/contacts/parent_R13_U13.html) documenting advance permission to submit an application must be included as part of the PHS 398 Cover Letter component of the application. Potential applicants must contact the funding IC before submission for specific information as well as to ensure compliance with submission requirements. Applications for conference support must be submitted based on the published receipt dates. In general, NIH will not issue a conference grant award unless the Federal award date can precede the conference start date. Awarding a conference grant after a conference has been held should only be done when an IC can determine or document that funding of post-conference activities is consistent with the approved application.

14.2 APPLICABILITY

This chapter applies to grants that support domestic and international conferences. If a policy is not addressed in this chapter, then IIA coverage applies.

Questions concerning the allowability of conference activity under research grants should be directed to the GMO.

14.3 DEFINITIONS

Conference (in general). 45 CFR 75.432 defines a conference as a meeting, retreat, seminar, symposium, workshop or event whose primary purpose is the dissemination of technical information beyond the non-Federal entity and is necessary and reasonable for successful performance under the Federal award.

Scientific Meeting (Conference). A gathering, symposium, seminar, workshop, or any other organized, formal event where people assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge.

International Conference. A scientific meeting so designated by its sponsor or one to which open invitations are issued on an equal basis to potential participants in two or more countries other than the United States or Canada. The meeting may be held in the United States or any country, subject to U.S. Department of State travel restrictions.

Domestic Conference. A scientific meeting held in the United States or Canada primarily for U.S. or U.S.-Canadian participation (even if foreign speakers are invited).

14.4 ELIGIBILITY

Domestic institutions or organizations, including established scientific or professional societies, are eligible to apply for conference support. Both domestic and international conferences may be supported; however, an international conference may be supported only through the U.S. representative organization of an established international scientific or professional society. An individual is not eligible to receive a grant in support of a conference.

14.5 APPLICATION REQUIREMENTS

Conference grant applications are electronically submitted using an application package that combines SF424 (R&R) and PHS398 components. Applications packages and instructions are provided with each FOA. Applicants must complete and submit a detailed categorical budget using the Research & Related Budget component; however, no indirect (F&A) costs may be requested. The appropriate NIH IC Conference Grant Contact (http://grants.nih.gov/grants/guide/contacts/parent_R13_U13.html) should be consulted for guidance regarding any IC-specific budget and project duration requirements. Application requirements and further information on NIH support for conferences and scientific meetings (R13 and U13) may be found on the NIH Web site at http://grants.nih.gov/grants/funding/r13/ or in applicable FOAs.

14.6 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

In addition to any applicable public policy requirements and objectives specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA, the following apply to NIH Conference Grants.

14.6.1 The United States Hotel and Motel Fire Safety Act of 1990

The Hotel and Motel Fire Safety Act of 1990 (PL101-391) was passed into law by Congress to save lives and protect property by promoting fire and life safety in hotels, motels and other places of public accommodation. PL101-391 states that federally funded meetings and conferences cannot be held in properties that do not comply with the law. PL101-391 is applicable to all places of public accommodation, and requires that such properties are equipped with:

- hard-wired, single-station smoke detectors in each guestroom in accordance with the National Fire Protection Association (NFPA) standard 72;
- an automatic sprinkler system, with a sprinkler head in each guest room in compliance with NFPA standards 13 or 13R. Properties three stories or lower in height are exempt from the sprinkler requirement.

The United States Fire Administration (USFA) is charged with carrying out FEMA's responsibilities with respect to the Hotel and Motel Fire Safety Act of 1990. In addition to compiling, maintaining and publishing the National Master List, USFA is also responsible for taking steps to encourage states to promote the use of automatic sprinkler systems and automatic smoke detection systems.

14.6.2 Guideline on the Inclusion of Women

Conference grant applicants address the appropriate representation of women, minorities, and persons with disabilities in the application. Appropriate representation of women, individuals who are members of racial and/or ethnic minority groups, people with disabilities, and other individuals who have been traditionally underrepresented in science must be included in all aspects of planning, organization, and

implementation of NIH-sponsored or -supported meetings. "Appropriate representation" is based on the availability of scientists from these groups known to be working in a particular field of biomedical or behavioral research. If appropriate representation is not apparent, NIH will not make an award until the applicant has submitted acceptable documentation of its compliance.

14.7 APPLICATION REVIEW

Applications for conference grants will be reviewed for programmatic relevance and for merit as described in The Peer Review Process in Part I and applicable FOA.

14.8 FUNDING

Grants or cooperative agreements may be used to provide conference support. A cooperative agreement may be awarded if the NIH awarding IC determines that it needs to have substantial involvement in the planning and conduct of a conference.

Grant funds may not be used to provide general support for international conferences held in the United States or Canada. Grant funds may be awarded to support only specific aspects of such conferences. An example would be a selected symposium, panel, or workshop, including the costs of planning and travel of U.S. participants.

Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference and post-conference follow-up, usually 1 year. A conference grant made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic may be awarded for up to a total of 5 years and will be funded annually, based on the availability of funds. Continued funding beyond the first year will be contingent on a report of satisfactory progress submitted in accordance with SNAP instructions. A change in conference focus requires NIH awarding IC prior approval.

14.9 ACKNOWLEDGMENT OF FUNDING SOURCE AND DISCLAIMER

When a conference is funded by an NIH grant or cooperative agreement, recipients must include the following statement on conference materials (including promotional materials, agenda, and internet sites):

> *"Funding for this conference was made possible (in part) by (Insert Grant/Cooperative Agreement #) from (insert name of NIH IC). The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the NIH; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government."*

Appropriate use of the NIH or HHS logo on conference materials is of particular importance. Neither logo should be displayed if it would cause confusion as to the source of the conference or give the false appearance of government endorsement. Accordingly, unless specifically authorized by the award, any use of the HHS and/or NIH logo requires prior approval. Unauthorized use of the HHS or NIH name or logo may result in imposition of civil monetary penalties (as provided in 42 CFR 1003).

14.10 ALLOWABLE AND UNALLOWABLE COSTS

The following highlights allowable and unallowable costs under conference grants. No costs other than those specified in this subsection as allowable, including any qualifications on their allowability, are permitted under conference grants.

14.10.1 Allowable Costs

In general, consistent with 45 CFR 75.432, conference hosts/sponsors must exercise discretion and judgment in ensuring that conference costs are appropriate, necessary and managed in a manner that minimizes costs to the Federal award.

Conference Services. Grant funds may be used for necessary recording of proceedings, simultaneous translation, and subsequent transcriptions.

Consultant Services. Grant funds may be used to pay consultant fees, including travel and supporting costs (per diem or, where applicable, subsistence).

Equipment Rental. Grant funds may be used for the rental of necessary equipment.

Federal Employees. See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter.

Meals. When meals are justified by the applicant as an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, as qualified under Travel below. However, direct charges for meals/food and beverages are unallowable charges to an NIH grant where the primary purpose is to support a scientific meeting/conference.

Publication Costs. When grant funds are awarded to pay for either the entire or partial cost of publication of proceedings or a book or pamphlet, allowable costs include special plates, charts, diagrams, printing, distribution, mailing, postage, and general handling, unless otherwise specified at the time the grant is awarded.

Registration Fees. Grant funds may not be used for registration fees paid by the recipient to other organizations on behalf of attendees. Grant funds may be used to help defray registration costs for some select conference attendees (for example, women, racial/ethnic minorities, persons with disabilities, other individuals who have been traditionally underrepresented in science, graduate students).

Salaries. In accordance with the policy of the recipient organization, grant funds may be used for all or part of the salaries of professional personnel, clerical assistants, editorial assistants, and other non-professional staff in proportion to the time or effort directly related to the conference.

Speakers Fees. Speakers' fees for services rendered are allowable.

Supplies. Grant funds may be used for the purchase of supplies for the conference if the supplies are received and used during the budget period.

Travel. Funds may be used for the travel of staff, speakers, participants, and attendees, if identified in the application and approved at the time of award. Travel expenses for employees of the recipient organization are governed by the recipient's travel policies, consistently applied regardless of the source of funds.

Any U.S. foreign travel restrictions that are in effect at the time of the award will be followed, such as

- limitations or restrictions on countries to which travel will be supported or
- budgetary or other limitations on availability of funds for foreign travel.

Proposed per diem or subsistence allowances must be reasonable and limited to the days of attendance at the conference plus the actual travel time to reach the conference location by the most direct route. Local mileage costs only may be paid for local participants. Where meals and/or lodgings are furnished without charge or at a nominal cost (e.g., as part of the registration fee), the proposed per diem or subsistence allowance must take this into consideration.

Transportation costs for attendees and participants at the conference may not exceed coach class fares. In all cases, U.S. flag carriers will be used where possible (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Travel in IIA).

In accordance with 45 CFR 75.474, temporary dependent care costs (as dependent is defined in 26 USC § 152) above and beyond regular dependent care that directly results from travel to conferences is allowable provided that:

1. The costs are a direct result of the individual's travel for the Federal award;
2. The costs are consistent with the non-Federal entity's documented travel policy for all entity travel; and
3. Are only temporary during the travel period.

Travel costs for dependents are unallowable, except for travel of duration of six months or more with prior approval of the HHS awarding agency. However, as indicated in 45 CFR 75.432, as needed, the costs of identifying, but not providing, locally available dependent-care resources are allowable.

14.10.2 Unallowable Costs

A&R. Not allowable.

Entertainment and Personal Expenses. Costs of amusement, diversion, social activities, ceremonials, and related incidental costs, such as bar charges, tips, personal telephone calls, and laundry charges of participants or guests, are unallowable. However, meals may be allowable as provided under Allowable Costs—Meals above.

Equipment Purchase. Grant funds may not be used for the purchase of equipment.

F&A Costs. Not allowable.

Honoraria. Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration may not be paid from grant funds.

Local Participants' Expenses. With the exception of local mileage as indicated under Allowable Costs—Travel above, grant funds may not be used to pay per diem or expenses for local participants in the conference.

Meals. Direct charges for meals/food and beverages are unallowable charges to an NIH grant where the primary purpose is to support a scientific meeting/conference.

Membership Dues. Not allowable.

Research Patient Care. Not allowable.

Visas and Passports. Not Allowable.

14.11 ADMINISTRATIVE REQUIREMENTS

14.11.1 Intellectual Property: Publications, Copyright, and Public Disclosure

If the recipient publishes material developed in whole or in part with NIH funds, the material may be distributed free of charge. If the recipient organization charges for the material, the sales proceeds are con-

sidered program income, and must be accounted for as specified in the NoA and reported on the FFR (see Administrative Requirements—Reporting and Record Retention in this chapter).

Unless otherwise provided in the terms and conditions of the award, the recipient is free to arrange for copyright of any publication resulting from an NIH-supported conference. However, any such copyrighted publication shall be subject to a nonexclusive, irrevocable, royalty-free license to the Federal government to reproduce, translate, publish, and dispose of the material and to authorize others to use the work for government purposes. Copyright does not extend to any materials prepared by Federal employees as part of their official duties.

The recipient is cautioned to remind conference participants that any presentation or discussion constitutes public disclosure of information. Any such public disclosure could seriously impact the degree to which any intellectual property rights could be protected.

14.11.2 Reporting and Record Retention

Upon completion or termination of a grant in support of a conference, recipients are responsible for submitting the final RPPR and the final FFR in accordance with the Closeout provisions described in Administrative Requirements—Closeout in IIA. Submission details of the final FFR and Final Progress Report are described in respective subsections of Closeout.

14.11.2.1 Progress/Final Report

For single conferences, a final report of the conference must be submitted electronically through the eRA Commons, or by paper submission to the NIH DCGP within 120 days after the end of the project period. The report must include the following:

- Grant number
- Title, date, and place of the conference
- Name(s) of the person(s) shown on the application as the conference director or PD/PI(s)
- Name of the organization that conducted the conference
- A list of the individuals, and their organizational affiliations, who participated as speakers or discussants in the formally planned sessions of the meeting
- A summary of topics discussed/conclusions.

Under multiple-year awards, i.e., ones that support more than one conference, NIH requires an annual progress report that contains a description of specific plans for the next budget period, in similar detail and format as for a single conference. The annual progress report must be submitted at least 6 months before the next scheduled conference. The final progress report should be submitted within 120 days after the end of the project period.

With the approval of the NIH awarding IC, copies of proceedings or publications resulting from the conference(s) may be substituted for the final report, provided that they contain the information specified for inclusion in the final report.

14.11.2.2 Federal Financial Report

Electronic submission through the eRA Commons of the final FFR is required from the recipient within 120 days after the end of the project period. Records of expenditures and any program income generated must be maintained in accordance with the provisions of 45 CFR 75.341 (see Administrative Requirements—Monitoring—Record Retention and Access in IIA).

15 CONSORTIUM AGREEMENTS

15.1 GENERAL

This chapter includes the requirements for an applicant/recipient under consortium agreements in which the recipient collaborates with one or more other organizations in carrying out the grant-supported research. The recipient, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance of the project, the appropriate expenditure of grant funds by all parties, applicable reporting requirements, and all other obligations of the recipient, as specified in the NIHGPS. In general, the requirements that apply to the recipient, including the intellectual property requirements in IIA and the program income requirements of the award, also apply to consortium participant(s). Exceptions are noted in this chapter. The recipient is responsible for including the applicable requirements of the NIHGPS in its agreements with collaborating organizations (see Written Agreement in this chapter).

Under grants that include consortium agreements:

- The award will be made to a single recipient with a single PD/PI even though one or more organizations other than the recipient will carry out portions of the planned programmatic activity. When the multiple PD/PI model is used, all PD/PIs are listed on the award regardless of organization affiliation, with the Contact PD/PI so noted.
- The prime recipient must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. This includes being able to provide appropriate oversight of all scientific, programmatic, financial, and administrative matters related to the grant.

Applicants are expected to detail their proposed collaborations as part of the grant application. If the application is approved as submitted, no further approval is required unless, during performance, the recipient plans to undertake additional or alternative collaborations that would constitute a change in the scope of the approved project (see Administrative Requirements—Changes in Project and Budget in IIA). Applicants for STTR grants should follow the specific requirements for research collaboration established for that program (see Grants to For-Profit Organizations chapter).

The following information must be provided to NIH as part of a competing application that proposes consortium arrangements:

- Include all proposed performance sites; those of the applicant organization and the consortium participant(s); and
- Non-modular grant applications must include complete detailed budgets for each consortium participant. Modular grant applications must include an estimate of consortium total costs (direct costs plus F&A costs) each year as part of the budget narrative justification (see Modular Applications and Awards chapter).

For the consortium site, it is appropriate and expected that someone will be designated as the consortium lead investigator responsible for ensuring proper conduct of the project or program at the consortium site. However, this individual must only be assigned the PD/PI role when a multiple PD/PI application is being submitted. Otherwise, this individual should be assigned some other project role in the Senior/Key Personnel section of the application.

The signature (or electronic equivalent) of the AOR/SO on the application signifies that the applicant organization and all proposed consortium participants understand and agree with the following statement:

> "The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy."

NIH may request additional information before award and may place a special condition(s) on the award.

15.2 ADMINISTRATIVE AND OTHER REQUIREMENTS

The following highlights several areas within the consortium relationship that the recipient needs to address with consortium organizations receiving subawards under a grant to ensure compliance with NIH requirements. The requirement for a written agreement addressing these and other areas is specified in this section.

Note that most of these requirements only apply to a recipient's consortium relationships with subawardees. When the relationship is with a vendor that is providing routine goods and services within normal business operations that are ancillary to the operation of the research program, the public policy requirements listed below do not apply. The vendor must also be providing similar goods and services to many different purchasers and provide them in a competitive environment.

15.2.1 Written Agreement

The recipient must enter into a formal written agreement with each consortium participant that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. At a minimum, this agreement must include the following:

- Identification of the individual who will serve as the consortium lead investigator and other individuals responsible for the research activity at each consortium participant along with their roles and responsibilities.
- When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role including the requirement for the prime institution to secure and retain all PD/PI signatures for all applications, progress reports, and post-award prior approval requests. Further, such signatures must be made available to NIH or other authorized DHHS or Federal officials upon request. See Multiple Program Director/Principal Investigator Applications and Awards for additional information.
- Procedures for directing and monitoring the research effort.
- Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures of grant funds at each organization and timing of applicable reporting requirements. This includes provisions on access to core facilities and resources and whether access will be provided as a fee-for-service.

- If different from those of the recipient, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits (the policies of the consortium participant may be used as long as they meet NIH requirements).
- Terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution.
- If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the written agreement shall specify time period(s) for the subrecipient to report all identified Financial Conflicts of Interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by the regulation.
- Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's Financial Conflict of Interest policy, the written agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under the 2011 revised FCOI regulation.
- A provision addressing ownership and disposition of data produced under the consortium agreement. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.
- A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources in IIA), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.
- Expectations for authorship and co-authorship on publications.
- Provisions regarding property (other than intellectual property), program income, publications, reporting, and audit necessary for the recipient to fulfill its obligations to NIH.
- Provisions regarding compliance with requirements for a DUNS number and subrecipient reporting under FFATA (see Recipient Reporting of Subrecipient Data and Executive Compensation Information for FFATA). Note, the recipient must provide the FAIN to all subrecipients to aid in this requirement.
- Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA).

15.2.2 Public Policy Requirements and Objectives

The recipient is responsible for determining whether a consortium participant, including foreign consortium participants under domestic or foreign grants, has filed assurances with NIH that would cover its activities within the consortium and, if not, for ensuring that any required assurances or certifications are submitted to NIH. See Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA for the full statement of these requirements and their applicability to consortium participants.

The recipient is responsible for ensuring that all sites engaged in human subjects research have an appropriate OHRP-approved assurance and IRB approval of the research consistent with 45 CFR 46 (see *Guidance on Engagement of Institutions in Human Subjects Research* http://www.hhs.gov/ohrp/policy/engage08.html), and for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget in IIA). The list of organizations with approved assurances is available at the OHRP Web site: http://www.hhs.gov/ohrp/.

The animal welfare requirements that apply to recipients also apply to consortium participants and subprojects. The primary recipient is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the recipient and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted. If the prime recipient does not have an Assurance and the animal work will be conducted at an institution with an Assurance, the recipient must obtain an Inter-institutional Assurance from OLAW. Under the Inter-institutional Assurance, the recipient and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance. The recipient is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements in IIA). The list of organizations with approved assurances is available at the OLAW Web site (domestic institutions: http://grants.nih.gov/grants/olaw/assurance/300index.htm, and foreign organizations: http://grants.nih.gov/grants/olaw/assurance/500index.htm).

15.2.3 Allowable and Unallowable Costs

The recipient must include in consortium agreements the applicable government-wide cost principles and NIH cost policies described in the Cost Considerations chapter in IIA and, as appropriate, requirements related to allowable and unallowable costs in other sections of IIB. For example, a university recipient must flow down the cost principles of 45 CFR 75, Appendix IX to a consortium participant that is a hospital. This includes the application of F&A rates in determining consortium budgets and the reimbursement of costs.

Recipients must use an approved federally recognized indirect cost rate negotiated between the subrecipient and the Federal Government. If no such rate exists, the recipient must use either a rate it has negotiated with the subrecipient, including commercial organizations (except for the SBIR/STTR program, as described in 18.5.4.3,or a de minimis indirect cost rate of 10 percent of modified total direct costs (MTDC) if the subrecipient has never received a negotiated indirect cost rate from the Federal Government. Recipients are reminded that F&A reimbursement rates are restricted for certain classes of awards. If the consortium participant is a Federal organization, direct costs will be limited and no F&A will be provided.. (See Reimbursement of Facilities and Administrative Costs.) For more information on

allowable costs to Federal organizations, see Grants to Federal Institutions and Payments to Federal Employees Under Grants.

15.2.4 Approval Authorities

The recipient is responsible for obtaining NIH awarding IC approval for any actions to be undertaken by consortium participants that require prior approval. Recipients may establish requirements for review of consortium participants' activities consistent with those requirements and with any authorities provided to the recipient; however, a recipient may not provide any authority to a consortium participant that the recipient has not been provided under its NIH award.

Regardless of whether there is a change in scope, in all cases, if a recipient (or consortium participant) proposes the transfer of work to a foreign site, awarding IC prior approval is required.

15.2.5 Tangible Personal Property

15.2.5.1 Exempt Property

If the recipient provides exempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered exempt if acquired by the recipient, the recipient may vest title in the consortium participant upon transfer or purchase or may reserve the right to do so at a later time. The recipient also may establish its own use, disposition, and accountability requirements, provided they are consistent with the NIH right to transfer title (see Administrative Requirements—Management Systems and Procedures—Property Management System Standards—Equipment and Supplies in IIA).

15.2.5.2 Nonexempt Property

If the recipient provides nonexempt property to a consortium participant or authorizes a consortium participant to purchase property that would be considered nonexempt if purchased by the recipient, title to such property must remain with the recipient or be vested in the recipient upon acquisition of the property. The recipient may establish use, accountability, and disposition requirements for the property, provided they are consistent with, and do not impair, the recipient's ability to comply with the requirements of 45 CFR 75.318, as appropriate.

15.2.6 Audit

The recipient must require consortium participants to comply with the requirements of 45 CFR 75 Subpart F or 45 CFR Parts 75.501(h) through 75.501(k), as applicable, for audit of NIH grant funds expended by consortium participants. A consortium participant also may be a direct NIH recipient or contractor or may be receiving funds only under the consortium agreement. Regardless, if a non-profit consortium participant meets the 45 CFR 75.501 threshold criterion of aggregate annual expenditures of $750,000 or more under applicable Federal awards, the recipient must receive a copy of that organization's 45 CFR 75.501 audit and take appropriate action based on any findings that relate to the consortium agreement. If a consortium participant will not reach that expenditure threshold, the recipient is responsible for monitoring the organization's activities to ensure compliance with NIH requirements. The recipient may not require a consortium participant to have an audit and charge the audit costs to NIH grant funds unless required or authorized by 45 CFR 75.501(h) through 75.501(k).

16 GRANTS TO FOREIGN ORGANIZATIONS, INTERNATIONAL ORGANIZATIONS, AND DOMESTIC GRANTS WITH FOREIGN COMPONENTS

16.1 GENERAL

Most of the policies contained in IIA apply to NIH grants made to foreign organizations and international organizations (hereafter "foreign grants"), including the requirements of 45 CFR 75 and the cost principles incorporated by reference in those regulations. If an applicant/recipient would be unable to comply with these requirements, the AOR should contact the GMO. Specific exceptions and modifications of IIA requirements for foreign grants, and highlights of other policies, are set forth in this chapter. This chapter also includes policies that apply to domestic grants with a foreign component.

16.2 ELIGIBILITY

In general, foreign organizations and international organizations, including public or private non-profit or for-profit organizations, are eligible to apply for research project grants, but are not eligible to submit a modular grant application. International organizations are treated as foreign organizations for the purpose of eligibility. If the Funding Opportunity Announcement (FOA) allows foreign organizations to apply, international organizations may apply. If the FOA does not allow foreign organizations to apply, international organizations may not apply. Foreign organizations and international organizations are not eligible to apply for Kirschstein-NRSA institutional research training grants, program project grants, center grants, resource grants, SBIR/STTR grants, or construction grants. However, some activity codes, such as program project grants (P01), may support projects awarded to a domestic institution with a foreign component. For purposes of this policy, a foreign component is defined as performance of any significant element or segment of the project outside the United States either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include the following:

- The involvement of human subjects or vertebrate animals at a foreign site.
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities.
- Any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.

Examples of other grant-related activities that may be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site; or
- receipt of financial support or resources from a foreign entity.

Foreign travel exclusively for consultation is not considered a foreign component.

See Support of Scientific Meetings (Conference Grants) chapter for NIH policy on support of international conferences.

Grants may not be made to individuals in a foreign location (i.e., outside of the United States and its territorial possessions). Occasionally, a Kirschstein-NRSA individual fellowship award is made to a U.S. citizen or a non-citizen national to study in a foreign organization. (A "non-citizen national" is a person

who although not a citizen of the United States owes permanent allegiance to the United States, such as a resident of American Samoa.) See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships for additional information.

16.3 APPLICATION REVIEW

Applications from foreign organizations or international organizations will be evaluated and scored during the initial review process using the standard review criteria. In addition, the following will be assessed as part of the review process and award decision:

- Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.
- Whether the proposed project has specific relevance to the mission and objectives of the IC and has the potential for significantly advancing the health sciences in the United States.

Note, these additional criteria are not applied to applications from domestic organizations with foreign components or applications in response to an FOA requesting applications from foreign organizations only.

Research grant applications from foreign organizations or international organizations may not be funded unless approved by the IC National Advisory Council or Board.

16.4 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

A complete listing of public policy requirements and objectives and their applicability to foreign grants is included in Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA. Several of the public policy requirements and objectives are highlighted below:

- ***Research Misconduct.*** The research misconduct requirements included in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Research Misconduct apply to foreign grants.
- ***Animal Welfare.*** The animal welfare requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Animal Welfare apply to foreign grants, regardless of the requirements of the home country.
- ***Human Subjects.*** The human subjects requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Human Subjects Protections, including the requirement for an assurance pursuant to 45 CFR 46, apply to foreign grants and foreign consortium participants under domestic or foreign grants.
- ***Financial Conflict of Interest.*** The financial conflict of interest requirements contained in Public Policy Requirements, Objectives, and Other Appropriation Mandates— Financial Conflict of Interest apply to foreign grants.
- ***Inclusiveness in Research Design.*** Foreign grants are subject to the requirements for inclusion of women, minorities, and children in research design as specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Inclusion of Children as Subjects in Clinical Research and Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender and Racial and Ethnic Participation.
- ***Civil Rights.*** The civil rights requirements specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Civil Rights do not apply to foreign grants.

- ***Lobbying.*** The requirements of Public Policy Requirements, Objectives, and Other Appropriation Mandates—Lobbying Prohibition, including disclosure reporting, apply to foreign grants.
- ***Debt.*** Foreign applicants are required to provide a certification of nondelinquency on debts owed to the United States as specified in Public Policy Requirements, Objectives, and Other Appropriation Mandates—Nondelinquency on Federal Debt.
- ***Debarment and Suspension.*** Applicants/recipients that are foreign governments or governmental entities, public international organizations, or foreign-government-owned or -controlled (in whole or in part) entities are not subject to the debarment or suspension certification requirement or to debarment or suspension under 2 CFR 376. All other foreign organizations and international organizations are subject to these requirements. See Public Policy Requirements, Objectives, and Other Appropriation Mandates—Debarment and Suspension for additional information on this requirement.
- ***Drug-Free Workplace.*** Foreign applicants and recipients may be exempted from the drug-free workplace requirements of 2 CFR 182 based on a documented finding by the NIH awarding IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government. See Public Policy Requirements, Objectives, and Other Appropriation Mandates—Drug-Free Workplace for additional information on this requirement.

16.5 FUNDING AND PAYMENT

The application budget, requests for funds, and financial reports (see Reporting and Record Retention in this chapter) must be stated in U.S. dollars. Cost increases for fluctuations in exchange rates are allowable costs subject to the availability of funding, as determined by the awarding IC. Prior approval of exchange rate fluctuations is required only when the charge results in the need of additional Federal funding, or the increased costs result in the need to significantly reduce the scope of the project. The non-Federal entity is required to make reviews of local currency gains to determine the need for additional federal funding before the expiration date of the Federal award. Subsequent adjustments for currency increases may be allowable only when the non-Federal entity provides the awarding IC with adequate source documentation from a commonly used source in effect at the time the expense was made, and to the extent that sufficient Federal funds are available.

Awards to foreign organizations and international organizations issued prior to October 1, 2012 are not paid through PMS. These grants normally will be paid by U.S. Treasury check by OFM, NIH on a predetermined quarterly advance basis, usually in four equal installments. If the amount advanced to an organization based on the predetermined quarterly advance is insufficient to meet the grant's cash requirements, the recipient must make a written request to the GMO for any additional funds needed. All payments will be in U.S. dollars. Foreign recipients are strongly encouraged to use U.S. banks to ensure that payments arrive on time. In special circumstances, foreign recipients may be eligible to receive funds by electronic deposit or wire transfer.

Awards to foreign organizations and international organizations issued after October 1, 2012, are paid through PMS. PMS is operated by the PSC in accordance with Department of the Treasury and OMB requirements as implemented by 45 CFR 75.305. These requirements are intended to minimize the time elapsing between the transfer of funds from the U.S. Federal government and disbursed by the recipient. Therefore, although the grant may be financed by advance payments, the intent is that recipients draw funds on an as-needed basis – specifically, no more than 3 days before the funds are needed.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds should be directed to PSC/PMS (see Part III).

The funding and payment information outlined in this subsection applies when the foreign organization is the recipient organization. When a foreign component participates in a consortium arrangement, the funding and payment information should be reflected in the formal written agreement. Recipients are required to maintain grant funds in an interest bearing account; however, interest earned in excess of $500 per year in the aggregate on advances of Federal funds must be returned in U.S. dollars by reimbursement check to OFM, and reflected on the annual FFR.

For more information on payment, see Payment Chapter.

Any questions regarding payments to foreign recipients may be addressed to the Grants Management Specialist noted on the NoA or PSC (see Part III for address and telephone and fax numbers).

16.6 ALLOWABLE AND UNALLOWABLE COSTS

The cost principles that apply to foreign organizations depend on the type of organization, i.e., for a university, 45 CFR 75, Subpart E—Cost Principles would apply, with the following exceptions:

- ***Major A&R (>$500,000).*** Unallowable under foreign grants and domestic grants with foreign components.
- ***Minor A&R (<$500,000).*** Generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations. Minor A&R costs may be included and justified in any detailed budget of a competing application. Further, rebudgeting of active grants to accommodate minor A&R is also allowable; however, this does require NIH prior approval of the GMO. Additional information may be required (see Administrative Requirements—Alteration and Renovation Projects under Non-construction Grants in IIB).
- ***F&A Costs.*** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. Some examples of NIH compliance requirements are the protection of human subjects (including the required education in the protection of human research participants), animal welfare, invention reporting, other post-award reporting requirements, financial conflict of interest and research misconduct. Note, these are just a few representative examples of compliance requirement; this list is not all inclusive. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Therefore, these expenses may not be requested as a direct cost; however, equipment is an allowable direct cost. *Other items normally treated as F&A costs (e.g., rent) may be requested as direct costs and will be evaluated by NIH for allowability.*
- ***Patient Care Costs.*** Patient care costs are provided only in exceptional circumstances.

16.7 ADMINISTRATIVE REQUIREMENTS

For SNAP awards to foreign organizations issued after October 1, 2012 recipients are required to submit FFR expenditure data at the end of the competitive segment only. NIH staff now monitors financial aspects of these grants through subaccounts in PMS. For all non-SNAP awards to foreign organizations and awards to foreign organizations issued prior to October 1, 2012 recipients are required to submit FFR expenditure data annually.

16.7.1 Changes in Project and Budget

Foreign grants are subject to the NIH Standard Terms of award, see Administrative Requirements—NIH Standard Terms of Award in IIA. Inclusion in SNAP is at the discretion of the NIH awarding IC and will be specified in the NoA.

16.7.2 Change in Scope

A change in the performance site within a foreign country or the addition of a performance site in a country other than that specified in the approved application requires NIH awarding IC prior approval. The transfer of work by a domestic recipient to a foreign component also requires awarding IC prior approval.

16.7.3 Change of Recipient Organization

A change of recipient organization that involves the transfer of a grant to or between foreign organizations or international organizations requires approval of the NIH awarding IC and its National Advisory Council or Board. NIH awarding IC approval also is required for the transfer of a grant from a foreign organization to a domestic organization. Recipients adding or changing a foreign performance site within a funded grant award must obtain approval from the GMO before work can be performed at the added or changed foreign site.

16.7.4 Audit

Foreign recipients are subject to the same audit requirements as for-profit organizations (specified in 45 CFR 75.501(h) through 75.501(k) and in the Grants to For-Profit Organizations chapter).

16.7.5 Reporting and Record Retention

For awards issued with Federal award dates prior to October 1, 2012, whether or not they are under SNAP, foreign recipients submit annual FFRs. For SNAP awards issued with Federal award date after October 1, 2012, foreign recipients submit FFR expenditure data at the end of the competitive segment only. The requirement for quarterly cash reporting does not apply to foreign recipients. Awards issued with Federal award dates after October 1, 2012 are administered in PMS using subaccounts and payments will be specific to each grant at the time the recipient draws funds.

The FFR expenditure data must be submitted electronically through the eRA Commons and must be submitted in U.S. dollars and in English. For awards issued with Federal award date prior to October 1, 2012, the currency rate in effect at the time the FFR is prepared should be used in preparing the report. For awards issued with Federal award dates after October 1, 2012, the currency rate in effect at the time the funds are drawn down from PMS should be used in preparing the FFR. For the final FFR, NIH requires recipients to reimburse the U.S. government for funds not spent. Mail reimbursement checks in U.S. dollars to the OFM.

All foreign recipients, contractors, consortium participants, and/or subcontractors must comply with Bayh-Dole invention reporting requirements. Regarding intellectual property, foreign recipients have the same rights and obligations regarding invention ownership as U.S. recipients. (See http://www.iedison.gov.)

Record retention requirements are the same as those for domestic recipients.

17 GRANTS TO FEDERAL INSTITUTIONS AND PAYMENTS TO FEDERAL EMPLOYEES UNDER GRANTS

17.1 GENERAL

NIH may award grants to Federal entities. Although the activity under these grants will take place in a research environment, certain terms and conditions vary from those included in IIA due to the recipient's status as a Federal institution. This chapter specifies those differences as well as differences in treatment among different Federal institutions. This chapter does not apply to Federally Funded Research and Development Centers (also known as Government Owned Contract Operated facilities) since the recipient institution is the institution operating the facility. In addition, this chapter addresses the policies that apply to payments to (or on behalf of) Federal employees under grants, including grants awarded to organizations other than Federal institutions.

17.2 ELIGIBILITY

In general, Federal institutions are eligible to apply for NIH grants, including research project grants. Specific eligibility will be stated in each FOA. Federal institutions also must meet the eligibility requirements of the grant program from which support is sought. PHS organizational segments, other than IHS hospitals, may receive NIH grant support under exceptional circumstances only. Such circumstances may include situations where a project cannot be supported within the mission of the applicant PHS agency or organizational segment, the activity cannot be performed elsewhere, or its nonpursuit would have an adverse impact or potentially important effect on the NIH mission, and NIH determines a grant is the appropriate means of carrying out the activity. However, NIH may not award a grant to an NIH component.

Although the performance site may be at a level lower than the agency or department level of the Federal institution, when an award is made to an eligible Federal institution, the Federal agency or department will be the recipient of record and must assume responsibility for the project. A Federal institution also must ensure that its own authorizing legislation will allow it to receive NIH grants and to be able to comply with the award terms and conditions.

A document that assures both the assumption of responsibility and authority to receive a grant must accompany each new and competing continuation application. The assurance must be signed by the head of the responsible Federal department or independent agency or a designee who reports directly to the department or agency head. (In the case of the DoD, the Departments of the Army, Navy, and Air Force are considered the Federal department, and their Secretaries the responsible Department head.) This assurance is in addition to those made by the AOR's signature on the face page of the application. The assurance requirement does not apply to VAMCs, Bureau of Prisons' (Department of Justice) hospitals, IHS hospitals, or other PHS organizational segments.

17.3 VA-UNIVERSITY AFFILIATIONS

Investigators with joint appointments at a VAMC (VA hospital) and an affiliated university must have a valid MOU that specifies (at both the university and the VAMC) the title of the investigator's appointment, distribution of compensation, the responsibilities of the proposed investigator, and the percentage of effort available for research at each institution. The MOU must be signed by the appropriate officials of the recipient and the VAMC, and must be updated with each significant change of the investigator's

responsibilities or distribution of effort and, without a significant change, not less than annually. The joint VA/university appointment of the investigator constitutes 100 percent of his or her total professional responsibilities. However, NIH will recognize such a joint appointment only when a university and an affiliated VA hospital are the parties involved.

A grant application from a university may request the university's share of an investigator's salary in proportion to the effort devoted to the research project. The institutional base salary as contained in the individual's university appointment determines the base for computing that request.

The signature of the AOR of the submitting university on an application to NIH that includes such an arrangement certifies that

- the individual whose salary is included in the application serves under a joint appointment documented in a formal MOU between the university and the VA, and
- there is no possibility of dual compensation for the same work or of an actual or apparent conflict of interest.

Under the above-described arrangement, there is no involvement of a VA-affiliated non-profit research corporation, which is eligible to apply for and receive NIH grants in its own right as a non-profit organization. The limitations on the payment of Federal salaries apply (see Allowable and Unallowable Costs in this chapter).

17.4 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

The requirements concerning disclosure of financial conflicts of interest (see Public Policy Requirements, Objectives, and Other Appropriation Mandates—Financial Conflict of Interest in IIA) do not apply to Federal employees and/or Federal agencies. All other Public Policy Requirements described in IIA apply to Federal recipients.

17.5 PAYMENT

The NIH Office of Financial Management (OFM) will pay grants and cooperative agreements to Federal departments and agencies through the Interagency Payment and Collection method (IPAC). Upon receipt of an NIH award, in order to be reimbursed, Federal recipient institutions may send IPACs to NIH Agency Location Code (ALC) 75080031 for payment.

17.6 ALLOWABLE AND UNALLOWABLE COSTS

Allowable and unallowable costs under grants to Federal institutions will be determined by the established policies of the institution, consistently applied to both its own activities and to grant-supported activities, and the requirements of this subsection. In the absence of a governing organizational policy, the cost principles in 45 CFR 75, Subpart E will apply.

Salaries. See Federal (U.S. Government) Employees below.

Institutional Allowances Under Kirschstein-NRSA Individual Fellowships. Institutional allowances may be requested by Federal institutions sponsoring a predoctoral or postdoctoral fellow.

F&A Costs. F&A costs will not be provided to Federal institutions.

Federal (U.S. Government) Employees. Whether or not costs will be charged to the grant, when a Federal employee will be involved in an NIH grant-supported activity in any capacity other than as an employee working on a grant to a Federal institution, or a study subject, special conditions apply as provided in this subsection. The limitations in this subsection do not apply to individuals that are

classified as special government employees because of service on advisory groups or as a result of a formal consulting arrangement with a Federal agency. (See the HHS Standards of Conduct at 45 CFR 73, Subpart J for additional guidance.) The Federal employee should consult with their agency ethics officials to determine whether outside activity approval is required by their employing agency.

Only four types of costs—consultant fees, subject costs, salary or fringe benefits, and travel costs—can be charged to NIH grants on behalf of Federal employees, whether by a recipient or a consortium participant, and under the conditions specified only. Applicants/recipients should advise any Federal employee with whom these types of arrangements may be made to consult with their employing agency concerning their ability to participate and to meet the required conditions for payment. The applicant organization must submit, as part of the grant application, any letters or documentation specified below, and that documentation must be deemed acceptable by the GMO before the Federal employee's involvement in the project.

Consultant Fees. Consultant fees are allowable only for medical personnel of the Uniformed Services of the United States (excluding PHS Commissioned Officers) and when all of the following conditions are present:

- The employees are providing the kind and extent of medical services approved in the grant award.
- Adequate numbers of qualified civilian personnel are not available to provide these services, and eligible Federal medical personnel are hired only in addition to those qualified civilian medical personnel, if any, who are available.
- The applicant organization provides prior written authorization from the proposed consultant's commanding officer that he or she is authorized to work on the grant-supported activity during non-duty hours or while on authorized leave, and can be paid for his or her efforts.

Outpatient or Subject Costs. These costs are allowable when the federal employee is an outpatient or subject under study in connection with grant-supported activities.

Salary or Fringe Benefits. In most circumstances no salary or fringe benefit payments may be made from NIH grant funds to support Federal employees. While the level of effort required for the research project must be allowed by the employing agency as part of the individuals' official duties, salary and fringe benefit costs associated with an individual participating in an official capacity as a career, career-conditional, or other Federal employees (civilian or uniformed services) are not allowable. Salary and fringe benefits payments may only be made when prior approval is obtained from an authorized official of the employee's agency and the employee is one of the following:

- A temporary employee specifically hired to assist in the performance of an NIH grant.
- A PHS Commissioned Officer or a civil service employee carrying out duties for which specific statutory authorization exists permitting direct Federal assistance in lieu of cash under the grant, or where the government is reimbursed for services rendered subject to restrictions applicable to such personnel, including the applicable Federal standards of conduct (for HHS, 45 CFR 73).

- A PHS Commissioned Officer on LWOP if the
  - recipient has obtained written prior approval from the NIH awarding IC;
  - total amount of salary paid from NIH grant funds is proportional to the time devoted to the project and does not exceed the total annual amount of pay and allowances the individual would have received if not in LWOP status; and
  - parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.
- A civil service employee participating in a grant to a non-Federal organization and all of the following conditions are met:
  - The individual is participating as part of an approved IPA assignment in a role other than as PD/PI. IPA assignments generally do not exceed 2 years and may not exceed 4 years of continuous duration (5 U.S.C. 3372). Based on this statutory time restriction, the involvement of the civil service employee should be limited in scope. Therefore, the proposed PD/PI for an NIH grant may not be participating through an IPA. On a case-by-case basis, the NIH awarding IC may determine that certain other senior/key personnel on the project are sufficiently critical to its long-term success that participation through an IPA is not appropriate. Note, a Federal agency may not send or receive on assignment an employee who has served under the mobility authority for 4 continuous years without at least a 12-month return to duty with the organization from which originally assigned (5 CFR 334).
  - Before making any payment from NIH grant funds to such an employee, the recipient must certify that the employee is on an IPA assignment and must provide adequate documentation, as determined by NIH, of the IPA assignment and information about its nature and duration.
  - The level of effort required for the research project must be allowed by the employing agency as part of the individual's official duties. Salary payments from NIH grant funds must be proportional to the time an individual devotes to the grant-supported project. The total salary support may not exceed the normal level of compensation from Federal salary if the individual were not participating in the grant.
  - The parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.
- A part-time VA employee at VANPCs for which NIH grant funds are used to pay the differential between the individual's VA part-time salary and the salary level for a full-time VANPC commitment in proportion to the level of effort devoted to the project. Compensation must be in accordance with the established policies and salary structure of the VANPC and the total number of VA and VANPC hours should not exceed a full time position. Therefore, if the PD/PI has a part-time appointment with the VANPC, an appropriate portion of the individual's salary that would otherwise be supported by the non-profit VANPC may be charged to the NIH grant. The work paid for by the VANPC must not be for the same project paid for by VA time for VA salary in accordance with the VA policy set forth in the VHA Handbook 1200.17.

Travel Costs. Travel costs are allowable if the employee is

- working under a grant to a Federal institution;
- performing allowable reimbursable services as specified under Salary or Fringe Benefits immediately above; or
- attending an NIH grant-supported conference
    - during non-duty hours,
    - while in a preexisting LWOP status or one that continues beyond the conference, or
    - while on detail to a State or local government, Institution of Higher Education (IHE), or other non-profit organization.

Such payments must be made in accordance with established organizational policy and consistently applied regardless of the source of funds, and the parties concerned must take reasonable steps to ensure that there is no actual or apparent conflict of interest.

17.7 ADMINISTRATIVE REQUIREMENTS

17.7.1 Equipment Accountability

NIH will consider all nonexpendable personal property acquired under a grant awarded to a Federal institution as exempt (see 45 CFR 75.319) for purposes of determining the accountability requirements of 45 CFR 75.320. However, NIH has the right to require transfer of equipment, including title, to NIH or an eligible third party named by the NIH awarding IC under the conditions specified in 45 CFR 75.320.

17.7.2 Procurement Requirements

Procurement under grants to Federal institutions is governed by the FAR and the recipient agency's FAR supplement.

17.7.3 Intellectual Property

Inventions resulting from grants supporting the activities of Federal employees under grants to Federal institutions must be reported simultaneously to NIH and to the employing agency under the terms of EO 10096, as amended, and are subject to the government assignment of rights in invention of government employee requirements of 37 CFR 401. (See http://iEdison.gov for reporting requirements.) Any resulting patent applications and patents must identify the NIH award, consistent with the language of 37 CFR 401.14(f)(4). In cases where the VA is involved with the invention but is not the grant recipient, and the recipient institution chooses not to elect title or pursue practical application of an invention, the recipient must note VA's involvement on its notice to NIH and provide a courtesy copy of the NIH notification to the appropriate VA office. NIH will notify the recipient and the VA whether NIH has an interest in taking title and/or continuing the pursuit of practical application of the invention.

17.7.4 Reporting Requirements

Federal institutions must electronically submit annual expenditure FFRs regardless of whether the award is subject to SNAP. Since these grants are paid directly by OFM, NIH rather than through PMS, Federal recipients are not required to complete the Federal cash transactions section of the Federal Financial Report (FFR).

18 GRANTS TO FOR-PROFIT ORGANIZATIONS

18.1 GENERAL

Some of the terms and conditions for grants to for-profit (commercial) organizations vary from the standard terms and conditions included in IIA. In addition, the terms and conditions of the SBIR and STTR programs vary from those otherwise applicable to for-profit organizations. This chapter addresses separately the policies applicable to for-profit organizations generally, and those that apply to SBIR and STTR awards specifically. It also highlights several policies in IIA that apply equally to for-profit and non-profit recipients. If an exception is not stated below or in the NoA, the terms and conditions specified in IIA apply, including requirements for the protection of human subjects and animal welfare.

18.2 ELIGIBILITY

For-profit organizations are eligible to apply under all NIH programs and support mechanisms unless specifically excluded by statute.

18.3 ALLOWABLE AND UNALLOWABLE COSTS

18.3.1 Cost Principles

There are no cost principles specifically applicable to grants to for-profit organizations. Therefore, the cost principles for commercial organizations set forth in the FAR (48 CFR 31.2) generally are used to determine allowable costs under NIH grants to for-profit organizations. As provided in those costs principles, allowable travel costs may not exceed those established by the FTR (available on-line at http://gsa.gov/portal/content/104790). The cost principles in 45 CFR 75, Appendix IX, Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals, are used to determine allowable costs under NIH grants to proprietary hospitals.

18.3.2 Independent Research and Development Costs

As provided in 45 CFR 75.476, NIH does not allow for-profit organizations to be reimbursed for IR&D (self-sponsored) costs.

18.3.3 Facilities and Administrative Costs (Indirect Costs)

F&A costs are allowable under awards to for-profit organizations.

18.3.4 Profit or Fee

Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a for-profit organization, whether as a recipient or as a consortium participant. A profit or fee under a grant is not a cost, but is an amount in excess of actual allowable direct and F&A costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an NIH grant providing routine goods or services to the recipient.

18.4 ADMINISTRATIVE REQUIREMENTS

For-profit organizations generally are subject to the same administrative requirements as non-profit organizations, including those relating to personal property title and management. Exceptions to or

elaboration of those requirements for for-profit organizations are indicated below.

18.4.1 Equipment Accountability

For-profit recipients of NIH grants are nonexempt and subject to the requirements in 45 CFR 75.320, as well as the conditions set forth in Administrative Requirements—Management Systems and Procedures—Property Management System Standards and Administrative Requirements—Management Systems and Procedures—Procurement Systems Standards and Requirements in IIA. Under the conditions specified in 45 CFR 75.320, for-profit recipients are permitted to retain title to equipment purchased under a research grant though NIH reserves the right to order the transfer of equipment, including title, to NIH or an eligible third party named by the NIH awarding office when such third party is otherwise eligible under existing statutes. In keeping with the provisions of 45 CFR 75.216, for-profit recipients must not use equipment acquired with NIH funds to provide services to non-Federal organizations for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise, and any user charges shall be treated as program income and must be reported on the FFR. Conditions for the sale of equipment are specified at Administrative Requirements—Management Systems and Procedures—Sale of Real Property, Equipment, and Supplies in IIA.

18.4.2 Intellectual Property

Intellectual property requirements set forth in 37 CFR 401 apply to for-profit organizations, whether small businesses or large businesses. However, invention reporting requirements for for-profit organizations differ somewhat from those for non-profit organizations. When the recipient is a for-profit organization, assignment of invention rights to a third party does not require NIH approval, but ongoing reporting remains a requirement for each invention. (See Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources in IIA.) Additional information about the requirements of 37 CFR 401 may be obtained from the Division of Extramural Inventions and Technology Resources, OPERA, NIH (see Part III for address and telephone number).

To the extent authorized by law, the Federal government will not make public any information disclosing a Federal government-supported invention.

18.4.3 Program Income

Consistent with NIH Standard Terms of Award, for-profit recipients, including those under the SBIR/STTR programs, are subject to the additive alternative for the use of program income described in Administrative Requirements—Management Systems and Procedures—Program Income in IIA.

18.4.4 Operating Authorities

Awards to for-profit organizations are subject to NIH Standard Terms of Award; however, some mechanisms do not allow automatic carryover of unobligated balances of funds. Under those mechanisms, the NIH awarding IC will specify the disposition of the reported unobligated balance in the NoA. (See Administrative Requirements—Changes in Project and Budget in IIA).

18.4.5 Audit

The requirements for non-Federal audits of for-profit organizations are specified in 45 CFR 75.501(h)-(k). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended

a total of $750,000 or more under one or more HHS award (as a direct recipient or consortium participant). 45 CFR 75.216(d) (1)(ii) incorporates the thresholds and deadlines of 45 CFR 75, Subpart F—Audit Requirements but provides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements. The recipient either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), available from the U. S. Government Publishing Office (GPO), of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program, or (2) an audit that meets the requirements of 45 CFR 75, Subpart F—Audit Requirements. Audits must be completed and submitted to the National External Audit Review Center within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. The address is found in Part III.

For-profit organizations expending less than $750,000 a year are not required to have an annual audit for that year but must make their grant-related records available to NIH or other designated officials for review or audit.

18.4.6 Labor Distribution Requirements for For-Profit Organizations

Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate labor distribution system that distributes payroll costs in accordance with generally accepted practices of like organizations. Standards for labor distribution systems are contained in the applicable cost principles (other than those for for-profit organizations).

NIH requires for-profit organizations to conform with industry standards to support salary and wage charges to NIH grants. Therefore, unless an alternate system is approved by the GMO, the recipient must maintain a time and-effort reporting system for both professional and other-than-professional staff reflecting daily after-the-fact reporting of hours expended on individual projects or indirect activities. The system must record both hours worked and hours absent. This information must be certified by an AOR no less frequently than every pay period.

18.5 SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAMS

NIH is required by statute to reserve a portion of its annual extramural budget for projects under the SBIR and STTR programs. These programs primarily are intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

The SBIR and STTR programs were reauthorized by Congress in P.L. 112-81, December 31, 2011. The reauthorization modified several aspects of the programs, including small business eligibility requirements. Updates on reauthorization implementation will be posted on http://sbir.nih.gov. NIH will issue Guide Notice/s to advise the community about the impact on NIH's SBIR and STTR programs.

Both the SBIR and STTR programs consist of the following three phases:

- ***Phase I.*** The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the applicant (small business concern or SBC) before providing further Federal support in Phase II.

- ***Phase II.*** The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding will be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. Only Phase I recipients are eligible to receive Phase II funding. Unless submitted as a Fast-Track application (see here), Phase II applications may be submitted only after the Phase I award is made. NIH expects non Fast-Track Phase II applications to be submitted within the first six receipt dates following expiration of the Phase I budget period, i.e., normally 2 years beyond the completion date of the Phase I award.

  Some NIH ICs offer Phase II SBIR/STTR awardees the opportunity to apply for Phase IIB Competing Renewal awards. These are available for those projects that require extraordinary time and effort in the R&D phase and may or may not require FDA approval for the development of such projects, including drugs, devices, vaccines, therapeutics, and medical implants related to the mission of the IC. Some ICs have announced this opportunity through the NIH Guide for Grants and Contracts and some are using the Omnibus SBIR/STTR Grant Solicitation. Only those small business concerns who have been awarded a Phase II are eligible to apply for a Phase IIB Competing Renewal award. Prospective applicants are strongly encouraged to contact NIH staff prior to submission. Additional requirements and instructions (e.g., submission of a letter of intent) are available in the specific IC research topics section and in the specific IC Program Funding Opportunity Announcements.

- ***Phase III.*** The objective of this phase, where appropriate, is for the SBC to pursue, with non-SBIR/STTR funds, the commercialization of the results of the research or R&D funded in Phases I and II.

There are two major differences between the SBIR and STTR programs:

- Under SBIR Program, the Project Director/Principal Investigator (PD/PI) must have his/her primary employment with the small business concern at the time of award and for the duration of the project period. However, under the STTR Program the PD/PI may have his/her primary employment with either the small business concern or the collaborating research institution. On an STTR project, the PD/PI must devote at least 10 percent of his/her time to the STTR project. For purposes of the SBIR and STTR Programs, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee. The STTR program *requires* for both phases I and II that the SBC formally partner with a single, non-profit research institution. At least 40 percent of the STTR research project is to be conducted by the SBC and at least 30 percent of the work is to be conducted by the single, "partnering" research institution through a formal, cooperative arrangement. Such organizations include universities, non-profit hospitals, and other non-profit research organizations as well as Federally Funded Research and Development Centers. STTR grants are awarded to the SBC, which will receive all of the funding for the project and disburse the appropriate funding to the research institution. The SBIR program allows subcontracting, it does not require it so the SBC may conduct the entire SBIR project without outside collaboration.

SBIR/STTR program policy now allows the following:

- Phase I STTR Awardees may apply for NIH SBIR or STTR Phase II.
- Phase I SBIR Awardees may apply for NIH SBIR or STTR Phase II.
- Phase II STTR Awardees may apply for NIH SBIR or STTR Phase IIB.
- Phase II SBIR Awardees may apply for NIH SBIR or STTR Phase IIB.

Applicants may 'switch' programs to any active and open NIH SBIR or STTR solicitation, including the Omnibus and any targeted funding opportunity.

Note: There are distinct policies for each program—SBIR and STTR—and each phase within these programs. Applicants that 'switch' programs must comply with the policies for the program and FOA to which they submit the application. See 18.5.5.4 SBIR Life Cycle Certification and Sec. 18.5.5.5 STTR Life Cycle Certification for further information.

- NIH launched a pilot project in February 2014 (PAR-14-088) allowing an eligible small business entity to apply directly to Phase II if it had already completed Phase I-like research and development work using funding from sources other than the SBIR/STTR program. Small business concerns (SBCs) eligible to submit Phase II applications for projects that were supported with a Phase I SBIR or STTR award from NIH or any other agency are expected to submit the regular Phase II application through SBIR/STTR solicitations as "Renewal" applications based on the awarded Phase I SBIR or STTR project. Only one Phase II application may be awarded for a specific project supported by a Phase I award. NIH policies regarding overlapping applications (Sec. 2.3.7.4) still apply. A Phase II awardee may receive one additional, sequential Phase II award (called the NIH Phase IIB) to continue the work of an initial Phase II award.

18.5.1 NIH Fast-Track Application Process

The NIH Fast-Track application process expedites award decisions and funding of SBIR and STTR Phase II applications for scientifically meritorious projects that have a high potential for commercialization. The Fast-Track process allows Phase I and Phase II grant applications to be submitted and reviewed together. Fast-Track applications receive a single rating. Before submitting applications for Fast-Track review, applicants are strongly encouraged to consult with cognizant NIH program staff to assure Fast-Track is appropriate. For additional information on the submission of Fast-Track applications, see the SF424 (R&R) SBIR/STTR Application Guide available at http://sbir.nih.gov.

18.5.2 Eligibility

Only United States small business concerns (SBCs) are eligible to submit SBIR and STTR applications. A small business concern is one that, at the time of award for both Phase I and Phase II SBIR awards, meets all the following criteria. If it appears that an applicant organization does not meet the eligibility requirements, NIH will request a size determination by the SBA. If eligibility is unclear, NIH will not make an SBIR or STTR award until the SBA provides a determination.

1. SBIR Eligibility Requirements

a. Organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials;

b. In the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there must be less than 50 percent participation by foreign business entities in the joint venture;

c.
    i. Be a concern which is more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), or any combination of these; OR
    ii. Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these. No single venture capital operating company, hedge fund, or private equity firm may own more than 50% of the concern; OR
    iii. Be a joint venture in which each entity to the joint venture must meet the requirements set forth in paragraph c(i) or c(ii) of this section. A joint venture that includes one or more concerns that meet the requirements of paragraph (ii) of this section must comply with § 121.705(b) concerning registration and application requirements.

d. Has, including its affiliates, not more than 500 employees and meets the other regulatory requirements found in 13 CFR 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

2. STTR Eligibility Requirements

a. Organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials;

b. In the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there must be less than 50 percent participation by foreign business entities in the joint venture;

c.
    i. Be a concern which is more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), or any combination of these; OR
    ii. Be a joint venture in which each entity to the joint venture must meet the requirements set forth in paragraph c(i) of this section.

d. Has, including its affiliates, not more than 500 employees and meets the other regulatory requirements found in 13 CFR 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Size District Office at http://sba.gov/size.

18.5.2.1 Place of Performance

For both Phase I and Phase II SBIR/STTR awards, the research or R&D project activity must be performed in its entirety in the United States. (The United States is defined as the 50 States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, the Federated States of Micronesia, the Republic of Palau, the Republic of the Marshall Islands, and the District of Columbia.)

In those rare instances where the study design requires use of a foreign site (e.g., to conduct testing of specific patient populations), the investigator must provide compelling scientific justification in the application for the need/use of a foreign site. Similarly, in those rare instances where it may be necessary to purchase materials from other countries, investigators must thoroughly justify the request. NIH will consider these instances on a case-by-case basis, and they should be discussed with cognizant NIH staff before submitting an application. Approval will not be considered unless the application is being considered for an award. IC GMOs have the authority to approve these waiver requests. Whether the request is approved or disapproved, it will be explicitly addressed in the NoA if an award is made. Whenever possible, work outside the United States, which is necessary to the completion of the project, should be supported by funding other than SBIR/STTR.

18.5.2.2 Change in Organization Status & Change of Recipient Institution Actions

Applicant organization eligibility is determined at the time of the initial SBIR/STTR award. If a legal action occurs such as a merger or successor-in-interest, that changes the organization status so that they are no longer eligible for the SBIR/STTR programs, existing SBIR/STTR grants can continue. However, the organization would no longer be eligible for any new SBIR/STTR grants.

When there is a desire to transfer an SBIR/STTR grant to a different organization, the new organization must continue to meet the SBIR/STTR program eligibility requirements. Recipients should contact the NIH awarding office to discuss options when considering a move to a new organization.

18.5.2.3 Minimum Level of Effort

Generally, under SBIR Phase I awards, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the SBC. Payments, in the aggregate, to consultants, consortium participants and contractors for portions of the scientific/technical effort generally may not exceed 33 percent of the total requested amount.

Generally under SBIR Phase II awards a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the SBC. In addition, payments, in the aggregate, to consultants, consortium participants, and contractors for portions of the scientific/technical effort generally may not exceed 50 percent of the total requested amount.

For STTR awards (both Phase I and Phase II), at least 40 percent of the work must be performed by the SBC and at least 30 percent of the work must be performed by the single, non-profit research institution. These percentages are Congressionally mandated and waivers are not permitted. The basis for determining the percentage of work to be performed by each of the cooperating parties is the total cost (direct and F&A costs, and fee) attributable to each party, unless otherwise described and justified in the “Consortium/Contractual Arrangements” portion of the of the grant application.

18.5.2.4 Multiple Program Director/Principal Investigator Applications and Awards

The Multiple Program Director/Principal Investigator (multiple PD/PI) option is available for NIH SBIR/STTR applicants for team science efforts. All of the policy and requirements described in Multi PD/PI apply to SBIR/STTR projects, with the exception of sections that are not relevant to the SBIR/STTR program (e.g., new investigators, multi-project applications). In addition, the following criteria apply to multiple PD/PI SBC applicants and awards:

- The small business concern (SBC) is *always* the applicant/awardee organization. Organizations other than the SBC with PD/PIs participating in the multiple PD/PI project, including the STTR non-profit research institution partner, are subcontractors to the SBC.
- For Phase I and Phase II SBIR projects, the Contact PD/PI must meet the primary employment requirement; other PD/PIs are not required to meet the requirement. Primary employment means that more than one half of the PD/PI's time is spent in the employ of the SBC at the time of award and during the conduct of the proposed project. Deviations from this requirement are rare and must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.
- For Phase I and Phase II STTR projects, the PD/PI is not required to be employed by the SBC. However, the Contact PD/PI, the first PD/PI listed, must have a formal appointment with, or commitment to, the SBC, which must be in the form of an official relationship between the parties, but need not include a salary or other form of remuneration. Each PD/PI on a multiple PD/PI award must commit a minimum of 1.2 calendar months (10% effort) to the project.
- An STTR applicant organization must officially affiliate a PD/PI with the SBC in the eRA Commons if the PD/PI is not an employee of the SBC.
- A Phase IIB Competing Renewal submitted as a multiple PD/PI application requesting support for a project previously supported through a single PD/PI award should state the changes in the Project's direct and management that led to the proposed multiple PD/PI model.

18.5.3 Public Policy Requirements and Objectives

For-profit organizations receiving SBIR/STTR awards generally are subject to the same public policy requirements as non-profit organizations. However, the requirements concerning reporting of financial conflicts of interest (see Public Policy Requirements, Objectives, and Other Appropriation Mandates—Financial Conflict of Interest in IIA) do not apply to applications or awards under Phase I of the SBIR/STTR programs. The requirements do, however, apply to Phase II applications and awards.

Consistent with SBA program policy directives and NIH's omnibus FOAs for SBIR and STTR, when purchasing equipment or a product under the SBIR/STTR award, the small business concern should purchase only American-made items whenever possible.

18.5.4 Allowable Costs and Fee

18.5.4.1 Program Levels (Total Costs)

SBA SBIR and STTR Policy Directives provide program levels for SBIR and STTR programs based on statutory guidelines. However, these directives also give agencies discretion to exceed these levels up to 50% over the guideline (Hard Cap) when the proposed budget and requested period of support are fully justified and scientifically appropriate in relation to the proposed research. The Small Business Administration may adjust award guidelines annually. The current levels are:

- SBIR Phase I: $150,000 Total Costs; 6 months
- SBIR Phase II: $1,000,000 Total Costs; 2 years
- STTR Phase I: $150,000 Total Costs; 1 year
- STTR Phase II: $1,000,000 Total Costs; 2 years

HARD CAPS

- SBIR Phase I: May not exceed guideline amounts by more than 50% = $225,000
- SBIR Phase II: May not exceed guideline amounts by more than 50% = $1.5 million
- STTR Phase I: May not exceed guideline amounts by more than 50% = $225,000
- STTR Phase II: May not exceed guideline amounts by more than 50% = $1.5 million

As written in the statute and under appropriate circumstances, NIH can apply for a waiver from SBA to issue an award exceeding the Hard Cap ($225,000 for Phase I or $1,500,000 for Phase II) if this cap will interfere with NIH's ability to meet its mission. Award waivers from the SBA are not guaranteed and may delay the release of funds.

Some ICs offer Phase II SBIR/STTR awardees the opportunity to apply for Phase IIB Competing Renewal awards. These are available for those projects that require extraordinary time and effort in the R&D phase and may or may not require FDA approval for the development of such projects, including drugs, devices, vaccines, therapeutics, and medical implants related to the mission of the IC. Only those small business concerns who have been awarded a Phase II are eligible to apply for the Phase IIB award. Program levels are:

- SBIR Phase II Competing Renewals (Phase II "B"): $3,000,000; 3 years
- STTR Phase II Competing Renewals (Phase II "B"): $3,000,000; 3 years

Applicants must request an appropriate level in the competing application; applications will not be adjusted after submission. See the NIH Special Announcements for Small Business Research Opportunities for a list of these unique SBIR funding opportunities.

18.5.4.2 Profit or Fee

A reasonable profit or fee may be paid to a SBC receiving an award under Phase I or Phase II of the SBIR and STTR programs. However, this profit or fee must be included in the budget request at the time of application. The profit or fee is not considered a "cost" for purposes of determining allowable use, program income accountability, or audit thresholds. The profit or fee may be used by the SBC for any purpose, including additional effort under the SBIR/STTR award. It is intended to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work; however, the amount of the profit or fee normally will not exceed seven (7) percent of total costs (direct and F&A) for each phase of the project. The profit or fee should be drawn from PMS in increments proportional to the drawdown of funds for direct and F&A costs. The profit or fee applies solely to the SBC receiving the SBIR/STTR award and not to any other participant; however, in accordance with normal commercial practice, the SBC may pay a profit or fee to a contractor providing routine goods or services to the SBC under the grant.

18.5.4.3 Facilities and Administrative Costs (Indirect Costs)

18.5.4.3.1 Phase I

If the applicant SBC has a currently effective F&A cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. NIH ICs use the term F&A costs for all types of applicants and recipients; however, for-profit organizations will find that DFAS and organizations external to NIH refer to these costs as indirect costs. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose estimated F&A costs at a rate not to exceed 40 percent of the total direct costs. However, SBCs are reminded that only actual F&A costs are to be charged to projects. (If awarded at a rate of 40 percent or less, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with a Federal agency.) NIH will not negotiate indirect cost rates for Phase I awards.

18.5.4.3.2 Phase II

If the applicant SBC has a currently effective negotiated indirect cost rate(s) with a Federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose an estimated F&A rate in the application. If the requested F&A cost rate is 40 percent of total direct costs or less, no further justification is required at the time of award, and F&A costs will be awarded at the requested rate. However, SBCs are reminded that only actual F&A costs may be charged to projects. If awarded at a rate of 40 percent or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with DFAS. DFAS—the office authorized to negotiate indirect cost rates with SBC's receiving NIH SBIR/STTR awards—will negotiate indirect cost rates for SBCs receiving Phase II awards that requested a rate greater than 40 percent of total direct costs.

Upon request, the applicant SBC should provide DFAS with an indirect cost proposal and supporting financial data for its most recently completed fiscal year. If financial data is not available for the most recently completed fiscal year, the applicant should submit a proposal showing estimated rates with supporting documentation. Further information about DFAS is available at its Web site or by telephone (see Part III).

18.5.5 Administrative Requirements

For-profit organizations that receive SBIR/STTR awards generally are subject to the same administrative requirements as non-profit organizations. (See 45 CFR 75 for further.)

18.5.5.1 Market Research

NIH will not support market research, including studies of the literature that lead to a new or expanded statement of work, under the grant. For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the proposed research. It includes various types of research, such as the size of potential markets and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that include a survey of

the public as part of the objectives of the project to determine the impact of the subject of the research on the behavior of individuals.

18.5.5.2 Intellectual Property

Rights to data, including software developed under the terms of any funding agreement resulting from an NIH award, shall remain with the recipient except that any such copyrighted material shall be subject to a royalty-free, nonexclusive and irrevocable license to the Federal government to reproduce, publish or otherwise use the material, and to authorize others to do so for Federal purposes. In addition, under the SBIR/STTR programs, in contrast to awards to for-profit organizations under other support mechanisms, such data shall not be released outside the Federal government without the recipient's permission for a period of 4 years from completion of the project.

Rights in Data Developed Under SBIR Funding Agreement. The Small Business Innovation Research Program Reauthorization Act of 2000, Public Law 106-554, amended section 9 of the Act (15 U.S.C. 638), referred to as the "Act" provides for "retention by an SBC of the rights to data generated by the concern in the performance of an SBIR award."

1. Each agency must refrain from disclosing SBIR technical data to outside the Government (except reviewers) and especially to competitors of the SBC, or from using the information to produce future technical procurement specifications that could harm the SBC that discovered and developed the innovation.
2. SBIR agencies must protect from disclosure and non-governmental use all SBIR technical data developed from work performed under an SBIR funding agreement for a period of not less than four years from delivery of the last deliverable under that agreement (either Phase I, Phase II, or Federally-funded SBIR Phase III) unless, subject to (b)(3) of this section, the agency obtains permission to disclose such SBIR technical data from the awardee or SBIR applicant. Agencies are released from obligation to protect SBIR data upon expiration of the protection period except that any such data that is also protected and referenced under a subsequent SBIR award must remain protected through the protection period of that subsequent SBIR award. For example, if a Phase III award is issued within or after the Phase II data rights protection period and the Phase III award refers to and protects data developed and protected under the Phase II award, then that data must continue to be protected through the Phase III protection period. Agencies have discretion to adopt a protection period longer than four years. The Government retains a royalty-free license for Government use of any technical data delivered under an SBIR award, whether patented or not. This section does not apply to program evaluation.
3. SBIR technical data rights apply to all SBIR awards, including subcontracts to such awards, that fall within the statutory definition of Phase I, II, or III of the SBIR Program, as described in Section 4 of this Policy Directive. The scope and extent of the SBIR technical data rights applicable to Federally-funded Phase III awards is identical to the SBIR data rights applicable to Phases I and II SBIR awards. The data rights protection period lapses only: (i) Upon expiration of the protection period applicable to the SBIR award, or (ii) by agreement between the awardee and the agency.

4. Agencies must insert the provisions of (b)(1), (2), and (3) immediately above as SBIR data rights clauses into all SBIR Phase I, Phase II, and Phase III awards. These data rights clauses are non-negotiable and must not be the subject of negotiations pertaining to an SBIR Phase III award, or diminished or removed during award administration. An agency must not, in any way, make issuance of an SBIR Phase III award conditional on data rights. If the SBIR awardee wishes to transfer its SBIR data rights to the awarding agency or to a third party, it must do so in writing under a separate agreement. A decision by the awardee to relinquish, transfer, or modify in any way its SBIR data rights must be made without pressure or coercion by the agency or any other party. Following issuance of an SBIR Phase III award, the awardee may enter into an agreement with the awarding agency to transfer or modify the data rights contained in that SBIR Phase III award. Such a bilateral data rights agreement must be entered into only after the SBIR Phase III award, which includes the appropriate SBIR data rights clause, has been signed. SBA must immediately report to the Congress any attempt or action by an agency to condition an SBIR award on data rights, to exclude the appropriate data rights clause from the award, or to diminish such rights.

The STTR program requires that the small business recipient and the single, non-profit research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research. (A model agreement, entitled "Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization," is available at the NIH Web site at http://-grants.nih.gov/grants/funding/sbir.htm.) By signing the face page of the grant application, the SBC's AOR certifies that the agreement with the research institution will be effective at the time the grant award is made. A copy of the agreement must be furnished upon request to the NIH awarding IC.

SBIR/STTR recipients are covered by 35 U.S.C. 200-212 and 37 CFR 401 with respect to inventions and patents (see Grants to For-Profit Organizations—Administrative Requirements—Intellectual Property in this chapter).

18.5.5.3 Data Sharing

Applicants for SBIR Phase II funding of $500,000 or more of direct costs in any single year must comply with the NIH policy on data sharing as modified by the Small Business Act. If the final data would not be amenable to sharing, e.g., proprietary data, the SBC should explain that in the application. In addition, as indicated under Intellectual Property in this chapter, whether or not the award meets the threshold for data sharing, NIH will not release data outside the Federal government without the recipient's permission for a period of 4 years from completion of the project. The entire policy may be found at http://-grants.nih.gov/grants/policy/data_sharing.

18.5.5.4 SBIR Life Cycle Certification

All SBIR Phase I and Phase II awardees must complete a Life Cycle Certification at all times set forth in the Notice of Award (see §8(h) of the SBIR Policy Directive). This includes checking all of the boxes on the actual certification document and having an authorized officer of the awardee sign and date the certification each time it is required. Awardees are not required to submit a certification directly to NIH but must instead complete a certification and maintain it on file in accordance with the records and retention policy in Section 8.4.2 of the NIH Grants Policy Statement.

A certification is required at the following times:

- For SBIR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System.

- For SBIR Phase II Awardees: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System.

In addition, SBIR awardees indicate compliance with these certification requirements by drawing or requesting funds from the Payment Management System. If the recipient cannot complete the certification or cannot ensure compliance with the certification process, it should notify the GMO immediately. If resolution cannot be reached, the GMO will void or terminate the grant, as appropriate.

The certification form is available in fillable format at: https://grants.nih.gov/grants/forms/manage_a_small_business_award.htm. However, the requirements are outlined below.

Overview Certification Information. The Federal government relies on this information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award. The definitions for the terms used in the certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Grants Management Officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to the certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing a certification may be prosecuted if they have provided false information.

Recipients will verify and certify the following provisions:

1. The principal investigator spent more than half of his/her time as an employee of the awardee or has requested and received a written deviation from this requirement from the Grants Management Officer. When a deviation has been approved by the NIH, the certification will also document the adjusted percentage of time approved.
2. All, essentially equivalent work, or a portion of the work performed under this project:
    a. Has not been submitted for funding by another Federal agency.
    b. Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.
    c. A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management Officer.
3. Upon completion of the award it will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. SBIR Phase I: at least two-thirds (66 2/3%) of the research
    b. SBIR Phase II: at least half (50%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer

4. The work is completed and it has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. SBIR Phase I: at least two-thirds (66 2/3%) of the research
    b. SBIR Phase II: at least half (50%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer
    d. N/A because work is not completed
5. The research/research and development is performed in the United States unless a deviation is approved in writing by the Grants Management Officer.
6. The research/research and development is performed at my facilities with my employees, except as otherwise indicated in the SBIR application and approved in the Notice of Award.

The recipient will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

The recipient will further certify that they understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

Finally, the individual certifying on behalf of the recipient will certify they are:

1. An officer of the business concern authorized to represent it and sign the certification on its behalf.
2. Representing on his/her own behalf, and on behalf of the business concern, that the information provided in the certification, the application, and all other information submitted in connection with the award, is true and correct as of the date of submission.
3. Acknowledging that any intentional or negligent misrepresentation of the information contained in the certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and non-procurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

18.5.5.5 STTR Life Cycle Certification

All STTR Phase I and Phase II awardees must complete a Life Cycle Certification at all times set forth in the Notice of Award (see §8(h) of the SBIR Policy Directive). This includes checking all of the boxes on the actual certification document and having an authorized officer of the awardee sign and date the certification each time it is required. Awardees are not required to submit the certification directly to NIH but must instead complete a certification and maintain it on file in accordance with the records and retention policy in Section 8.4.2 of the NIH Grants Policy Statement.

A certification is required at the following times:

- For STTR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System.
- For STTR Phase II Awardees: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System.

In addition, STTR awardees indicate compliance with these certification requirements by drawing or requesting funds from the Payment Management System. If the recipient cannot complete the certification or cannot ensure compliance with the certification process, it should notify the GMO immediately. If resolution cannot be reached, the GMO will void or terminate the grant, as appropriate.

The certification is available in fillable format at: http://grants.nih.gov/grants/forms.htm#sbir. However, the requirements are outlined below.

Overview Certification Information. Please read carefully the following certification statements. The Federal government relies on this information to determine whether the business is eligible for a Small Business Technology Transfer Research (STTR) Program award. The definitions for the terms used in the certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the STTR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Grants Management Officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to the certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing a certification may be prosecuted if they have provided false information.

Recipients will verify and certify the following provisions:

1. The principal investigator spent more than half of his/her time as an employee of the awardee or the research institution, or the awardee has requested and received a written deviation from this requirement from the Grants Management Officer. When a deviation has been approved by the NIH, the certification will also document the adjusted percentage of time approved.
2. All, essentially equivalent work, or a portion of the work performed under this project:
    a. Has not been submitted for funding by another Federal agency.
    b. Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.
    c. A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management Officer.
3. Upon completion of the award it will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. STTR Phase I: at least forty (40%) of the research
    b. STTR Phase II: at least forty (40%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer
4. The small business concern, and not the single, partnering Research Institution, is exercising management direction and control of the performance of the STTR funding agreement.

5. The work is completed and it has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Grants Management Officer. Options on the certification document will include:
    a. STTR Phase I: at least forty (40%) of the research
    b. STTR Phase II: at least forty (40%) of the research
    c. Percent deviation approved in writing by the Grants Management Officer
    d. N/A because work is not completed
6. The research/research and development is performed in the United States unless a deviation is approved in writing by the Grants Management Officer.
7. The research/research and development is performed at my facilities with my employees, except as otherwise indicated in the STTR application and approved in the Notice of Award.

The recipient will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

The recipient will further certify that they understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

Finally, the individual certifying on behalf of the recipient will certify they are:

1. An officer of the business concern authorized to represent it and sign the certification on its behalf.
2. Representing on his/her own behalf, and on behalf of the business concern, that the information provided in the certification, the application, and all other information submitted in connection with the award, is true and correct as of the date of submission.
3. Acknowledging that any intentional or negligent misrepresentation of the information contained in the certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and non-procurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Phase I Final RPPR: If a Phase I awardee does not intend to submit a Phase II application within four months of the Phase I project period end date, then Phase I Final RPPR must be submitted to the Grants Management Office of the Awarding Component *within 120* days of the completion date of the Phase I grant period. An Interim-RPPR is required if an application for a Phase II or Phase IIB, respectively, is submitted before a final report for the Phase I award would otherwise be due. In the event that the Type 2/Phase II/Phase IIB application is funded, NIH will treat the Interim –RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPR.

Instructions for the Final RPPR are found at: https://grants.nih.gov/grants/rppr/index.htm. See in particular, Chapter 7.3, SBIR/STTR RPPRs.

Phase II Data Collection Requirement for Government SBIR Reporting Database: The SBA maintains a Database System on SBIR.gov to track and report on statistics regarding the SBIR and the STTR programs. Each small business concern applying for a Phase II award is required to update the appropriate information in the reporting database on SBIR.gov for any of its prior Phase II awards.

In meeting this requirement, the small business concern may apportion sales or additional investment information relating to more than one Phase II award among those awards, if it notes the apportionment for each award. Each Phase II awardee is required to update the appropriate information in the SBIR.gov database on that award upon completion of the last deliverable (e.g., Final RPPR, Federal Financial Report, Final Invention Statement) under the funding agreement. In addition, the awardee is requested to voluntarily update the appropriate information on that award in the SBIR.gov database annually thereafter for a minimum period of 5 years.

Questions about this requirement may be submitted to SBA directly through the Contact Us/Send Feedback link on SBIR.gov. To register on and use the database system, visit http://sbir.gov. Online help is available. SBA will minimize the data reporting requirements of small business concerns, make updating available electronically, and provide standardized procedures.

Project commercialization and sales data can only be viewed by Congress, General Accounting Office (GAO), agencies participating in the SBIR/STTR programs, Office of Management and Budget (OMB), Office of Science and Technology Policy (OSTP), Office of Federal Procurement Policy (OFPP), and other authorized persons (for example, authorized contractors) who are subject to a use and nondisclosure agreement with the Federal Government covering the use of the database. Pursuant to 15 U.S.C. 638(k)(4), information provided to the SBIR.gov database is privileged and confidential and not subject to disclosure pursuant to 5 U.S.C. 552 (Government Organization and Employees); nor must it be considered to be publication for purposes of 35 U.S.C. 102 (a) or (b).

Examples of the data to be entered by applicants into SBIR.gov include revenue from the sale of new products or services resulting from the research conducted under each Phase II award or additional investment from any source, other than Phase I or Phase II awards, to further the research and development conducted under each Phase II award.

19 RESEARCH PATIENT CARE COSTS

19.1 GENERAL

This chapter provides NIH policy on the determination and reimbursement of research patient care costs under grants. This general policy is intended to be applied in conjunction with the requirements of 45 CFR 75, Appendix IX, Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals. In addition, specific NIH programs may have additional or alternative requirements with which an applicant/recipient must comply.

19.2 DEFINITIONS

Research Patient Care Costs. The costs of routine and ancillary services provided by hospitals to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts (hereafter "rates"). Research patient care costs do not include: (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors, (2) costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service , (3) recruitment or retention fees or (4) the data management or statistical analysis of clinical research results.

Hospital. Includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.

Research Patients. Inpatient and outpatient subjects, volunteers, or donors participating in a research protocol.

Routine Services. Regular room services, minor medical and surgical supplies, and the use of equipment and facilities, for which a separate charge is not customarily made.

Ancillary Services. Those special services for which charges are customarily made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology.

Outpatient Services. Services rendered to subjects/volunteers/donors who are not hospitalized.

Usual Patient Care. Items and services (routine and ancillary) ordinarily furnished in the treatment of patients by providers of patient care under the supervision of the physician or other responsible health professional. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services. These expenses are for care that would have been incurred even if the research study did not exist. The patient and/or third-party insurance generally will provide for reimbursement of charges for "usual patient care" as opposed to not reimbursing those charges generated solely because of participation in a research protocol.

Discrete Centers. Groups of beds that have been set aside for occupancy by research patients and are physically separated from other hospital beds in an environment that normally permits an ascertainable allocation of costs associated with the space they occupy and the service needs they generate.

Scatter Beds. Beds assigned to research patients based on availability. These beds are not physically separate from nonresearch beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital and are not usually distinguishable in terms of services or costs from other general service beds within the hospital.

Cost-Finding Process. The technique of apportioning or allocating the costs of the non-revenue-producing cost centers to each other and to the revenue-producing centers on the basis of the statistical data that measure the amount of service rendered by each center to other centers.

19.3 POLICY

NIH provides funds for research patient care costs under grants and cooperative agreements. Research patients may receive routine services as inpatients or ancillary services as either inpatient or outpatient subjects/volunteers/donors. In order to receive reimbursement for research patient care costs, any hospital that, as a direct recipient of NIH funds, expects to incur more than $100,000 in patient care costs in any single budget period on a single NIH grant must either have in place or take steps to negotiate a research patient care rate agreement with the cognizant DCA office. These rates must be shown in all requests and/or claims for reimbursement of research patient care costs. Hospital recipients that expect to incur $100,000 or less in research patient care costs per budget period on a single NIH grant and patient care for all consortium participants/contractors under grants no matter the dollar figure are subject to the requirements specified in the subsection on Special Procedures for Certain Hospitals below. Failure to negotiate a research patient care rate with DCA when required may result in the disallowance of all research patient care costs charged to a grant.

19.4 ALLOWABLE COSTS

The type of patient and services received are the determining factors for allowing research patient care costs as charges to NIH grants. If the patient is receiving service or care that neither differs from usual patient care nor results in expenses greater than those that would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and the grant will generally not support the costs. When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the grant may pay the additional costs. The recipient must decide whether, in fact, the hospitalization period, the tests, or the services have been extended beyond or added to what would ordinarily have been expected, and to what extent. Patient care costs for individuals who are receiving accepted treatment according to standard regimens would not ordinarily be acceptable charges to an NIH grant. Similarly, in certain kinds of clinical trials where accepted treatments are compared against new therapies, research patient care costs generally may be charged to a grant only insofar as they are measurements or services above and beyond those that constitute usual patient care and are specified by the study protocol. Acceptable exceptions are listed below.

NIH funds may be used to pay all costs (whether usual care costs or research care costs) for the entire period of hospitalization or research tests or services for individuals who would not have been hospitalized or received such tests or services except for their participation in the research study. Any such exceptions should be documented in the recipient's records. These individuals may include the following:

- Volunteers to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be normal controls for metabolic or other studies; people with genetic or certain abnormalities of interest to the investigator; healthy individuals participating in a clinical trial, for example a vaccine trial; and sick people brought to the hospital solely for studies when they otherwise would not require hospitalization.

- Volunteers who are sick and of research importance to the protocol but economically unable or without funds available to them through a responsible third party to pay hospitalization expenses. This includes patients for whom some third-party payer, such as a city, county, or State government, might pay hospitalization expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.
- Volunteers of research importance who are unwilling to spend their own money or use their hospital plan coverage at that particular time. (Fear of more urgent need in the future for both personal funds and health insurance might be one reason for the patient's reluctance to participate in the study.) The investigator has a special responsibility in making the decision to include patients in this group with full charges to the grant, since NIH expects the patient and/or third party to pay the total costs of usual care. However, in exceptional circumstances, the investigator may decide to pay the total expenses for hospitalization, research services, or tests from the grant if this is required to secure timely cooperation of a valuable study patient not otherwise available.

19.4.1 Computing Research Patient Care Costs

Research patient care costs, whether expressed as a rate or an amount, shall be computed in an amount consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs. Separate cost centers must be established for each discrete bed unit for purposes of allocating or distributing allowable routine costs to the discrete unit.

When provisional rates are used as the basis for award of research patient care costs, the amount awarded shall constitute the maximum amount that the NIH awarding IC is obligated to reimburse the recipient for such costs. Provisional rates must be adjusted if a lower final rate is negotiated.

19.4.2 Facilities and Administrative Costs

F&A costs should not be paid on any cost component representing the cost of research patient care activities. Research patient care rates (routine and ancillary) include F&A costs related to "hospital-type" employees (nurses, medical technicians, and similar personnel) supported as a direct cost under a grant. Therefore, to preclude over-recoveries of costs similar to these F&A costs, salaries and wages of all "hospital-type" employees working on the grant must be excluded from the salary and wage (S&W) base used to claim F&A costs. Related fringe benefits also should be excluded if such costs are part of the S&W base. If a "total-direct-costs" base is used to compute and claim F&A costs, the above-mentioned "hospital-type" salaries also must be excluded from the base as well as any other base costs chargeable to the grant through the application of a research patient care rate.

If the grant or a consortium agreement/contract under a grant provides funding exclusively for research patient care activities, no F&A costs normally will be allowed as a separate cost element since all allocable F&A costs will be accounted for in the routine or ancillary activity costs contained in research patient care rates.

Although foreign organizations are not prohibited from requesting research patient care costs, all F&A expenses must be excluded from the charges to the grant.

19.4.3 Special Procedures for Certain Hospitals

19.4.3.1 Recipients

If a recipient does not meet the threshold for negotiation of a research patient care rate agreement with DCA in a given budget period, as specified under Policy in this chapter, but has a currently negotiated research patient care rate, that rate will be used in awarding and reimbursing research patient care costs, regardless of the amount that the recipient expects to incur. In all other cases, the recipient will be reimbursed at a rate not to exceed the lesser of actual research patient care costs or the rate included in its Medicare cost report.

19.4.3.2 Consortium Participants/Contractors under Grants

If a hospital incurring research patient care costs is not the recipient, the recipient will be responsible for establishing the rate or amount that will be reimbursed for such costs unless the hospital also is a direct recipient of other HHS awards and in that capacity has established a research patient care rate with DCA.

If a participating hospital expects to incur more than $100,000 in research patient care costs as specified under Policy in this chapter, the recipient must negotiate a rate for that hospital unless the relationship between the recipient and the hospital is considered "less-than-arms-length." In this case, the recipient should contact the GMO to determine whether DCA should negotiate the rate.

If a participating hospital expects to incur $100,000 or less in research patient care costs (as provided under Policy in this chapter), the recipient will use the lesser of actual costs or the rate in the hospital's Medicare cost report as the basis for determining reimbursement. For purposes of this paragraph, the recipient will apply the thresholds to each hospital individually.

19.4.4 Financial Responsibilities

If the costs of patient care are funded by the grant, and whether those costs are classified as usual patient care or research patient care, the amount recovered from third parties must be credited to the grant. However, patient charges must be adjusted for both routine services and ancillaries prior to applying the third-party recoveries. The recipient is obligated to pursue recovery to the fullest extent possible and should be able to document those efforts. An example of such an adjustment follows:

If the standard fee schedule charge for a CT scan is $500, the negotiated research patient care agreement rate is 75 percent, and third-party insurance pays $300, the maximum amount that may be charged to the NIH grant is $75, based on the following calculation.

Standard Fee Schedule X (multiplied by) Negotiated Rate = Cost—(minus) Insurance = Maximum Charge to NIH Grant

$500 x .75 = $375 - $300 = $75

In those instances when the recipient determines that the balance of the patient's bill may be charged to the grant (see Allowable Costs in this chapter), the total bill must be adjusted to cost before applying any third-party recoveries. The remaining balance of allowable costs may then be charged to the grant.

In certain circumstances, funds may be awarded that support tests specifically developed for research purposes that are subsequently billed to third parties. In such cases, funds recovered from third parties must be credited to the grant account.

19.5 PROGRAM REQUIREMENTS

An individual NIH IC/program may adopt special implementing procedures consistent with this section to meet its own specific needs.

19.6 POST-AWARD REQUIREMENTS

Post-award rebudgeting into or out of the patient care costs category is likely to be considered a change in scope and require prior approval of the NIH awarding IC (see Administrative Requirements - Prior Approval Requirements - Change in Scope in IIA).

PART III: POINTS OF CONTACT

Various offices and officials are mentioned throughout the preceding parts of the NIHGPS as sources of information or as responsible for certain activities in the NIH grants process. Contact information for these and other offices and officials is provided in this part. These addresses should not be used for express mail or other types of hand-deliveries. The IC should be contacted to obtain the address to use for express mail.

For each IC that awards grants, a listing is provided for the CGMO as well as an extramural program official that may be contacted for general information. The web address for the IC's home page also is included. Requests related to particular applications submitted or grants awarded should be directed to the individual(s) specified in formal communications from NIH, e.g., in the NoA.

20 INSTITUTES AND CENTERS

Institute/Center	Chief Grants Management Officer	Extramural Program Official
John E. Fogarty International Center (FIC) http://www.fic.nih.gov/	Building 31C, Room B2C29, MSC-2220 Bethesda, MD 20892-2220 301-451-1670 301-594-1211 (fax)	Building 31C, Room B2C29, MSC-2220 Bethesda, MD 20892-2220 301-496-1653 301-402-0779 (fax)
National Cancer Institute (NCI) http://www.nci.nih.gov	9609 Medical Center Dr., 2W344 MSC 9710 Bethesda, MD 20892-9710 (for U.S. Postal Service) Rockville, MD 20850 (for express delivery) 240-276-6277 240-276-7902 (fax)	9609 Medical Center Drive, Room 7W444 Bethesda, MD 20892-9750 (for U.S. Postal Service mail) Rockville, MD 20850 (for express delivery) 240-276-6340 240-276-7683 (fax)
National Center for Complementary and Integrative Health (NCCIH) http://nccig.nih.gov	6701 Democracy Boulevard One Democracy Plaza, Suite 1036, MSC-4874 Bethesda, MD 20892-4874 301-435-0844 301-480-3777 (fax)	6701 Democracy Boulevard One Democracy Plaza, Room 902, MSC-4874 Bethesda, MD 20892-4874 301-435-0879 301-480-3658 (fax)
National Center for Complementary and Alternative Medicine (NCCAM) http://nccam.nih.gov	6707 Democracy Boulevard, II Suite 401, MSC-5475 Bethesda, MD 20892-5475 301-451-6330 301-480-1552 (fax)	6707 Democracy Boulevard, II Suite 401, MSC-5475 Bethesda, MD 20892-5475 301-594-2014 301-480-2419 (fax)
National Eye Institute (NEI) http://www.nei.nih.gov	5635 Fishers Lane, Suite 1300, MSC-9300 Bethesda, MD 20892-9300 301-451-2020 301-496-9997 (fax)	5635 Fishers Lane, Suite 1300, MSC-9300 Bethesda, MD 20892-9300 301-451-2020 301-402-0528 (fax)

Institute/Center	Chief Grants Management Officer	Extramural Program Official
National Heart, Lung and Blood Institute (NHLBI) http://www.nhlbi.nih.gov	6701 Rockledge Drive Rockledge II, Room 7160, MSC-7926 Bethesda, MD 20892-7926 301-435-0166 301-480-3310 (fax)	6701 Rockledge Drive Rockledge II, Room 7100, MSC-7922 Bethesda, MD 20892-7922 301-435-0260 301-480-1124 (fax)
National Human Genome Research Institute (NHGRI) http://www.nhgri.nih.gov or http://www.genome.gov	5635 Fishers Lane, Suite 4076, MSC-9306 Bethesda, MD 20892-9306 301-435-7858 301-451-5434 (fax)	5635 Fishers Lane, Suite 4080, MSC-9305 Bethesda, MD 20892-2033 301-496-7531 301-480-2770 (fax)
National Institute on Aging (NIA) http://www.nia.nih.gov	7201 Wisconsin Avenue Gateway Bldg., Room 2N212, MSC-9205 Bethesda, MD 20892-9205 301-496-1472 302-402-3672 (fax)	7201 Wisconsin Avenue Gateway Bldg., Room 2C218F, MSC-9205 Bethesda, MD 20892-9205 301-402-7715 301-402-2945 (fax)
National Institute on Alcohol Abuse and Alcoholism (NIAAA) http://www.niaaa.nih.gov	5635 Fishers Lane, Room 3023, MSC-9304 Bethesda, MD 20892-9304 301-443-4704 301-443-3891 (fax)	5635 Fishers Lane, Room 2085, MSC-9304 Bethesda, MD 20892-9304 301-443-9737 301-443-6077 (fax)
National Institute of Allergy and Infectious Diseases (NIAID) http://www.niaid.nih.gov	5601 Fishers Lane, MSC-9833 Rockville, MD 20892-9833 301-496-7075 301-480-2599 (fax)	5601 Fishers Lane, MSC-9824 Rockville, MD 20892-9824 301-496-7291 301-402-0369 (fax)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) http://www.niams.nih.gov	6701 Democracy Boulevard One Democracy Plaza, Suite 800, MSC-4872 Bethesda, MD 20892-4872 301-594-3535 301-480-5450 (fax)	6701 Democracy Boulevard One Democracy Plaza, Suite 800, MSC-4872 Bethesda, MD 20892-4872 301-594-2463 301-480-4543 (fax)

Institute/Center	Chief Grants Management Officer	Extramural Program Official
National Institute of Biomedical Imaging and Bioengineering (NIBIB) http://www.nibib.nih.gov	6707 Democracy Boulevard, Suite 900, MSC-5469 Bethesda, MD 20892-5469 301-451-4782 301-480-4974 (fax)	6707 Democracy Boulevard, Suite 200, MSC-5477 Bethesda, MD 20892-5477 301-402-7039 301-480-4973 (fax)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) http://www.nichd.nih.gov	6710B Rockledge Drive, Room 3302 Bethesda, MD 20817-1834 301-496-5001 301-480-4782 (fax)	6710B Rockledge Drive, Room 2216 Bethesda, MD 20817-1834 301-435-6856 301-402-2083 (fax)
National Institute on Deafness and Other Communication Disorders (NIDCD) http://www.nidcd.nih.gov	6001 Executive Boulevard, Room 8335 MSC-9670 Bethesda, MD 20892-9670 301-402-0909 301-402-1758 (fax)	6001 Executive Boulevard, Room 8345 MSC-9670 Bethesda, MD 20892-9670 301-402-0909 301-402-1758 (fax)
National Institute of Dental and Craniofacial Research (NIDCR) http://www.nidcr.nih.gov	6701 Democracy Boulevard, Room 658, MSC-4878 Bethesda, MD 20892-4878 301-594-4808 301-480-3562 (fax)	6701 Democracy Boulevard, Room 660, MSC-4878 Bethesda, MD 20892-4878 301-594-4805 301-480-8303 (fax)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) http://www.niddk.nih.gov	6707 Democracy Boulevard 2 Democracy Plaza, Room 731, MSC-5450 Bethesda, MD 20892-5450 301-594-8854 301-480-3504 (fax)	6707 Democracy Boulevard 2 Democracy Plaza, Room 715, MSC-5453 Bethesda, MD 20892-5453 301-594-8834 301-480-3504 (fax)
National Institute on Drug Abuse (NIDA) http://www.nida.nih.gov	6001 Executive Boulevard Neuroscience Center, Suite 4128, MSC-9560 Bethesda, MD 20892-9560 301-443-6710 301-594-6849 (fax)	6001 Executive Boulevard Neuroscience Center, Suite 200, MSC-8401 Bethesda, MD 20892-8401 301-443-2755 301-443-0538 (fax)

Institute/Center	Chief Grants Management Officer	Extramural Program Official
National Institute of Environmental Health Sciences (NIEHS) http://www.niehs.nih.gov	79 T.W. Alexander Drive, MSC EC-22 Research Triangle Park, NC 27709 919-541-2749 919-541-2860 (fax)	615 Davis Drive, Durham, NC 27713 919-541-7723 919-541-2843 (fax)
National Institute of General Medical Sciences (NIGMS) http://www.nigms.nih.gov	45 Center Drive Natcher Bldg., Room 2AN32C., MSC-6200 Bethesda, MD 20892-6200 301-594-5520 301-480-1969 (fax)	45 Center Drive Natcher Bldg., Room 2AN.24H, MSC-6200 Bethesda, MD 20892-6200 301-594-4499 301-480-1852 (fax)
National Institute of Mental Health (NIMH) http://www.nimh.nih.gov	6001 Executive Boulevard Neuroscience Center, Room 6122, MSC 9605 Bethesda, MD 20892-9605 301-443-2811 301-480-1965 (fax)	6001 Executive Boulevard Neuroscience Center, Room 6154, MSC-9609 Bethesda, MD 20892-9609 301-443-3367 301-443-4720 (fax)
National Institute on Minority Health and Health Disparities (NIMHD) http://www.nimhd.nih.gov/	6707 Democracy Boulevard, Suite 800, MSC 5464 Bethesda, MD 301-594-8412 301-480-4049 (fax)	6707 Democracy Boulevard, Suite 800, MSC 5465 Bethesda, MD 301-402-1366 301-402-4049 (fax)

Institute/Center	Chief Grants Management Officer	Extramural Program Official
National Institute of Neurological Disorders and Stroke (NINDS) http://www.ninds.nih.gov	6001 Executive Boulevard Neuroscience Center, Room 3254, MSC-9537 Bethesda, MD 20892-9537 301-496-9231 301-402-0219 (fax)	6001 Executive Boulevard Neuroscience Center, Room 3307, MSC-9531 Bethesda, MD 20892-9531 301-496-9248 301-402-4370 (fax)
National Institute of Nursing Research (NINR) http://www.ninr.nih.gov	6701 Democracy Boulevard One Democracy Plaza, Suite 710, MSC-4870 Bethesda, MD 20892-4870 301-594-6869 301-402-4502 (fax)	6701 Democracy Boulevard One Democracy Plaza, Suite 710, MSC-4870 Bethesda, MD 20892-4870 301-402-7889 301-480-4969 (fax)
National Library of Medicine (NLM) http://www.nlm.nih.gov	6705 Rockledge Drive Rockledge I, Suite 301, MSC-7968 Bethesda, MD 20892-7968 301-496-4222 301-402-0421 (fax)	6705 Rockledge Drive Rockledge I, Suite 301, MSC-7968 Bethesda, MD 20892-7968 301-496-4621 301-402-0421 (fax)

20.1 OTHER NIH OFFICES

NIH Office	Address
Division of Grants Policy Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	6705 Rockledge Drive, Suite 350 Rockledge I, MSC-7974 Bethesda, MD 20892-7974 301-435-0949 301-435-3059 (fax) E-mail: GrantsPolicy@mail.nih.gov
Division of Grants Compliance and Oversight Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	6705 Rockledge Drive, Suite 350 Rockledge I, MSC-7974 Bethesda, MD 20892-7974 301-435-0938 301-435-3059 (fax) E-mail: GrantsCompliance@mail.nih.gov Financial Conflicts of Interest E-mail: FCOICompliance@mail.nih.gov
Division of Extramural Inventions and Technology Resources Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research	6705 Rockledge Drive, Suite 310 Rockledge I, MSC-7980 Bethesda, MD 20892-7980 301-435-1986 301-480-0272 (fax) E-mail: Edison@nih.gov Inventions@nih.gov
Division of Communications and Outreach Office of Planning and Communication Office of Extramural Research Grants Information (general grants information)	6705 Rockledge Drive, Suite 5040 301-435-0714 E-mail: GrantsInfo@nih.gov https://grants.nih.gov/grants/oer.htm
Division of Central Grants Processing Office of Extramural Research	Centralized Mailing Address for hard copy submission of documents: NIH Closeout Center Division of Central Grants Processing, OER 6705 Rockledge Drive, RM 5016 Bethesda, MD 20892 (for regular or U.S. Postal Service Express mail) Bethesda, MD 20817 (for other courier/express deliveries only) E-mail: NIHCloseoutCenter@mail.nih.gov

NIH Office	Address
Office of Extramural Programs Office of Extramural Research E-mail: OEPMailbox@mail.nih.gov https://grants.nih.gov/aboutoer/oer_offices/oep.htm	1. For issues regarding NRSA Payback contact: Division of Loan Repayment NRSA Payback Service Center 6011 Executive Blvd., Room 206 Bethesda, MD 20892-7650 Phone Number: 1-866-298-9371 E-mail: nrsapaybackcenter@mail.nih.gov 2. For issues regarding Peer Review, Human Research Protections and Research Training contact: Division of Scientific Programs 6705 Rockledge 1, Room 3520Bethesda, MD 20892-7982 301-435-1418 301-480-0146 (fax) 3. For issues regarding SBIR/STTR Programs, AREA grants and conference grants contact: Division of Special Programs 6705 Rockledge 1, Room 3522 Bethesda, MD 20892-7982 301-435-2688 301-480-0146 (fax) Web sites for these topic areas can be found from the main OER Grants site: http://grants.nih.gov/grants/oer.htm
Office of Laboratory Animal Welfare (OLAW) Office of Extramural Research https://olaw.nih.gov/	6700 Rockledge Drive, Suite 2500 MSC-6910 Bethesda, MD 20892 301-496-7163 301-480-3394 (fax) E-mail: OLAW@mail.nih.gov

NIH Office	Address
Center for Scientific Review (CSR) https://public.csr.nih.gov/	Division of Receipt and Referral 6701 Rockledge Drive Rockledge II, MSC-7768 Bethesda, MD 20892-7768 301-435-1115
Center for Scientific Review (CSR) https://public.csr.nih.gov/	For submission of paper competing applications: Center for Scientific Review National Institutes of Health Suite 1040 6701 Rockledge Drive, MSC-7710 Bethesda, MD 20892-7710 (zip code for applications sent by USPS regular or Express mail) Bethesda, MD 20817 (zip code for applications sent using a courier service)
Biosafety, Biosecurity, and Emerging Biotechnology Policy Division Office of Science Policy https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/	6705 Rockledge Drive Suite 750, MSC-7985 Bethesda, MD 20892-7985 301-496-9838 E-mail: SciencePolicy@od.nih.gov
Office of Intramural Research (OIR) https://oir.nih.gov/	1 Center Drive Building 1, Room 160 Bethesda, MD 20892-0151 301-496-1921 301-402-4273 (fax)

NIH Office	Address
Office of Financial Management (OFM) http://ofm.od.nih.gov	Office of Financial Management 2115 East Jefferson Street Bethesda, MD 20892-8500 301-402-9123 301-402-4934 (fax) Electronic submission of Financial Status Reports: https://commons.era.nih.gov/commons
Division of Financial Advisory Services (DFAS) Office of Acquisition Management and Policy (OAMP) https://oamp.od.nih.gov/	6011 Executive Boulevard, Room 549C MSC-7663 Bethesda, MD 20892-7663 301-496-4401 301-402-0177 (fax)
Office of Management Assessment (OMA) https://oma.od.nih.gov/DPI/Pages/Home.aspx	Report allegations of non-criminal misuse of grant funds to: Division of Program Integrity 6011 Executive Boulevard, Suite 601, MSC-7669 Bethesda, MD 20892-7669 301-496-5586 301-480-1204 (fax)

20.2 OTHER HHS GOVERNMENT OFFICES

Office	Address
Advisory Council on Historic Preservation (ACHP) http://www.achp.gov	1100 Pennsylvania Avenue NW Washington, DC 20004 202-606-8503
Office of the Inspector General (OIG) http://www.oig.hhs.gov	Report allegations of criminal offenses to: Office of Inspector General Department of Health and Human Services Attn: HOTLINE PO Box 23489 Washington, DC 20026 1-800-HHS-TIPS (1-800-447-8477) E-mail: HHSTips@oig.hhs.gov http://oig.hhs.gov/fraud/hotline TTY: 1-800-377-4950 Fax: 1-800-223-8164
Office of the Inspector General (OIG) http://www.oig.hhs.gov	Questions concerning audit requirements: HHS National External Audit Review Center Office of Audit Services 1100 Walnut St, Suite 850 Kansas City, Missouri 64106 1-800-732-0679 (voice) 816-426-7720 (voice) 816-426-7745 (fax) http://harvester.census.gov/facweb
Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp/	The Tower Building 1101 Wootton Parkway, Suite 200 Rockville, MD 20852 240-453-6900 Toll Free within the U.S. 1-866-447-4777 E-mail: OHRP@hhs.gov
Office of Research Integrity (ORI) https://ori.hhs.gov/	The Tower Building 1101 Wootton Parkway, Suite 750 Rockville, MD 20852 240-453-8400 E-mail: askori@hhs.gov

Office	Address
Departmental Appeals Board (DAB) https://www.hhs.gov/about/agencies/dab/index.html	330 Independence Avenue, SW Cohen Building, Room G-644, MS 6127 Washington, DC 20201 202-565-0200
Office for Civil Rights (OCR) http://www.hhs.gov/ocr	Headquarters 200 Independence Avenue, SW Hubert H. Humphrey Building Bldg., Room 509 F Washington, DC 20201 1-800-368-1019
Program Support Center (PSC), Payment Management Services (PMS) https://www.psc.gov/	P.O. Box 6021 Rockville, MD 20852 1-877-614-5533 (PMS Help Desk) 301-443-8362 (fax) E-mail: PMSSupport@psc.gov Payment Management System: https://pms.psc.gov/
Division of Cost Allocation (DCA) http://rates.psc.gov/	Mid-Atlantic Field Office (Services Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia and West Virginia) 330 Independence Avenue, S.W. Cohen Building, Room 10-67 Washington, DC 20201 202-401-2808 http://rates.psc.gov/fms/dca/midatlantic.html
Division of Cost Allocation (DCA) http://rates.psc.gov/	Northeastern Field Office (Services Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, the Virgin Islands, Canada and Europe) 26 Federal Plaza Room 41-122 New York, NY 10278 212-264-2069 http://rates.psc.gov/fms/dca/northeastern.html

Office	Address
Division of Cost Allocation (DCA) http://rates.psc.gov/	Central States Field Office (Services Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas and Wisconsin) 1301 Young Street Room 732 Dallas, TX 75202 214-767-3261 http://rates.psc.gov/fms/dca/central.html
Division of Cost Allocation (DCA) http://rates.psc.gov/	Western Field Office (Services Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, Australia, and Asia) 90 7th Street Suite 4-600 San Francisco, CA 94103-6705 415-437-7820 http://rates.psc.gov/fms/dca/western.html
Federal Audit Clearinghouse (Single Audit Reports)	4700 Silver Hill Road Suitland, MD 20746 Questions: 866-306-8779 govs.fac.ides@census.gov Online submission: Form SF-SAC and Single Audit reporting package must be submitted on line using the Internet Data Entry System (IDES) found at https://harvester.census.gov/facweb