U.S. Department of Health and Human Services
Public Health Service

SF424 (R&R) SBIR/STTR Application Guide for NIH and Other PHS Agencies

A guide developed and maintained by NIH for preparing and submitting SBIR/STTR applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)*

Forms Version C application packages

Updated November 25, 2015

*Use for due dates on and between January 25, 2016 and May 24, 2016. For due dates on or before January 24, 2016, use the previous guide, updated November 25, 2014.

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PART I

Instructions for Preparing and Submitting an Application

1. Foreword

Forms Version C Application Guide —Revised November 25, 2015

This application guide includes changes to the SF424 Research & Related (R&R) form C instructions necessitated by the OMB renewal and Grants.gov's subsequent release of updated forms in June 2013. Changes have also been made to various PHS 398 instructions necessitated by the OMB renewal in October 2015. Parts II (Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan and Human Subjects Research Policy) and III (Policies, Assurances, Definitions, and Other Information) of the previous version of the application guide remain a stand-alone document titled, "Supplemental Grant Application Instructions."

Modifications include the following:

Creating PDFs for Text Attachments

- Removed outdated language on Grants.gov PDF Download Software page.

Process for Application Submission via Grants.gov

- Changed "receipt date" to "due date" throughout this guide.
- Changed "submission date" to "due date" throughout this guide.

SF424 (R&R) Forms

SF 424 (R&R) Form

- Cover letter should contain a statement if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy.

SF 424 (R&R) Other Project Information Form

- Inter-institutional Assurance from OLAW required if the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance.
- Authentication of Key Biological and/or Chemical Resources added as an Other Attachment for Research applications.

PHS 398 Forms

PHS 398 Research Plan Form

- Added language regarding scientific premise, sex as a biological variable, and human subjects to the research plan attachment.
- For renewal and revision applications, previous participant enrollment information needed for any studies meeting the NIH definition of clinical research should be included in the research plan attachment.
- Vertebrate animals section revised.

For additional details on all the changes noted above, see NIH Guide Notice NOT-OD-16-004.

Notes

This application guide contains instructions and other useful information for preparing SBIR/STTR grant applications to the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies for:

Small Business Innovation Research (SBIR) Grants

Small Business Technology Transfer (STTR) Grants

This application guide is used as a companion document to the SF424 Research and Related (R&R) application forms. In addition to the SF424 (R&R) forms, applications to NIH and other PHS agencies will include agency-specific forms, titled "PHS 398." These PHS 398 forms were developed to continue the collection of agency-specific data required for a complete application. While these agency-specific forms are not identical to the PHS 398 application form pages, the PHS 398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) forms. A complete SBIR/STTR application to NIH and other PHS agencies will include SF424 (R&R) forms and PHS 398 forms. Instructions for all application forms, SF424 (R&R) and PHS 398, are found in this document.

The use of these forms also involves electronic submission of completed applications through Grants.gov. Specific Funding Opportunity Announcements (FOAs) will clearly indicate which forms and submission process an applicant should use. NIH will continue to use Requests for Applications (RFAs) and Program Announcements (PAs) as categories of FOAs. See Section 2.4.2 for definitions.

For purposes of this document, any references to "NIH" may also mean "NIH and other PHS agencies" such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Administration for Children and Families (ACF).

1.1 Application Guide Format

This application guide is organized into three distinct parts:

Part I: **Instructions for Preparing and Submitting the Application.** Part I includes specific instructions for completing the application forms as well as information on electronically submitting applications through Grants.gov.

Parts II and III are incorporated into this application guide by reference. They are in a separate document titled "Supplemental Instructions."

Part II: **Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan and Human Subjects Research Policy.** Part II is to be used if your proposed research will involve human subjects. These instructions assist in determining whether human subjects are involved and include scenarios and detailed instructions for completing the PHS 398 Research Plan form.

Part III: **Policies, Assurances, Definitions, and Other Information.** Part III includes information on policies, assurances, definitions, and other information relating to submission of applications to the PHS. Applicants should refer to this document as well as the

instructional materials, Grants Information (GrantsInfo), and the relevant Grants Policy Statement for additional sources of information. The *NIH Grants Policy Statement* applies to all NIH awardees; other PHS agencies use the *HHS Grants Policy Statement*.

1.2 NIH Extramural Research and Research Training Programs

The NIH Office of Extramural Research Grants homepage (http://grants.nih.gov/grants/oer.htm) provides an array of helpful information. Applicants are encouraged to bookmark this site and visit it often.

The Division of Communications and Outreach (DCO) is the central source for general information about NIH extramural research and research training programs, funding activity codes, the peer review system, and application procedures. Grants Information (GrantsInfo) is a communication service within the DCO. Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by e-mailing your request to: GrantsInfo@nih.gov or by calling (301) 435-0714.

1.3 Program Guidelines

1.3.1 Three-Phase Program

Both the SBIR and STTR programs are structured in three phases, the first two of which are supported using SBIR/STTR funds. The stated Phase I and Phase II award levels and project periods are statutory guidelines, not ceilings. Therefore, applicants are encouraged to propose a budget and project duration period that is reasonable and appropriate for completion of the research project.

Deviations from the indicated statutory award amount and project period guidelines are acceptable, but must be well justified and should be discussed with NIH Program Staff *prior to submission* of the application. (CDC, FDA, and ACF do not make awards greater than the stated guidelines.) The budgets of SBIR and STTR applications will be evaluated to assess the appropriateness of the budget to the timeliness of the research goals and may be reduced on a case-by-case basis as recommended by peer reviewers, Institute/Center Advisory Board/Council, or program staff. When making awards, NIH reserves the right to withhold or reduce grant funding on applications at any ranking based on program priority.

Funding levels for projects are determined through the combined interaction among peer review, grants management, program, budget, and other Institute and/or Centers (IC) staff. These levels are based on allowable costs that are consistent with the principles of sound cost management and in consideration of IC priorities, constraints on the growth of average grant costs, and the availability of funds.

Phase I. The objective of Phase I is to establish the technical/scientific merit and feasibility of the proposed R/R&D efforts. *Preliminary data may be included but are not required.* The application

should concentrate on R/R&D efforts that will significantly contribute to proving the scientific or technical feasibility of the approach or concept that would be a prerequisite to further support in Phase II.

SBIR Phase I awards normally may not exceed $150,000 total (direct costs, facilities and administrative (F&A)/indirect costs, and fee) for a period normally not to exceed 6 months. STTR Phase I awards normally may not exceed $150,000 total for a period of 1 year.

Phase II. The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.

All Phase II, Direct Phase II and Fast-Track applications must include a succinct Commercialization Plan. Specific details for preparing this section are described in Section 4.9 of this Application Guide.

SBIR Phase II awards normally may not exceed $1,000,000 total (direct costs, F&A/indirect costs, and fee) for a period normally not to exceed 2 years. STTR Phase II awards normally may not exceed $1,000,000 total (direct costs, F&A/indirect costs, and fee) for a period normally not to exceed 2 years.

According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II, a hard cap). As written in the statute and under appropriate circumstances, NIH can apply for a waiver from SBA to issue an award exceeding $225,000 for Phase I or $1,500,000 for Phase II, if this hard 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. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

Unless the Funding Opportunity Announcement (FOA) states otherwise, only Phase I awardees are eligible to apply for and obtain Phase II funding. Awardees identified via a "successor-in-interest" or "novated" or similarly-revised funding agreement, or those that have reorganized with the same key staff, regardless of whether they have been assigned a different tax identification number, are eligible to apply for Phase II funding. Agencies may require the original awardee to relinquish its rights and interests in an SBIR/STTR project in favor of another applicant as a condition for that applicant's eligibility to participate in the SBIR/STTR program for that project.

Only one new Phase II award may be made per single Phase I SBIR/ STTR project.

You may submit a Phase II or IIB application either before or after expiration of the Phase I or II budget period respectively, unless you elect to submit a Phase I and Phase II application concurrently under the Fast-Track procedure. *To maintain eligibility to seek Phase II or IIB support, a Phase I grantee organization should submit a Phase II or IIB application within the first six due dates following the expiration of the Phase I or II budget period respectively.*

Phase III. An objective of the SBIR/STTR program is to increase private sector commercialization of innovations derived from Federal R/R&D. During Phase III, the small

business concern (SBC) is to pursue commercialization with non-SBIR/STTR funds (either Federal or non-Federal). In some Federal agencies, Phase III may involve follow-on, non-SBIR/STTR funded R&D, or production contracts for products or processes intended for use by the U.S. Government.

The competition for SBIR/STTR Phase I and Phase II awards satisfies any competition requirement of the Armed Services Procurement Act, the Federal Property and Administrative Services Act, and the Competition in Contracting Act. Therefore, an agency that wishes to fund an SBIR/STTR Phase III project is not required to conduct another competition in order to satisfy those statutory provisions. As a result, in conducting actions relative to a Phase III SBIR/STTR award, it is sufficient to state for purposes of a Justification and Approval pursuant to FAR 6.302-5 that the project is an SBIR/STTR Phase III award that is derived from, extends, or logically concludes efforts performed under prior SBIR/STTR funding agreements and is authorized under 10 U.S.C. 2304(b)(2) or 41 U.S.C. 253(b)(2).

NIH SBIR/STTR applicants may now 'switch' programs at Phase II or Phase IIB to any active NIH SBIR/STTR solicitation.

This means that:

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 must use the correct program specific FOA and follow the program rules and guidelines within if they intent to switch programs. Applicants are **strongly advised** to discuss this option with their program officer well in advance of any due date.

1.3.2 Fast-Track Applications

CDC, FDA, and ACF do not accept Fast-Track applications.

The NIH Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. Fast-Track incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together. The Specific Aims section of the Phase I portion of a Fast-Track must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II work. In addition, as is required for all Phase II applications, the Phase II portion of a Fast-Track application must present a Commercialization Plan (maximum 12 pages) that addresses specific points (see Section 4.8).

The Fast-Track application will receive a single rating for the entire proposed project (i.e., it will receive a numerical score or it will receive an "unscored" designation).

Below are general instructions for preparing NIH SBIR/STTR Fast-Track applications. More specific instructions are provided in Sections 4 and 5 of this application guide.

- Follow the instructions as provided through Section 3, using the Grant Application Package.
- Use the forms in Section 4.6, R&R Budget Form: Complete Budget Period 1 for Phase I; complete Budget Periods 2 and 3 (or more, if appropriate) for Phase II;
- Prepare the Research Strategy in accordance with Section 5.4, Research Plan Form, using the PHS 398 Research Plan for items 2-3 in each Phase (Phase I and Phase II plans must be contained within 12 pages).
- Identify the application as "Fast-Track" at the beginning of the "Specific Aims" portion of the PHS 398 Research Plan.
- Under the heading "Phase I Segment," follow the instructions for the remainder of the application as provided in the Research Plan Form.
- Upon completion of all the requirements for Phase I, use the heading "Phase II Segment" and repeat the process for that portion of the proposed project.

Phase I and Phase II are considered separate funding agreements under the Fast-Track Initiative. Therefore, Phase I Fast-Track awardees must recertify that they meet all of the eligibility criteria for an SBIR or STTR award prior to issuance of the Phase II award.

1.3.3 Supplemental Applications

Under special circumstances, requests for supplemental funds to existing NIH SBIR/STTR grants or requests for an extension of the period of support with funds may be considered. *(The awarding of supplemental funds applies to NIH ONLY, as CDC, FDA, and ACF do not make awards greater than the stated guidelines.)* See Section 2.8.

1.3.4 SBIR/STTR Program Eligibility

Each applicant submitting an SBIR/STTR grant application must qualify as a small business concern (SBC) *at the time of award*. The following sections provide more details about these eligibility criteria.

SBA released the revised, final size rule on December 27, 2012, with a 30-day implementation window effective January 28, 2013.

SBCs that are majority-owned by multiple venture capital operating companies (VCOCs), hedge funds or private equity firms are NOW eligible to apply to the NIH SBIR program at this time for any NIH SBIR funding opportunity announcement (FOA) issued after January 28, 2013. As of July 10, 2014, CDC will now accept SBIR applications from VC-owned SBCs in response to NEW SBIR solicitations issued going forward. Small business concerns that are more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these are NOT eligible to apply to the FDA and ACF SBIR program and to the NIH STTR program.

NIH has many SBIR and STTR FOAs available for the community, many of which were issued prior to January 28, 2013. Applicants are advised to read FOAs very carefully, as eligibility and budget requirements may differ, depending on when the FOA was issued. Applicants are required to follow the guidance and instructions within the FOA they choose to apply for. As such, the eligibility requirements for small business concerns will depend on whether the FOA was issued prior or after January 28, 2013 as listed below.

1.3.4.1 Organizational Criteria

SBIR Program

For SBIR FOAs issued prior to January 28, 2013:

Only United States small business concerns (SBCs) are eligible to submit SBIR applications. A small business concern is one that, on the date of award for both Phase I and Phase II funding agreements:

1. Is 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 or labor;
2. Is 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 can be no more than 49 percent participation by foreign business entities in the joint venture;
3. Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States; and
4. Has, including its affiliates, not more than 500 employees.

FOR SBIR FOAs issued after January 28, 2013:

Only United States small business concerns (SBCs) are eligible to submit applications for this opportunity. A small business concern is one that, at the time of award of Phase I and Phase II, meets *all* of the following criteria:

1. Is 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 or labor;
2. Is 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;

3. 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. NIH and CDC only. 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 3 (i) or 3 (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 proposal requirements.
4. Has, including its affiliates, not more than 500 employees.
   i. **NIH and CDC only**. If the concern is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these falls under 3 (ii) or 3 (iii) above, see Section IV. Application and Submission Information in the SBIR FOA for additional instructions regarding required application certification.

See 4.4 Other Project Information Form instructions for additional requirements for small business concerns that are more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms.

STTR Program

For STTR FOAs issued prior to January 28, 2013:

Only United States small business concerns (SBCs) are eligible to submit STTR applications. A small business concern is one that, on the date of award for both Phase I and Phase II funding agreements:

1. Is 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 or labor;
2. Is 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 can be no more than 49 percent participation by foreign business entities in the joint venture;
3. Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States; and
4. Has, including its affiliates, not more than 500 employees.

FOR STTR FOAs issued after January 28, 2013:

Only United States small business concerns (SBCs) are eligible to submit applications for this opportunity. A small business concern is one that, at the time of award of Phase I and Phase II, meets *all* of the following criteria:

1. Is 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 or labor;
2. Is 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;
3. (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
4. (ii) Be a joint venture in which each entity to the joint venture must meet the requirements set forth in paragraph 3 (i) 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 proposal requirements. Has, including its affiliates, not more than 500 employees.

SBIR and STTR

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.

One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees and/or other facilities (e.g., laboratory space). Access to special facilities or equipment in another organization is permitted (as in cases where the awardee organization has entered into a subcontractual agreement with another organization for a specific, limited portion of the research project). *However, research space occupied by an SBIR awardee organization must be space that is available to and under the control of the SBIR awardee for the conduct of its portion of the proposed project.*

Title 13 CFR 121.3 also states that control or the power to control exists when “key employees of one concern organize a new concern ... and serve as its officers, directors, principal stockholders, and/or key employees, and one concern is furnishing or will furnish the other concern with subcontracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise.” Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether such sharing constitutes control or the power to control.

For purposes of the SBIR and STTR program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the

awardee. This is consistent with SBA's size regulations, 13 CFR 121.106 – Small Business Size Regulations.

Note regarding affiliation arising under stock options, convertible securities, and agreements to merge: In determining size, SBA considers stock options, convertible securities, and agreements to merge (including agreements in principle) to have a present effect on the power to control a concern. SBA treats such options, convertible securities, and agreements as though the rights granted have been exercised. See http://edocket.access.gpo.gov/cfr_2005/janqtr/pdf/13cfr121.103.pdf.

If an Employee Stock Ownership Plan owns all or part of the concern, each stock trustee and plan member is considered an owner.

If a trust owns all or part of the concern, each trustee and trust beneficiary is considered an owner.

All SBIR and STTR grant applications will be examined with the above eligibility considerations in mind. 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.

Note: An applicant organization that has been determined previously by SBA to be "other than small" for a size standard of not more than 500 employees or for purposes of the SBIR/STTR program, the organization must be recertified by the SBA prior to any future SBIR/STTR awards

1.4 Interactions with PHS Staff

Applicants are **strongly encouraged** to communicate with PHS staff throughout the entire application, review and award process. Web site addresses and staff phone numbers of relevant NIH awarding components and other PHS agencies can be found at this website https://sbir.nih.gov/engage/ic-contacts.

More detailed information on each of the NIH awarding components, as well as the CDC, the FDA, ACF, and their research interests are available electronically on the home pages cited above and in the NIH, CDC, FDA, and ACF Program Descriptions and Research Topics and in the NIH, CDC, FDA, and ACF Program Descriptions and Research Topics of the SBIR and STTR funding opportunity announcements.

Before Submission

Applicants are strongly encouraged to contact NIH/CDC/FDA/ACF staff with their questions before submitting an application.

Contact GrantsInfo and/or the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH:

- To identify Institutes/Centers (ICs) at NIH or other non-NIH agencies and/or a Scientific Review Group (SRG) that might be appropriate for your application. N**ote: requests for assignment to an Institute/Center and/or an SRG may be made in the SF424 (R&R)** Form **in the** Cover Letter **attachment at the time of application submission**.
- To learn about grant programs.
- To receive advice on preparing and submitting an application (e.g., format, structure).

Contact program staff in the relevant awarding component:

- To determine whether your proposed application topic would fit into the NIH IC's or other non-NIH agency's programmatic area.
- To learn about programmatic areas of interest to the IC or other non-NIH agencies.
- To find out about requesting an assignment to an IC.
- To discuss whether you should respond to an RFA.

Contact Scientific Review Officers in the CSR to discuss requesting assignment to a CSR SRG.

After Submission

If the initial assignment to an IC or SRG seems inappropriate, the Program Director/Principal Investigator (PD/PI) may request reassignment. Such requests should be made in writing to:

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Suite 2030, MSC 7720
Bethesda, MD 20892-7720

Fax requests (301-480-1987) are also acceptable.

Although these requests will be carefully considered, the final determination will be made by the PHS agency.

Applicants must never contact reviewers regarding their applications because discussion of the scientific content of an application or an attempt to influence review outcomes will create serious breaches of confidentiality in the review process. Reviewers are required to notify the Scientific Review Officer if they are contacted by an applicant. Communication by the applicant to a reviewer may delay the review or result in the return of the application without review.

After Assignment

Contact your Scientific Review Officer to discuss the review assignment, to request permission to send additional/corrective materials, and/or to discuss any review concerns (e.g., expertise needed on your SRG, conflicts, reviewers that may have bias).

After Peer Review

Feedback to applicants is very important. Once the PD/PI reviews the Summary Statement in the eRA Commons (paper copies of the Peer Review Outcome Letter and Summary Statement will not be mailed to the PI. Electronic copies may be accessed through the eRA Commons), the appropriate awarding component program official noted in the Summary Statement may be contacted:

- To discuss the review outcome of the application and obtain guidance.
- To get feedback and answers to any questions about the Summary Statement.
- To find out the meaning of a numerical designation pertaining to human subjects or vertebrate animals in the Summary Statement.
- To find out the funding status of an application.

1.5 Grants Policy Statements

- The *NIH Grants Policy Statement* serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of NIH awards.
- The *HHS Grants Policy Statement* serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of grant awards from other PHS agencies, excluding NIH awards.

1.6 References

Applicants New to NIH: Getting Started

http://grants.nih.gov/grants/useful_links.htm

Award Information and Data

http://report.nih.gov/index.aspx

NIH Research Portfolio Online Reporting Tool (RePORT)

Contact Information for an NIH Staff Person

http://ned.nih.gov

NIH locator: (301) 496-4000

Applying Electronically

For additional information on the electronic submission process, including self-help resources, training material and answers to frequently asked questions, see:

http://grants.nih.gov/grants/ElectronicReceipt/index.htm

eRA Commons

https://commons.era.nih.gov/commons/index.jsp

Institutions and PD/PIs are required to register with the eRA Commons. Registered PD/PIs can check assignment/contact information, review outcome, and other important information. For more details on Commons registration, see Section 2.2.2.

Telephone: 1-866-504-9552 (toll-free) or 301-402-7469. Business hours are M-F 7am-8pm Eastern Time.

eRA Service Desk: http://era.nih.gov/help/

Grant Writing Tips and Sample Applications

http://grants.nih.gov/grants/grant_tips.htm

http://grants.nih.gov/grants/grants_process.htm

Grants Information

http://grants.nih.gov/grants/giwelcome.htm

E-mail: GrantsInfo@nih.gov

Telephone: (301) 435-0714; (301) 451-5936 (TTY)

Grants.gov User Guide

The Grants.gov User Guide is a comprehensive reference to information about Grants.gov. Applicants can download the User Guide at the following address: http://www.grants.gov/help/html/help/index.htm

NIH Grants and Funding Help Page

http://grants.nih.gov/support/index.html

This site provides a self-help wizard to guide inquiries to the correct NIH website for additional information on specific topics.

NIH Office of Extramural Research Human Subjects Website

http://grants.nih.gov/grants/policy/hs/index.htm

This site provides, in one place, HHS and NIH requirements and resources for the extramural community involved in human subjects research.

Office for Human Research Protections (Department of Health and Human Services)

http://www.hhs.gov/ohrp

Information about human subject protections, Institutional Review Boards, and Federal Wide Assurances

Telephone: 1-866-447-4777 or (301) 496-7005

Office of Laboratory Animal Welfare (OLAW)

http://olaw.nih.gov

Information about animal welfare policy requirements, Institutional Animal Care and Use Committees (IACUC), and Animal Welfare Assurances

Telephone: (301) 496-7163

Receipt/Referral of an Application

https://grants.nih.gov/grants/receipt_referral.htm

Division of Receipt and Referral

Center for Scientific Review

Telephone: (301) 435-0715

Fax: (301) 480-1987

Email: csrdrr@mail.nih.gov

SBA Company Registry

http://sbir.gov/registration

New requirement for all SBIR/STTR applicants. (Questions regarding required registration at the SBA Company Registry and for technical questions or issues)

Telephone: (571) 306-5201

Website to Email: http://sbir.gov/feedback?type=reg

Small Business Administration SBIR/STTR Website

http://sbir.gov

Specific Application: Before Review

Telephone or e-mail the Scientific Review Officer identified for the application in the eRA Commons.

Specific Application: Post Review

Telephone or e-mail the NIH Program Official named in the Summary Statement for the application.

1.6.1 Other Resources

FDA Resources and Useful Web Sites

The Food and Drug Administration offers various types of information to small businesses engaged in research projects that will ultimately require FDA approval. This information could be valuable in formulating research aims designed for this purpose, especially those in later stages of development (e.g., Investigational New Drug [IND] filing).

Small Business Assistance: http://www.fda.gov/cder/about/smallbiz/default.htm

Drug Approval Application Process: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/default.htm

Center for Drug Evaluation and Research (CDER): http://www.fda.gov/cder/

Center for Biologics Evaluation and Research (CBER): http://www.fda.gov/cber/

Center for Devices and Radiological Health (CDRH): http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/default.htm

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): http://www.ich.org

Guidance Documents: http://www.fda.gov/cder/guidance

Applicants should be aware that not all information in these documents apply to drugs intended for use in patients with serious and life-threatening diseases (e.g., for refractory metastatic cancers).

Drug development, drug review, and postmarketing activities:

The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective. FDA Consumer magazine article.

From Test Tube to Patient: Improving Health Through Human Drugs. In-depth review of drug development and post-marketing activities.

New Drug Development in the United States. Online seminar provides healthcare professionals with an overview of FDA's role in the new drug development process.

SBIR/STTR LISTSERV

To get timely information about the SBIR/STTR programs, send an e-mail to LISTSERV@LIST.NIH.GOV with the following text in the message body: subscribe SBIR-STTR <your name> (e.g., subscribe SBIR-STTR Jane Doe). (The LISTSERV will retrieve your e-mail address from the "From:" section of your e-mail message.)

1.7 Authorization

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Sections 301(a) and 487 of the PHS Act, as amended (42 U.S.C. 241a and 42 U.S.C. 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the ability of the PHS to review an application and to monitor the grantee's performance.

SBIR: This request for SBIR information is issued pursuant to the authority contained in P.L. 112-81 which authorizes the program through September 30, 2017. Government-wide SBIR policy is provided by the Small Business Administration (SBA) through its SBIR Program Policy Directive. Federal agencies with extramural research and development budgets over $100 million are required to administer SBIR programs using an annual set-aside of 3.0% (FY 2016) for small companies to conduct innovative research or research and development (R/R&D) that has potential for commercialization and public benefit. Currently, 11 Federal agencies participate in the SBIR program: the Departments of Health and Human Services (HHS); Agriculture (USDA); Commerce (DOC); Defense (DOD); Education (ED); Energy (DOE); Homeland Security (DHS); Transportation (DOT); the Environmental Protection Agency (EPA); the National Aeronautics and Space Administration (NASA); and the National Science Foundation (NSF).

STTR: This request for STTR information is issued pursuant to the authority contained in P.L. 112-81 which authorizes the program through September 30, 2017. Government-wide STTR policy is provided by the SBA through its STTR Program Policy Directive.

Federal agencies with extramural R&D budgets over $1 billion annually are required to administer STTR programs using a set-aside of 0.45% (FY 2016). Currently, five Federal agencies participate in the STTR program: DoD, HHS, DOE, NASA, and NSF.

1.7.1 Collection of Personal Demographic Data

Federal agencies have a continuing commitment to monitor the operation of its review and award processes to detect, and deal appropriately with, any instances of real or apparent inequities. In addition, section 403 of the 2007 NIH Reform Act requires NIH to report to Congress specifically on postdoctoral individuals supported on research grants, and section 489 of the PHS Act requires NIH to perform a continuing assessment of research personnel needs. Personal demographic data on PD/PIs and those with a postdoctoral role is vital to comply with these requirements.

NIH collects personal data through the eRA Commons Personal Profile. The data is provided one-time by the individual through a secure, electronic system, is confidential, and is maintained under the Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." When completing the data entry in the Commons Personal Profile, the individual is responsible for providing true, accurate, and complete data. All analyses conducted on date of birth, citizenship, gender, race, ethnicity, disability, and/or disadvantaged background data will report aggregate statistical findings only and will not identify individuals. Declining to provide information does not affect consideration of an application; however, for some programs (e.g., Ruth L. Kirschstein National Research Service Awards and Research Career Development Awards) citizenship data is required to determine eligibility.

The PHS also requests the last four digits of the Social Security Number (SSN) for accurate identification of individuals and for management of PHS grant programs. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this portion of the SSN. The PHS requests the last four digits of the SSN under Section 301(a) and 487 of the PHS act as amended (42 U.S.C. 241a and U.S.C. 288).

1.8 Paperwork Burden

The PHS estimates that it will take approximately 22 hours to complete this application for a regular research project grant. This estimate excludes time for development of the scientific plan. Other items such as human subjects are cleared and accounted for separately and therefore are not part of the time estimate. An agency may not conduct or sponsor the collection of information unless it displays a currently valid OMB control number. Nor is a person required to respond to requests for the collection of information without this control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATT: PRA (0925-0001). Do not send applications to this address.

2. Process for Application Submission via Grants.gov

Application submission through Grants.gov involves several steps. Some of the steps need only be done one time. Others are ongoing steps that will be necessary for each application submission. Before beginning the application process, you are encouraged to review Grants.gov and all the resources available there.

2.1 Overview

All registrations require that applicants be issued a Dun and Bradstreet Universal Numbering System (DUNS) number. After obtaining a DUNS number, applicants can begin both System for Award Management (SAM) (formerly CCR) and eRA Commons registrations. The same DUNS number must be used for all registrations and on the grant application itself.

Note that all applicant and grantee organizations must complete and maintain an active entity registration in SAM which requires renewal at least annually. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Foreign organizations must obtain a NATO Commercial and Government Entity (NCAGE) Code (in lieu of a CAGE Code) in order to register in SAM. Use the SAM.gov "Manage Entity" function to maintain your entity registrations. See the Grants Registrations User Guide at http://www.sam.gov for additional information.

For additional information regarding maintaining an active SAM registration, please see NIH Guide Notice NOT-OD-11-004.

The following steps must be taken in order to submit a grant application through Grants.gov. Please be sure to complete all steps to ensure that NIH receives the application in a timely manner.

1. Register your organization at Grants.gov. (This is a one-time only registration process for all Federal agencies. However, an annual renewal of information provided to the System for Award Management (SAM) is necessary to retain active Grants.gov credentials. If your organization has already completed this step for any Federal agency submission, skip to step #2. If your organization has not completed this step, see Section 2.2 for more details.)
2. Register your organization and Program Director/Principal Investigator (PD/PI) in the eRA Commons. (This is a one-time only registration process. If your organization has already completed this step, skip to step #3. If your organization has not completed this step, see Section 2.2 for more details.)
3. Find a Funding Opportunity Announcement (FOA) using the NIH Guide for Grants and Contracts or Grants.gov's "Search Grants" . (See Section 2.4 for more details.) A complete list of SBIR/STTR FOAs is available on the NIH Small Business Funding Opportunities Web site.

4. Download the associated Application Package from Grants.gov. (Adobe Reader required for download. See Section 2.3.1 for more details.)
5. Complete the appropriate application forms, including all text and PDF attachments. Upload all attachments into the appropriate application form (See Section 2.6 for more details on the requirements for text (PDF) attachments).
6. Review the completed application through your own organizational review process.
7. Coordinate with an Authorized Organization Representative (AOR) at the applicant organization to submit the application by the date and time specified in the FOA. (**Keep a copy locally at the Applicant Organization/Institution.**)
8. Receive the Grants.gov tracking number.
9. After successfully passing Grants.gov and agency validation, receive the agency tracking number (accession number). **Note: Any errors encountered at Grants.gov or eRA Commons must be corrected in order to successfully complete your submission successfully.**
10. PD/PI and Signing Official (SO) must view the application in eRA Commons to ensure the assembled application correctly reflects their submission. (See Section 2.11 for detailed information.)

The following sections explain each step in more detail.

2.2 Registration Process

New/potential applicant organizations must have completed both Grants.gov and eRA Commons registrations in order to submit an application. Grants.gov and eRA Commons are distinct, one-time registrations which may be completed simultaneously. Each registration process is described below.

2.2.1 Grants.gov Registration

Grants.gov requires a **one-time** registration *by the applicant organization* in order to submit applications. Registration is not needed to download an application package or to prepare an application for submission. PD/PIs do not have to individually register in Grants.gov unless they also serve as the Authorized Organization Representative (AOR) for their institution/organization. If an applicant organization has already completed Grants.gov registration for another Federal agency, they can skip this section and focus on the eRA Commons registration steps noted below. For those applicant organizations still needing to register with Grants.gov, registration information can be found at the Grants.gov "Applicants" tab. While Grants.gov registration is a one-time only registration process, it does involve several steps and will take some time. Applicant organizations needing to complete this process are encouraged to **start early** allowing at least six (6) weeks to complete all the steps before actually submitting an application through Grants.gov.

The AOR is an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. This individual has the authority to sign grant applications and required certifications and/or assurances that are necessary to fulfill the requirements of the application process. Once this individual is registered, the organization can

then apply for any government funding opportunity listed in Grants.gov, including NIH and other PHS agencies grants.

Questions regarding Grants.gov registration should be directed to the Grants.gov Contact Center at telephone: 1-800-518-4726 or by e-mail at support@grants.gov. The Contact Center is available 24 hours a day, 7 days a week.

2.2.2 eRA Commons Registration

The applicant organization, all PD/PIs, all individuals with the role of project lead on multi-project applications, and individuals with the role of Sponsor on individual fellowship applications must also complete a **one-time** registration in the eRA Commons as a requirement for application submission. Individuals in other roles do not need an eRA Commons ID for application submission. However, if the application is funded, those individuals whose effort will be included in NIH progress reports must also have an eRA Commons ID. Access to the Commons is vital for all steps in the process after application submission. An organization, PD/PIs, and individuals in other roles that require an ID must be registered in the Commons in order to have access to electronic submission and retrieval of grant information, such as reviewing grant applications, institute/center assignments, review outcomes, and Summary Statements (access varies by type of role). Applicants must have an active DUNS number in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO), also known as the Authorized Organization Representative (AOR in Grants.gov), and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application. Institutional/organizational officials are responsible for registering PD/PIs and other individuals with a role in NIH progress reports in the eRA Commons. PD/PIs and other individuals should work with their AOR/SO to determine their institutional/organizational process for registration.

IMPORTANT: The eRA Commons registration process should be started at least six (6) weeks prior to the submittal date of a Grants.gov submission. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field of the Senior/Key Person Profile Form will prevent the successful submission of an electronic application to NIH.

2.2.2.1 Commons Registration for the Organization

Organizations may verify their current registration status by accessing the Commons Registered Organizations link at https://public.era.nih.gov/chl/public/search/index.jsp.

To register an Organization in the eRA Commons:

1. Complete the online Institution Registration Form at: https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp
2. Print and fax the registration page
    a. The Signing Official (SO) must sign, date and fax the registration to the number listed on the form

3. Signing Official must verify email address
    a. Once the registration is submitted electronically, email verification is sent and the SO must click the link to verify email
    b. The above steps must be completed before NIH can process the registration
    c. The SO will receive an "Approval" email from NIH
    d. The "Approval" email contains a link to information that you must verify as correct before the confirmation process is completed
4. Account Administrator (AA) receives user names and temporary passwords
    a. After the completion of the confirmation, the SO and AA will receive two emails that contain the user names and temporary password for the SO and AA accounts created during the registration process
5. Log into Commons
    a. The SO and AA log into Commons and administer additional accounts as needed
6. Affiliate your PD/PIs
    a. Your Principal Investigators must work with your organization to be registered in eRA Commons if they do not have an existing account. IF they have an account, you must affiliate it with your organization. Verify that you've selected the correct PI account!

For more information, see http://era.nih.gov/commons/faq_commons.cfm#II2

This registration is independent of Grants.gov and may be done at any time.

Organizational data elements, such as Institutional Profile Number (IPF), Entity Identification Number (e.g., 5555555555A5) and DUNS Number must be accurately identified. **Note the DUNS number must be included in the Institutional Profile for applications to be accepted. In addition, the DUNS number in the Institutional Profile must match that entered in the SF424 (R&R) Form in Section 5, Applicant Information.**

Since eRA has not required a DUNS number during eRA Commons registration, there are many accounts that do not contain valid information in this field. Prior to submission, the AOR/SO should verify that their organization's eRA Commons profile contains the valid DUNS number that will be used for the submission process. The SO has the ability to edit this field in the organization profile in Commons.

To confirm that your organization has a DUNS number or to find out if the DUNS number you have matches the one in Commons, access the List of Grantee Organizations Registered in eRA Commons https://public.era.nih.gov/chl/public/search/index.jsp. This listing of grantee organizations registered in Commons and their DUNS numbers can be accessed without logging into Commons.

2.2.2.2 Commons Registration for the Program Directors/Principal Investigators (PD/PIs)

Once the organization is registered in the Commons, individuals can then be registered.

The individual(s) designated as PD/PI(s) on the application must be registered in the Commons. A PD/PI must hold a PI account and be affiliated with the application organization. **The initial registration must be done by an Authorized Organization Representative (AOR) who has the SO role in Commons**, or other authorized accounts administrator 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. If submitting an application reflecting Multiple PD/PIs, the individual designated as the contact PI must be affiliated with the applicant organization.

To register PD/PIs in the Commons, refer to(http://era.nih.gov/commons/user_guide.cfm). For applications reflecting Multiple PD/PIs, all such individuals must be assigned the PI role, even those at organizations other than the applicant organization.

Once a PD/PI has received e-mail confirming his/her registration within the Commons, the PD/PI must verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. The PD/PI should update, as needed, data elements such as first name, middle initial, last name, prefix and/or suffix to PD/PI name (including all embedded punctuation), e-mail, phone, fax, street address, city, state, country, zip and degrees earned. These data must contain the most recent information in order for the application to be processed accurately.

Both PD/PI and SO need separate accounts in Commons since each role enables different features within eRA Commons. For example, an SO can reject a submitted application to prevent it from being sent on to agency staff. A PI has access to review outcome information (scores and summary statement). If you are the SO for your organization as well as a PD/PI of the grant, you will need two separate accounts with different user names – one with SO authority and one with PI authority. When an organization is registered, an SO account is created. Log on to the account with the SO authority role and create another account with PI authority.

For additional information on how to prepare for electronic submission, see: http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm.

2.2.2.3 Commons Registration for Other Individuals Participating in NIH Progress Reports

Any individual with an Undergraduate, Graduate Student, and/or Postdoctoral Role who participates in an 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 will be required effective with RPRRs submitted October 2014 and beyond. The Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; grantees are encouraged to begin registering these individuals now.

See NOT-OD-14-129 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-129.html)

The Commons user name ID for other individuals is not required at the time of application submission, but will be required as part of the Non-Competing Continuation Progress Report (RPRR or PHS 2590).

For additional information on how to prepare for electronic submission, see: http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm.

The STTR applicant organization must officially affiliate the PD/PI with the small business concern in the Commons if the PD/PI is not an employee of the small business concern.

Following are the steps to affiliate a PD/PI to the applicant organization/institution:

1. PD/PI gives commons user ID and e-mail address to the administrator of the applicant organization/institution. (The e-mail address must be the one that is contained in the Personal Profile for the PI.)
2. Administrator logs into the Commons. (The Administrator can be the Signing Official, Administrative Official, or the Accounts Administrator.)
3. Administrator selects “Admin” tab and then “Accounts” tab and then “Manage Accounts” tab.
4. Administrator searches for the individual they wish to affiliate making sure the “Search outside your organization” box is checked.
5. Administrator clicks the “Create Affiliation: action link for the identified individual
6. Administrator provides the appropriate role and organization on the “Modify Account” screen and clicks “Save.”

See also

eRA Create Accounts

2.2.3 SBA Company Registration

All applicants to the SBIR and STTR programs **are required** to register at the SBA Company Registry prior to application submission and attach proof of registration. Completed registrations will receive a unique SBC Control ID and .pdf file. If applicants have previously registered, they are still required to attach proof of registration. The SBA Company Registry recommends verification with SAM, but a SAM account is not required to complete the registration. In order to be verified with SAM, your email address must match one of the contacts in SAM. If you are unsure what is listed in SAM for your company, you may verify the information on the SAM site. Confirmation of your company's DUNS is necessary to verify your email address in SAM.

Follow these steps listed below to register and attach proof of registration to your application:

1. Navigate to the SBA Company Registry.
2. If you are a previous SBIR/STTR awardee from any agency, search for your small business by Company Name, EIN/Tax ID, DUNS, or Existing SBIR/STTR Contract/Grant Number in the search fields provided. Identify your company and click "Proceed to Registration".
3. If you are a first time applicant, click the New to the SBIR Program? link on lower right of registry screen.
4. Fill out the required information on the "Basic Information" and "Eligibility Statement" screens.
5. Press "Complete Registration" on the lower right of the "Eligibility Statement" screen and follow all instructions.
6. Download and save your SBA registry PDF locally. The name will be in the format of SBC_123456789.pdf, where SBC_123456789 (9 digit number) is your firm's SBC Control ID. DO NOT CHANGE OR ALTER THE FILE NAME. Changing the file name may cause delays in the processing of your application.
7. When you are completing the application package, attach this SBA registry PDF as a separate file by clicking Add Attachments located to the right of Other Attachments on the "Research and Related Other Project Information" form.

For questions and for technical assistance concerning the SBA Company Registry, please contact the SBA at http://sbir.gov/feedback?type=reg.

SBA SBIR Website helpdesk: Telephone (571) 306-5201, M-F 9am-5pm (EST)

SBIR and STTR grant applications that do not have the SBA registry PDF uploaded to the correct section with the correct file title (both listed above) will receive an e-submission *Warning* message from eRA Commons upon grant submission. Your grant submission can proceed with this *Warning*.

2.3 Software Requirements

2.3.1 Adobe Reader

In order to access, complete and submit applications using Grants.gov's downloadable forms, applicants will need to download and install a compatible version of the Adobe Reader available at the Grants.gov website http://www.grants.gov/web/grants/support/technical-support/software/adobe-reader-compatibility.html.

For minimum system requirements and download instructions, please see the Grants.gov User Guide

2.3.2 Creating PDFs for Text Attachments

NIH and other PHS agencies require all text attachments to the SF424 (R&R) application forms to be submitted as PDF files.

Applicants should prepare text attachments using any word processing program (following the format requirements in Section 2.6) and then convert those files to PDF before attaching the files to the appropriate form in the application package. (The PDF format is used to preserve document

formatting.) Save all files with descriptive file names of 50 characters or less. Do not use the ampersand (&) character in file names. Use one space, (not two or more) between words or characters. Just like letters, a space counts as one character.

Note that all PDF attachments must be submitted as individual files. Although some software packages allow bundling of multiple PDFs into a single file, eRA systems cannot support "Bundling" or "Portfolio" features at this time. Use of these features may result in delays in the review of an application or an application not being reviewed.

It is recommended that, as much as possible, applicants avoid scanning text documents to produce the required PDFs. Instead, NIH recommends producing the documents electronically using text or word-processing software and then converting documents to PDF. Scanning paper documents, without the proper Optical Character Recognition (OCR) process, will hamper automated processing of your application for NIH analysis and reporting.

See additional information at NIH PDF Guidelines
http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm

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DISCLAIMER: References to software packages or Internet services neither constitute nor should be inferred to be an endorsement or recommendation of any product, service, or enterprise by the NIH or other PHS agencies, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

2.4 Funding Opportunities

Grants for health-related research and research training projects or activities make up the largest category of funding provided by the NIH Institutes/Centers (ICs) and other non-NIH agencies. Most applications for support are unsolicited and originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH. Research project grants are awarded to organizations/institutions on behalf of PD/PIs to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator. If the funding agency anticipates substantial program involvement during the conduct of the research, a cooperative agreement will be awarded, rather than a grant. The NIH typically awards grants and cooperative agreements for terms ranging from one to five years. Organizational/institutional sponsorship assures that the awardee organization will provide the facilities and the financial stability necessary to conduct the research, and be accountable for the funds. For a list and brief description of grant activity codes, see Supplemental Instructions Part III: Policies, Assurances, Definitions, and Other Information.

2.4.1 NIH Guide for Grants and Contracts

The NIH Guide for Grants and Contracts (http://grants.nih.gov/grants/guide), a weekly electronic publication, contains announcements about funding opportunities, such as Requests for Applications (RFAs) and Program Announcements (PAs), including Parent Announcements, from NIH and other PHS agencies. The NIH Guide also contains vital information about policies and procedures. To subscribe to the NIH Guide, visit http://grants.nih.gov/grants/guide/listserv.htm.

2.4.2 Funding Opportunity Announcements

To hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, an awarding component will encourage applications through the issuance of a PA to describe new, continuing, or expanded program interests, or issuance of an RFA inviting applications in a well-defined scientific area to accomplish a scientific purpose.

Definitions are as follows:

Parent Announcements: Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA). For applicants who wish to submit what were formerly termed "investigator-initiated" or "unsolicited" applications, NIH and other PHS agencies have developed Parent Announcements. 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. Additional information about, as well as links to published Parent Announcements, can be found at: http://grants.nih.gov/grants/guide/parent_announcements.htm.

Program Announcement (PA): 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 modifications 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. NIH may also make funds available through PARs (Program Announcements with special receipt, referral, and/or review considerations) and PASs (Program Announcements with set-aside funds).

Request for Applications (RFA): 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, and the application submission date(s). Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

PAs (including Parent Announcements) and RFAs are published in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide), the *Federal Register* (http://www.gpoaccess.gov/nara/index.html), and on Grants.gov under Grants.gov under Search Grants (http:/www.grants.gov/web/grants/search-grants.html). Read the announcement carefully for special instructions. The instructions in the announcement may differ from these general instructions, and the instructions in the announcement **always** supersede these general instructions. Each announcement published in the *NIH Guide for Grants and Contracts*, the *Federal Register*, Grants.gov Search Grants, or other public document contains contact information in addition to information specific to the announcement.

While individual announcements will continue to carry an announcement number reference to "PA" or "RFA", all announcements are "Funding Opportunity Announcements (FOAs)." This general term will be used to reference any type of funding announcement. NIH will continue to use the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

In reading any FOA in the NIH Guide for Grants and Contracts:

- A "Posted Date" refers to the date the FOA is posted on Grants.gov. An applicant can download the application package on that date and begin filling it out. However, the applicant has to wait until the FOA's "open date" to submit the application.
- An application can be submitted anytime between the "open date" and the "application due date(s)" noted for AIDS and non-AIDS applications. (Standard dates may apply; check http://grants.nih.gov/grants/funding/submissionschedule.htm for details.)
- When you download an application package from Grants.gov, the "expiration date" is pre-populated. Do not go strictly by this date since it may not apply to your particular situation; for instance, it may reflect the submission date for AIDS applications and you may be submitting a non-AIDS application that is due earlier. In this case, the pre-populated date has no bearing on your application and you should not be concerned by it.

All applications submitted to the NIH must be submitted in response to an FOA published in the NIH Guide for Grants and Contracts.

2.4.3 Finding a Funding Opportunity Announcement (FOA) for Grants.gov Submission

Implementation of the SF424 (R&R) application and electronic submission through Grants.gov will be announced through specific FOAs posted in the NIH Guide for Grants and Contracts and on Grants.gov under "Search Grants" (a.k.a. "Search") and "Apply for Grants" (a.k.a. "Apply"). From the "Applicants" section of the Grants.gov home page, select "Apply for Grants" and follow the steps provided. FOAs posted in Grants.gov "Search" reflect those the agency is prepared to receive through electronic Grants.gov submission. Applicants are encouraged to read each FOA carefully for specific guidance on the use of Grants.gov submission.

There are several ways a prospective applicant can find a FOA on Grants.gov.

Using the *NIH Guide for Grants and Contracts*

FOAs in the *NIH Guide for Grants and Contracts* that reference electronic submission via Grants.gov include a link from the FOA directly to the Grants.gov site where you can download the specific application package. The **Apply for Grants Electronically** button is found in the *NIH Guide* FOA directly under the Required Application Instructions section. This link is only provided in those announcements involving electronic submission through Grants.gov.

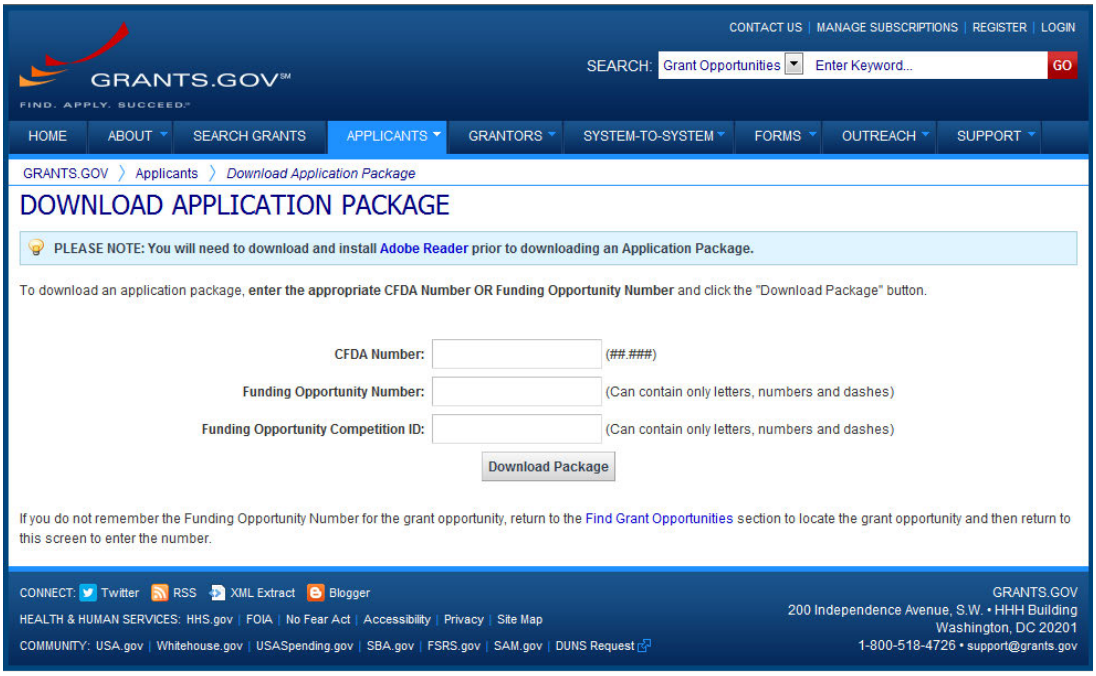
Using "Search" Grants

Grants.gov Search Grants provides general search capabilities. From the "Search Grants" page, you will find various options for: providing search criteria (e.g., keyword, Funding Opportunity Number, status, etc.) and identifying FOAs of interest.

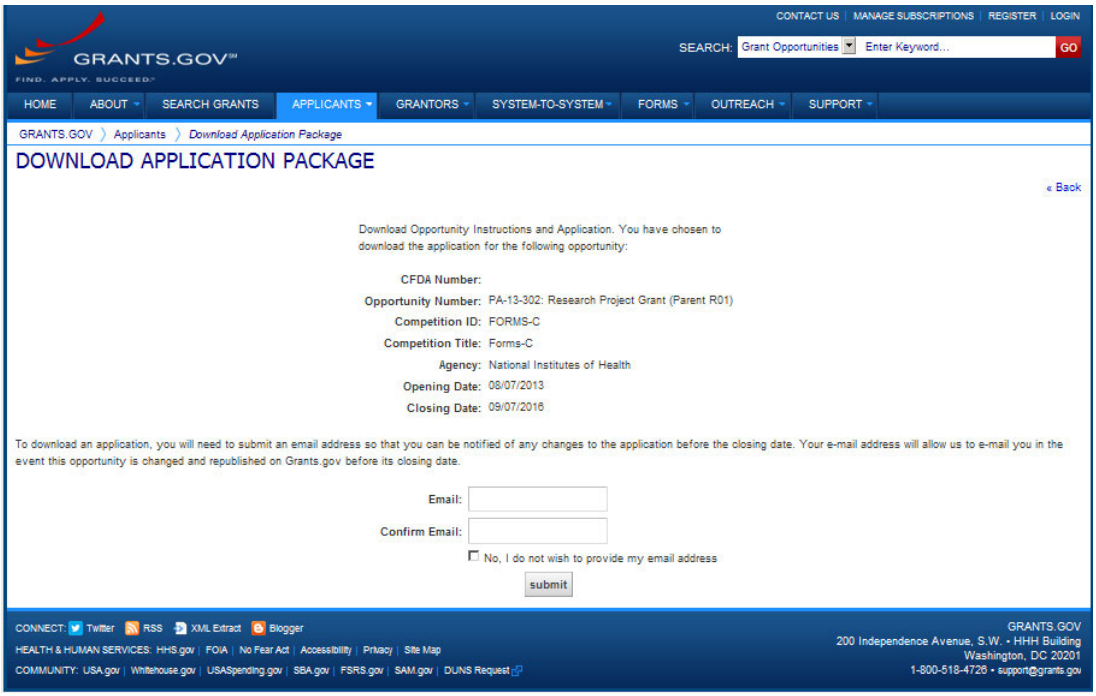
Once you find an opportunity for which you wish to apply, you may initiate the application download process from the Search page by selecting the FOA then selecting the "Application Package" tab and using the download link.

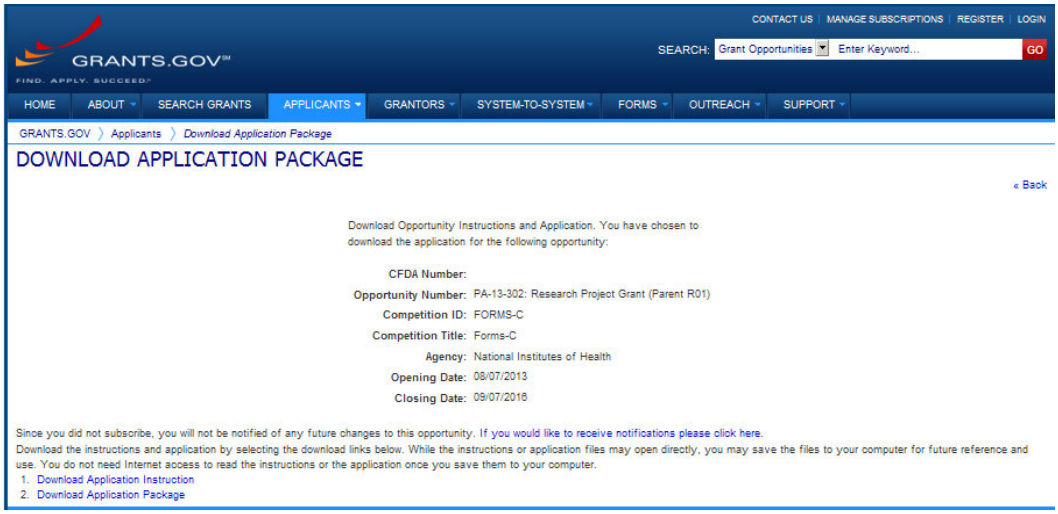
Using "Apply for Grants"

If you know the specific Funding Opportunity Announcement (FOA) number, from the Grants.gov homepage, select "Applicants" then "Apply for Grants" and follow the steps provided. "Step 1" allows you to download an application package by inserting an FOA number. If you do not know the specific FOA Number you may use Search Grants to find it.



Click the corresponding **download** link to access the actual application form pages and instruction material. If more than one application package is listed, use the Competition ID and Competition Title to determine the appropriate package to download. The following screens appear:





To access the instructions, click **Download Application Instructions**. For NIH opportunities and other PHS agencies using this Application Guide, this action will download a document containing a link to the NIH website where the most current set of application instructions is available (http://grants.nih.gov/grants/funding/424/index.htm). Applicants are encouraged to check this site regularly for the most current version.

To access the form pages, click **Download Application Package**. Section 2.5 provides specific information regarding the forms for an Application Package. Section 3 provides additional instructions for properly using a package.

On the Download Opportunity Instructions and Applications screen you will be given an opportunity to provide an e-mail address if you would like to be notified of any changes to this particular opportunity. Applicants to NIH and other PHS agencies are strongly encouraged to

complete this information. The agency can then use it to provide additional information to prospective applicants.

Note: The forms may or may not show a CFDA number and the CFDA field is not editable. Do not be concerned. The CFDA number is not used for assignment of the application. **Be assured the correct CFDA number will be assigned to the record once the appropriate IC assignment has been made.**

2.5 Forms for an Application to NIH or Other PHS Agencies

An application to NIH or other PHS agencies combines forms from the SF424 (R&R) with other agency-specific forms known as "PHS 398." All forms are listed in the table below.

SBIR/STTR applicants will also complete the "SBIR/STTR Information form."

Table 2.5-1. Forms for an NIH or Other PHS Agency Application

DOCUMENT	REQUIRED	OPTIONAL	INSTRUCTIONS
SF424 (R&R)	X		Section 4.2
Project/Performance Site Locations	X		Section 4.3
SF424 (R&R) Other Project Information	X		Section 4.4
SF424 (R&R) Senior / Key Person Profile Expanded	X		Section 4.5
SF424 (R&R) Budget	X		Section 4.7
SF424 (R&R) Subaward Budget Attachment Form (Use when required or allowed by the FOA)		X	Section 4.8
SBIR/STTR Information	X		Section 4.9
PHS 398 Cover Page Supplement	X		Section 5.3
PHS 398 Research Plan	X		Section 5.5
Planned Enrollment Report		X	Section 5.8
PHS 398 Cumulative Inclusion Enrollment Report		X	Section 5.8.2

All required and optional forms for electronic submission listed above are available through Grants.gov and should be downloaded from the FOA being applied to. Do not use any forms or format pages from other sources; these may include extraneous headers/footers or other information that could interfere with the electronic application process.

2.6 Format Specifications for Text (PDF) Attachments

Designed to maximize system-enforced validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff.

NIH and other PHS agencies require all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted below. Failure to follow these requirements may lead to rejection of the application during agency validation or delay in the review process. (See Section 2.3.2 for more information on creating PDFs.)

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. Additional tips for creating PDF files can be found at http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you must delete the previous attachment and then reattach the revised document to the application form. Use the **View Attachment** button to determine if the correct version has been attached.

File Name

Save all files with descriptive file names of 50 characters or less. Do not use the ampersand (&) character in file names. Use one space, (not two or more) between words or characters. Just like letters, a space counts as one character.

Font

Prepare the application using Arial, Helvetica, Palatino Linotype, or Georgia typeface in black font color. After text attachments are converted to PDF, font size in each final PDF document must be at least 11 points (or larger). (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Since some PDF converters may reduce font sizes, it is important to confirm that type density in each final PDF document, including both characters and spaces, is no more than 15 characters+spaces per linear inch and no more than six lines per vertical inch.

Paper Size and Page Margins

Final PDF documents should be formatted to be no larger than *standard paper size (8 ½" x 11)*.

The final PDF document should have at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI's name and page numbers.

Page Formatting

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

Grantsmanship

Use English and avoid jargon.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Page Limits

Although many of the sections of this application are separate text (PDF) attachments, page limits referenced in these instructions and/or funding opportunity announcements must still be followed. Agency validations will include many checks for page limits. Some accommodation will be made for sections that when combined must fit within a specified limitation. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they may not address all page limit requirements for a specific FOA and do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may lead to rejection of the application during agency validation or delay in the review process.

All applications for NIH and other PHS agency funding must be self-contained within specified page limits. Unless otherwise specified in an NIH solicitation, Internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.

Observe the page number limits given in Table 2.6-1. Only when specifically allowed in an FOA will the PHS accept applications that exceed the page number limitations noted in the Table. However, specific page number limits may still apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned. (See Table 1.4-1. Agency Contact Table.) **The page number limitations may also be different for other specialized grant applications.**

Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080.

Table 2.6-1. Page Limits

Please visit http://grants.nih.gov/grants/forms_page_limits.htm for a more detailed Table of Page Limits.

SECTION OF APPLICATION Also refer to the relevant section of the application instructions and the FOA.	PAGE LIMITS*
Introduction to Resubmission and Revision Applications	1 page
Specific Aims	1 page
Research Strategy (Item of Research Plan)	Phase I SBIR/STTR: 6 pages Phase II and Phase IIB SBIR/STTR: 12 pages Fast-Track SBIR/STTR: 12 pages
Biographical Sketches	5 pages per person
Commercialization Plans for Phase II, Phase IIB Competing Renewals, and Fast-Track Applications	12 pages
Appendix	Phase I SBIR/STTR: Not permitted unless specifically requested by NIH.
FOAs (PAs and RFAs)	Follow FOA Instructions

* FOA instructions always supersede these instructions.

Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html.

2.7 "Resubmission" Applications

The National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) have updated their policies for application submission. Following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for any due date in the future that is appropriate for the grant mechanism and Funding Opportunity Announcement. The policy does not preclude submission of a new (A0) application following an unsuccessful new (A0) application, without an intervening resubmission (A1) application. The NIH

and AHRQ will not assess the similarity of the science in the new (A0) application to any previously reviewed submission when accepting an application for review (see NOT-OD-14-074).

The updated policy applies to major types of applications and activity codes, including, the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, Eligibility criteria and any other restrictions or requirements in the Funding Opportunity Announcement (FOA) prevail. For example, an SBIR/STTR application must meet the eligibility requirements for each application submission. An application that was not accepted previously for being too similar to a resubmission application that had been reviewed previously can be submitted as a new application.

FAQs on the Resubmission Policy as it pertains to SBIR/STTR applications can be found here: http://sbir.nih.gov/faqs#insideCollapseNineteen

NIH's policy for accepting overlapping applications remains in effect (see NOT-OD-09-100). The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping resubmission (A1) application.
- a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- an application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101).

The NIH time limit for accepting resubmission (A1) applications remains in effect (see NOT-OD-12-128 and NOT-OD-10-140). The NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows.

NIH has established policies for application resubmissions of certain categories. See Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code in Part III, 1.2.

There are four requirements for a Resubmission application:

- The Summary Statement from the previous new application that it follows must be available in the eRA Commons (http://commons.era.nih.gov/commons).
- The PD/PI(s) must make significant changes to the application, compared to the new application that it follows.
- An Introduction must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction is separate from the Cover Letter. Use Item 2.1 Introduction of the PHS 398 Research Plan Form to provide this information. The page limit for the Introduction may not exceed one page unless indicated otherwise. Please refer to the relevant section of the application instructions and the FOA.

Acceptance of a resubmission application will not automatically withdraw the prior version. eRA keeps all versions (e.g., 01, A1) of a grant application active and provides an internal Multiple Active Applications (MAA) flag for each application in an active cluster. The cluster allows applicants to identify quickly all versions of one application. If any version in a cluster is awarded,

all other applications within the cluster will be automatically withdrawn without any additional action by applicants or staff.

2.8 "Revision" Application

A Revision application (formerly called a competing supplement) may be submitted to request support for a significant expansion of a project's scope or research protocol. 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 must not extend beyond the term of the current award period.

Provide a one-page "Introduction" that describes the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Use Introduction to application, of the PHS 398 Research Plan form to provide this information. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application. Note that all revision applications must be submitted by the same PD/PI (or Contact PD/PI for multi-PI grants) as listed on the current award and applicants must use the same budget format (i.e. R&R Budget Form) as the current award. Also, any budgetary changes for the remainder of the project period of the current grant should be discussed in the Budget Justification.

If the revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the SRG, then the applicant must respond to the criticisms in the prior Summary Statement, and substantial revisions must be clearly evident and summarized in the "Introduction."

Administrative Supplements

An administrative supplement is a noncompeting award that provides additional funding to a currently funded grant to meet increased costs that are within the scope of the approved project, but that were unforeseen when the new or competing renewal application was submitted. If you are considering requesting administrative supplement funding, you must consult in advance with your designated Grants Management Officer and Program Official. It is important to submit a request for supplemental funding before the awarded grant expires. NIH now publishes all administrative supplement programs as FOAs, which include specific programs such as the Research Supplements to Promote Diversity, and a general FOA for requests that do not fall under a specific program. Administrative Supplement requests may now be submitted in response to an FOA through either the eRA Commons or Grants.gov, as described in NOT-OD-12-024, or through the existing, paper-based process. Each FOA will link to an application package to use with the submission. It is important to note that since the applications for administrative supplements are non-competing, a cover letter attachment is not allowed to be included in an application submitted through eRA Commons or Grants.gov and will generate an error message if included. If you submit a request in writing, you must submit to the IC which awarded the original funded grant (not to the Division of Receipt and Referral, Center for Scientific Review). For additional information, see NIH Guide Notice NOT-OD-12-043. The request must be signed by the authorized Business Official and describe the need for additional funding and the categorical costs. The justification should also point out what will NOT be able to be accomplished if such a request is denied.

2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed.

Simultaneous submission 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 due 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 due date. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigators 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.

2.10 Submitting your Application via Grants.gov

The Authorized Organization Representatives (AORs) registered in Grants.gov are the only official with the authority to actually submit applications through Grants.gov. Therefore, PD/PIs will need to work closely with their AOR(s) to determine that all the necessary steps have been accomplished prior to submitting an application. This includes any internal review process required by the applicant organization.

Before starting the final submission step, **applicants are encouraged to save a copy of the final application locally**. Once you have properly completed all required documents and attached any required or optional documentation, click on the **Check Package for Errors** button to ensure that you have successfully completed all Grants.gov required data fields. If any of the required fields are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct any errors or if none are found, save the application package. Note that the Check Package for Errors button only checks a subset of Grants.gov application checks and does not guarantee that your application will pass subsequent Grants.gov and agency business rule checks done after submission. Only after the package has been saved with no errors will the **Save & Submit** button become active. Clicking the **Save & Submit** button will begin the application submission process. The application package must then be saved once more before the submission process begins. Only an AOR will be able to perform the submit action, and they will

be taken to the applicant login page to enter the Grants.gov username and password that was established in the Register with Grants.gov process (if not connected to the internet you will be instructed to do so).

Once logged in, the application package will be automatically uploaded to Grants.gov. A confirmation screen will appear once the upload is complete and a Grants.gov Tracking Number will be provided on this screen. Applicants should record this number so that they may refer to it should they need to contact Grants.gov Contact Center or the eRA Service Desk.

For additional information, see http://www.grants.gov/applicants/apply_for_grants.jsp.

Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) **before** 5 p.m. on the due date, local time of the applicant organization. Applicants are encouraged to submit their applications to Grants.gov several days early to ensure enough time to correct any errors before the deadline.

2.11 After you Submit your Application via Grants.gov

Grants.gov's Track My Application feature for Applicants (http://www.grants.gov/web/grants/applicants/track-my-application.html) provides basic status information for a specified Grants.gov Tracking Number. The Authorized Organization Representative (AOR) can also login to Grants.gov with their username and password to obtain a more detailed status of an application by using the Check My Application Status feature.

Once an application has been submitted via Grants.gov, several e-mails are sent to the email address on file with Grants.gov for the AOR (known at NIH/in eRA Commons as the Signing Official [SO]) who submitted the application. Each email notification will reference a Grants.gov tracking number that is assigned to the submission:

1. Submission Receipt: An e-mail is sent indicating your application has been received by Grants.gov and is currently being validated.
2. Submission Validation Receipt: An e-mail is sent indicating your application has been received and validated by Grants.gov and is being prepared for Grantor agency retrieval.
3. Grantor Agency Retrieval Receipt: An e-mail is sent indicating your application has been retrieved by the Grantor agency.
4. Agency Tracking Number Assignment for Application: An e-mail is sent indicating your application has been assigned an Agency Tracking Number. In Grants.gov, a status of Agency Tracking Number Assigned also indicates that NIH has processed the application without identifying any errors and an assembled application image is available in eRA Commons for viewing.

If the AOR/SO has not received a confirmation message from Grants.gov within 48 hours of submission, please contact:

Grants.gov Contact Center
Telephone: 1-800-518-4726
E-mail: support@grants.gov

At that point, the application will be scheduled for download into the eRA system for agency validation. It is imperative that the e-mail address provided in block 14 for the PD/PI and 19 for the AOR/SO on the SF424 (R&R) form be current and accurate. Once agency validation is completed, an agency notification (not Grants.gov) will be e-mailed to the PD/PI, AOR/SO, and the Applicant Contact e-mail (if provided) named in the application.

This e-mail notification will inform the PD/PI, AOR/SO, and the Applicant Contact (if named) that the application has been received and processed by the agency and will indicate whether any errors or warnings resulted during the validation process. The PD/PI, AOR/SO, and the Applicant Contact will be invited to log on the eRA Commons to view the assembled application or review the list of warnings/errors that were encountered during the validation process. SOs for the applicant organization, the PD/PI for the application and any Assistants that have been delegated in eRA Commons to view the PD/PIs status information will have access to the submission results in eRA Commons.

If there were no validation errors, this e-mail notification will also inform the PD/PI, AOR/SO, and the Applicant Contact of an agency accession number (e.g., AN654321), which represents the "agency tracking number." The Grants.gov system will indicate that the agency tracking number has been assigned, and will reflect both numbers. In subsequent interaction with the eRA Commons, however, it is the agency accession number that will be used to refer to the application, not the Grants.gov tracking number.

The eRA system will make every effort to send an e-mail to the PD/PI, AOR/SO, and the Applicant Contact summarizing download and validation results. **Since e-mail can be unreliable, applicants are responsible for checking on their application status in the Commons.**

Once an application package has been successfully submitted through Grants.gov, any encountered errors have been corrected by the applicant, and an application image has been assembled by the eRA Commons, PD/PIs and AORs/SOs will have two business days (Monday – Friday, excluding Federal holidays) to check the assembled application before it automatically moves forward to NIH staff for further processing and consideration. Once the application has moved forward, no additional changes to the application will be accepted through Grants.gov or eRA Commons. This window is known as the application viewing window.

Within the viewing window, SOs have the authority to reject an application to stop it from completing the submission process. After an application is rejected, a changed/corrected application can be submitted to address warnings or other issues if it is still before the submission deadline. However, changed/corrected applications overwrite previous submissions and if submitted after the submission deadline will be subject to the NIH Late Policy and may not be accepted.

Remember, warnings do not stop further application processing. If an application submission results in warnings (but not errors), the application will automatically move forward after the application viewing window if no action is taken. Some warnings may need to be addressed later in the process.

It is your responsibility to view the entire assembled application in eRA Commons and notify the eRA Service Desk within this window if the assembled application does not correctly reflect the information submitted to Grants.gov (e.g., submitted information is missing in image, graph/chart appears upside-down). The eRA Service Desk will provide guidance on appropriate corrective actions.

If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues.

Only the eRA Service Desk can confirm whether a system issue has taken place and provide instructions on how to resolve the issue. Applications affected by confirmed system issues will not be considered late as long as the applicant works diligently with the eRA Service Desk on a resolution. If the application needs to be Rejected and resubmitted, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications.

PD/PIs should work with their AOR/SO to determine when the "Reject" feature is appropriate.

To view the assembled application the AOR/SO should:

1. Login to the eRA Commons (https://commons.era.nih.gov/commons/) with your Signing Official (SO) account.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** on the left-hand side of the screen.
4. Search for your application by date received, Grants.gov tracking number, or accession number, to view a hit list of available applications.

5. When you find the appropriate application, click the accession number in the **Application ID** column to view the Status Information screen.
6. Click **e-Application** from the Other Relevant Documents section to view the assembled application.

Note: The SO can Reject the application by clicking on the Reject eApplication hypertext link from the Action column of the search hit list.

To view the assembled application the PD/PI should:

1. Login to the eRA Commons (https://commons.era.nih.gov/commons/) with your Principal Investigator (PI) account.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** near the top of the screen to view a hit list of available applications.
4. When you find the appropriate application, click the accession number in the **Application ID** column to view the status information screen.
5. Click **e-Application** from the Other Relevant Documents section to view the assembled application.

2.12 Correcting Errors

Prior to a specified application due date, applicants may make corrections and resubmit an application through Grants.gov. If applicants make corrections and resubmit the application after the due date, the application will be considered late. In this case, applicants *must* include a cover letter explaining the reasons for the delay and acceptance will be considered on a case-by-case basis. Also see Section 2.14 for additional information on submission dates.

If errors or warnings result from the validation process, the PD/PI, AOR/SO and Applicant Contact will be issued an e-mail instructing them to log on to the eRA Commons to review the list of warnings/errors that were encountered during the validation process. The eRA system will make every effort to send an e-mail to the PD/PI, AOR/SO and Applicant Contact indicating whether errors or warnings were detected. However, since e-mail can be unreliable, applicants are responsible for periodically checking on their application status in the eRA Commons, so that any errors or warnings can be resolved in the timeliest manner possible, before the deadline. SOs for the applicant organization, the PD/PI for the application and any Assistants that have been delegated in eRA Commons to view the PD/PIs status information will have access to the submission results in eRA Commons.

Please be aware of the distinction between *errors* and *warnings*. The word *error* is used to characterize any condition which causes the application to be deemed unacceptable for further consideration. Generally, errors will indicate significant inaccuracies, inconsistencies, omissions, or incorrect formatting that have been identified in the body of the application. Conversely, the word *warning* characterizes any condition that is acceptable, at least for the time being, but worthy of bringing to the applicant's attention. It is at the applicant's discretion whether a warning condition requires any action, but some warnings may need to be addressed later in the process.

Failure to comply with stated NIH policies can also result in a submitted application that will not be considered for review. For this reason, applicants are strongly encouraged to review all warnings, to ensure that they require no further attention and that they are satisfied with the validation results. If desired, warnings can be corrected in the same manner as errors.

A Changed/Corrected application may also be submitted if the PDF image, as viewed in the eRA Commons, is incomplete or inaccurate from that submitted.

Submitting a Changed/Corrected application will overwrite the previous submission and the previous application cannot be reinstated.

Errors and warnings may be reviewed in the Commons by performing the following steps:

1. After the application has been downloaded from Grants.gov and validated by the system, login to the eRA Commons (https://commons.era.nih.gov/commons/) using your username and password.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions**.
4. Search for your application by date received, Grants.gov tracking number, or accession number, if you are the SO. If you are the PI, clicking Recent/Pending eSubmissions will automatically display a hit list of your applications.
5. A hit list of applications is displayed. If the application was validated with warnings only, or without encountering any problems whatsoever, then it is identified in the hit list by its NIH accession number (e.g., "AN:2911064"). This is the same number that Grants.gov displays, and refers to as the "agency tracking number."
    - If any *errors* were identified during validation, then the application still appears in the hit list, but in this case it is identified by its Grants.gov tracking number (e.g., "GRANT87654321"). This is the number that Grants.gov assigned to your application at the time of submission.
6. When you find the appropriate application in the hit list (Application Status will read "eSubmission Error" if errors were received), use the Show Prior Errors link to view the list of errors/warnings.
7. The error/warning page appears, and you are then able to review all conditions that were identified during validation. If only warnings were identified, you may elect to take action and resubmit; however you may also disregard the warnings and proceed to view the application, as described earlier.

To correct errors and resubmit the application:

1. Make whatever corrections are necessary, wherever appropriate, to your local copy of the application. Most often this means that you have to edit the data within the application forms to correct whatever problem or inconsistency that was noted. Be as careful as possible when correcting your application; NIH's post-submission materials policy does not allow for applicants to correct oversights in their application after the due date.

2. Check the "Changed/Corrected Application" box in the Type of Submission field of the SF424 (R&R) form.
    - If you are submitting this Changed/Corrected application after the due date, be sure to document the reason for the late submission in the form of a cover letter. NIH makes no guarantees that applications submitted after the due date will be accepted. See the NIH late policy for more information.

      When you check the Changed/Corrected Application box, Previous Grants.gov Tracking ID field becomes a required field. Enter the Grants.gov Tracking ID (GRANT87654321) of the previous submission that you are correcting.
    - When you have made all of your corrections, save the Changed/Corrected application to your computer
3. The AOR will have to submit the Changed/Corrected application package to Grants.gov. A new Grants.gov tracking number will be assigned and the applicant will have to follow the Changed/Corrected application through Grants.gov to the eRA Commons to view the application image or the list of errors/warnings received during the validation process. It is the applicant's responsibility to track the application through to the eRA Commons. If you cannot view your application image in the Commons, NIH can't review your application! Successful submission may take several rounds of Changed/Corrected applications, since correcting one error may reveal or create an additional error.

The same e-mail notifications will be issued once the agency has downloaded and validated the re-submitted application and the PD/PI, AOR/SO, and Applicant Contact will once again be required to log on to the Commons either to view the application or to review the errors that were encountered during validation.

The application will only be assigned for scientific review once errors are resolved.

In addition to the validations performed by the eRA system, further administrative review will be conducted by agency staff. The PD/PI and/or the applicant organization may be contacted for further corrections/clarifications.

2.13 Post-Submission Application Materials

Grant application materials will only be accepted after submission of the application but before the initial peer review if they result from unforeseen administrative issues. Exceptions to this policy are indicated below. See NOT-OD-10-091 and NOT-OD-13-030 for additional information.

The materials should be sent by the AOR to the SRO as a PDF attachment to an e-mail. E-mail communication is preferred. If e-mail is not feasible, please send a hard copy, addressed to the SRO.

The original application is kept intact; any application material sent post-submission is sent separately to reviewers. Updated or supplemental grant application materials used in the peer review process will be retained as part of the official grant file and remain part of the permanent record for that application.

Acceptable post-submission materials include:

- Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition)
- Biographical sketches (e.g., change in senior/key personnel due to the loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the 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
- News of a professional promotion or positive tenure decision for any Program Directors/Principal Investigators and Senior/Key Personnel also will be accepted as post-submission application material. The news must be received by the Scientific Review Officer one month (30 calendar days) prior to the peer review meeting, and demonstrate concurrence from the Authorized Organization Representative (AOR) of the applicant organization.
- If an application proposed to use a human embryonic cell line(s) that is approved by the NIH Stem Cell Registry at least 30 days prior to the peer review meeting, the SRO can include this update to the reviewers as part of the post-submission materials (see NOT-OD-12-111).
- Videos, within defined limits, (see NOT-OD-12-141). Devices and other non-traditional materials will not be accepted after submission, unless the application is submitted for a Funding Opportunity Announcement that specifies other types of allowable post-submission materials.

Unacceptable post-submission materials [for all applications but those under Exceptions below] include:

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

Exceptions to this policy include:

- Applications submitted in response to Requests for Applications (RFAs) that have only one due date. Post-submission materials for these applications will be accepted as outlined in NOT-OD-10-070
- Applications for training grants (see NOT-OD-10-104)
- Certain NIH Funding Opportunity Announcements (FOAs) may allow certain other types of post-submission materials to facilitate the goals of the program. Such stipulations must be explained in the FOA in the NIH Guide for Grants and Contracts

Page limits for post-submission materials under this policy:

- All post-submission materials must conform to NIH policy on font size, margins, and paper size as referenced in Section 2.6 of the applicable application instructions

- NIH additional form pages such as budget, biographical sketches, and other required forms must follow NIH standards for required NIH form pages.
- If post-submission material is not required on a form page, each explanation or letter is limited to one page (see Acceptable post-submission materials above)
- If the application has subprojects or cores, each subproject or core is allowed explanations or letters (see Acceptable post-submission materials above), but each explanation or letter is limited to one page

The additional materials must be submitted to the NIH SRO with the concurrence of the applicant organization's designated AOR/SO. Although the content of post-submission materials may originate from the 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 deadline for receipt of additional materials is one month (30 calendar days) prior to the peer review meeting. FOAs may provide stricter or more lenient guidance.

After the initial peer review phase is completed, the NIH Chief Grants Management Officer is the NIH official responsible for accepting additional materials. Most of the materials submitted after the initial peer review can be submitted as part of the Just-In-Time process (see Part III.1.7).

2.14 Application Due Dates

Each Funding Opportunity Announcement (FOA) includes an Open Date and an Expiration Date. Many FOAs, are open for several years, including those using the "Standard Due Dates" noted in Section 2.15, and include multiple due dates. These FOAs are posted in Grants.gov and the NIH Guide to Grants and Contracts. Applicants should read the FOA carefully looking in the "Key Dates" section for specific due dates. If specific due dates are not referenced in the announcement, applicants should follow the link from the FOA to the Standard Due Dates for Competing Applications table at this website:
http://grants.nih.gov/grants/funding/submissionschedule.htm

***Note NIH and HHS recently changed the Standard Due Dates for SBIR/STTR grant applications. See NOT-OD-15-038 for details.

Applications are considered to be on time if an error-free application is submitted to Grants.gov on or before 5 p.m. local (applicant organization) time on the appropriate date. As always, applicants must check the eRA Commons to view their application and ensure they have addressed any errors (instances of non-compliance with NIH business rules) identified by NIH systems.

Weekend/Federal Holiday Due Dates. When an application due date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day. The application will be on time if it is submitted on or before the following business day.

Late Applications. Permission is not granted in advance for submission of a late application. Late applications may be accepted during a two week window of consideration after the application due date under specific circumstances and limitations defined in NOT-OD-15-039.

If an application is submitted late, a cover letter explaining the reasons for the delay must be submitted with the application.

Late applications are evaluated on an individual basis considering the reasons provided in the cover letter

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

Contacting the Division of Receipt and Referral (DRR), Center for Scientific Review (CSR), NIH, or any other NIH official in advance will not influence the acceptance of a late application

If an application is submitted late, attach a Cover Letter to the SF424 (R&R) form using the Cover Letter Attachment field to provide specific information on the timing and nature of the cause of the delay. No other documentation is expected. 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, or any other NIH official in advance will not influence the acceptance of a late application.

Related Guide Notices include:

- NOT-OD-15-039 Simplifying the NIH Policy for Late Application Submission at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html
- NOT-OD-11-035 NIH Policy on Late Submission of Grant Applications at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html

2.15 Submission, Review and Award Cycles

The PHS submission, review, and award schedule is provided at this website: http://grants.nih.gov/grants/funding/submissionschedule.htm. For specialized grant applications, consult with the appropriate PHS agency prior to the preparation of an application.

Application Assignment Information

Competing grant applications that have been successfully submitted through Grants.gov (including correcting all errors and the grant application assembled by the eRA Commons system) will be processed through the Division of Receipt and Referral (DRR), Center for Scientific Review (CSR), NIH unless otherwise stated. The application will be assigned to an awarding component (Institute/Center IC) and an appropriate Scientific Review Group (SRG) either at CSR or at the IC. Applications can only be assigned to ICs that are listed in Part 1: Components of Participating Organizations of the FOA. Assignment is based on the scientific content of the application using established referral guidelines. Business rule validations are conducted by the system as well as NIH staff.

Assignment to Relevant Potential Awarding Component(s) (ICs). DRR will assign each application to an agency awarding component that is the potential funding component. When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign your application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in your application

are designated as secondary assignees. If your application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in the Funding Opportunity Announcement.

Assignment to Review Group. The Center for Scientific Review (CSR) or IC staff will also assign applications to a Scientific Review Group (commonly referred to as "SRGs" or "study sections") that will perform the scientific/technical merit review. This may be a chartered study section or a special emphasis panel (SEP). The list of CSR recurring review panels can be found at (http://public.csr.nih.gov/StudySections/Standing/Pages/default.aspx), and you may suggest a specific group in the SF424 (R&R) Form in the Cover Letter attachment at the time of application submission. For individual Fellowship applicants, a Roster Index for IC and CSR Fellowship Study Sections are provided here: http://public.csr.nih.gov/StudySections/Fellowship/Pages/default.aspx

After the due date, usually within two (2) weeks, the PD/PI and the applicant organization will be able to access in the eRA Commons and view the following information regarding the grant application:

- Application assignment number;
- Name, address, and telephone number of the Scientific Review Officer (if the review takes place in CSR) of the Scientific Review Group to which the application has been assigned for peer review; and
- Assigned Institute/Center information.

Review outcome and other important information are also available in the Commons.

If assignment information is not available in the eRA Commons within two weeks of the due date, contact the Division of Receipt and Referral (DRR), Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715, email csrdrr@mail.nih.gov. If there is a change in assignment, you will receive a notification and the change will be reflected in the eRA Commons. DRR also uses eRA Commons to communicate with PIs regarding the status of their application. It is advisable for PIs log into eRA Commons often during the assignment and review process.

Applicant investigators must not communicate directly with any review group member about an application either before or after the review. Failure to strictly observe this policy is considered to be a serious breach of confidentiality and conflict of interest in the peer review process. From the time of assignment to the time the review of your application is complete, applicant investigators must direct all questions to the Scientific Review Officer. This individual is in charge of the review group and is identified in the eRA Commons.

Related Guide Notices include:

- NOT-OD-14-073 Maintaining Confidentiality in NIH Peer Review at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html;
- NOT-OD-15-106 Applicant Responsibilities in Maintaining the Integrity of NIH Peer Review at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html

2.16 Resources for Finding Help

2.16.1 Finding Help for Grants.gov Registration or Submissions

If help is needed with the Grants.gov registration process or with the technical aspects of submitting an application through the Grants.gov system, check first the resources available at Grants.gov. If you are on deadline for submitting an application and are experiencing technical difficulties with the submission, contact the Grants.gov and eRA Service Desk immediately.

Grants.gov customer support is also provided by the following office:

Grants.gov Program Management Office
200 Independence Avenue, SW
HHH Building, Room 739F
Washington, DC 20201

Grants.gov Self-Service Web Portal: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Grants.gov Help Desk: support@grants.gov

Grants.gov Contact Center Phone Number: 800-518-4726 (Toll Free), 606-545-5035 (Local or International)

The Contact Center is available 24 hours a day, 7 days a week (except Federal holidays).

2.16.2 Finding Help for the eRA Commons Registration or eRA Commons Validation Processes

If help is needed with the eRA Commons registration process for the applicant organization and PD/PIs; with using ASSIST, or with the application validation process in the Commons after submission through Grants.gov, check first the resources available at the Applying Electronically website: (http://grants.nih.gov/grants/ElectronicReceipt/).

eRA Commons customer support is also provided by the eRA Service Desk:

eRA Website: http://era.nih.gov

eRA Commons Website: https://commons.era.nih.gov/commons/index.jsp

eRA Commons On-line Resources and Web Ticketing: http://grants.nih.gov/support

eRA Commons Phone: 301-402-7469, 866-504-9552 (Toll Free), 301-451-5939 (TTY)

The eRA Service Desk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time (except Federal holidays).

NOTE: To help expedite your Service Desk request, we recommend that you have the following information readily available (NOTE: Additional details may be required depending upon the type of issue/request):

- Full Name of Affected User
- Full Name of Institution/Organization
- Grants.gov Tracking Number

- Submission Date
- Funding Opportunity Announcement (FOA)
- Principal Investigator's (PI) Username
- Signing Official's (SO) Username

2.16.3 Finding Help for Application Preparation

If after reviewing this application instruction guide, help is still needed in preparing the application, contact GrantsInfo:

GrantsInfo Phone: 301-435-0714, 301-451-5936 (TTY)

GrantsInfo E-mail: GrantsInfo@nih.gov

2.16.4 Finding Help for SBIR/STTR Specific Inquiries

Questions of a general nature about the NIH SBIR/STTR program should be directed to:

NIH SBIR/STTR Program Office
Phone: 301-435-2688
Fax: 301-480-0146
E-mail: sbir@od.nih.gov

2.16.5 Finding Help for SBA Company Registry

For questions and for technical assistance concerning the SBA Company Registry, please contact the SBA at http://sbir.gov/feedback?type=reg.

3. Using the Grant Application Package

This section describes the steps an applicant takes once the appropriate FOA (see Section 2.4) has been located and the corresponding grant application package has been successfully downloaded.

3.1 Verify Grant Information

When you select a funding opportunity in Grants.gov Apply, verify that the information shown in the Grant Application Package screen corresponds to the funding opportunity for which you wish to apply. Grants.gov auto-populates the following information:

- Opportunity Title
- Offering Agency
- CFDA Number
- CFDA Description
- Opportunity Number
- Competition ID
- Opportunity Open Date
- Opportunity Close Date
- Agency Contact

GRANTS.GOV™ **Grant Application Package** Print Cancel

Opportunity Title:	Limited Competition: Training Programs for Critical HIV
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PAR-13-215
Competition ID:	FORMS-C
Opportunity Open Date:	08/25/2013
Opportunity Close Date:	07/30/2015
Agency Contact:	eRA Commons Help Desk Monday to Friday 7 am to 8 pm ET E-mail: helpdesk@od.nih.gov Phone: 1-866-504-9552

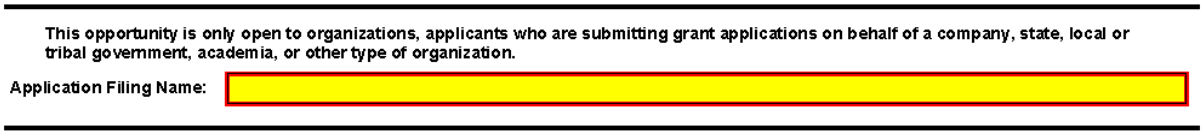
CFDA Number Field: Many FOAs include multiple CFDA (Catalog for Domestic Assistance) numbers. When this is the case, the CFDA Number and CFDA Description fields will appear blank in the Grants.gov Grant Application Package screen shown above. The appropriate CFDA number will be automatically assigned once the application is assigned to the appropriate agency awarding component.

Opportunity Open Date & Close Date Fields: Many FOAs posted by NIH and other PHS agencies include multiple submission/due dates and are active for several years. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active

period of the announcement. Applicants should read the funding opportunity announcement carefully for specific submission/due dates. If specific dates are not referenced in the announcement, applicants should refer to the PHS submission, review, and award schedule at http://grants.nih.gov/grants/dates.htm. Applications submitted after a posted submission date will normally not be held over into the next review cycle. Instead, the PD/PI will be notified and will have to submit the application again. See Part I, Section 2.14 of this Guide for more information on the late application policy.

3.2 Enter the Name for the Application

Enter a name for the application in the Application Filing Name field (this is a required field). This name is for use solely by the applicant for tracking the application through the Grants.gov submission process. It is not used by the receiving agency.



3.3 Open and Complete Mandatory Documents

Click the form name to navigate to the form in the application package and complete all of the Mandatory forms. **Complete the form titled SF 424 (R&R) first.** Data entered in this form populates other mandatory and optional forms where applicable.

3.4 Open and Complete Optional Documents

These documents can be used to provide additional information for the application or may be required for specific types of grant activities. Information on each of these documents is found later in these instructions.

Click the check box next to the form name to add the form to the application package. To navigate to the form, click on the form name. To remove an optional form from the application package, uncheck the box next to the form name.

Optional

- ☐ Planned Enrollment Report
- ☐ PHS 398 Cumulative Inclusion Enrollment Report
- ☐ R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT

3.5 Submitting the Application via Grants.gov

Once you have properly completed all required documents and attached any required or optional documentation, click on the **Check Package for Errors** button to ensure that you have successfully completed all required data fields. If any of the fields required by Grants.gov are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct any errors or if none are found, save the application package. The **Save & Submit** button will now become active and clicking this button will begin the application submission process. Only after the package has been saved with no errors will the **Save & Submit** button become active. The application package must then be saved once more before the submission process begins. Only an AOR will be able to perform the submit action, and they will be taken to the applicant login page to enter the Grants.gov username and password that was established in the Grants.gov registration process (if not connected to the internet you will be instructed to do so).

4. Completing the SF 424 Research and Related (R&R) Forms

4.1 Overview

This section contains all of the instructions you will need to complete the SF424 (R&R) forms.

Any agency-specific instructions on SF 424 (R&R) forms used federal-wide are denoted by the HHS logo displayed to the left of the paragraph, as illustrated here.

Conformance to all instructions is required and strictly enforced. Agencies may withdraw any applications from the review process that are not consistent with these instructions.

As you navigate through the Grants.gov forms, required fields are outlined in red. Data entered into a specific field is not accepted until you have navigated to the next field. If you enter invalid or incomplete information in a field, you will receive an error message.

Note the outlined fields required for submissions, and the **Check Package for Errors** button, only refer to Grants.gov requirements and errors. They do not reflect all agency requirements or PHS business processes. Agency validations will be performed by the eRA Commons system after the application has been submitted.

For those forms that are more than one page, click the **Next** button at the top of the form or scroll down (using the scroll bar on the right hand side of the screen) to navigate to a subsequent page. Once all data have been entered scroll up using the scroll bar to return to the Grant Application Package Screen.

4.2 SF 424 (R&R) Form

OMB Number: 4040-0001

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE | State Application Identifier

1. TYPE OF SUBMISSION
☐ Pre-application ☐ Application ☐ Changed/Corrected Application

4. a. Federal Identifier
b. Agency Routing Identifier
c. Previous Grants.gov Tracking ID

2. DATE SUBMITTED | Applicant Identifier

5. APPLICANT INFORMATION | Organizational DUNS:
Legal Name:
Department: | Division:
Street1:
Street2:
City: | County / Parish:
State: | Province:
Country: USA: UNITED STATES | ZIP / Postal Code:

Person to be contacted on matters involving this application
Prefix: | First Name: | Middle Name:
Last Name: | Suffix:
Position/Title:
Street1:
Street2:
City: | County / Parish:
State: | Province:
Country: USA: UNITED STATES | ZIP / Postal Code:
Phone Number: | Fax Number:
Email:

6. EMPLOYER IDENTIFICATION *(EIN) or (TIN)*:

7. TYPE OF APPLICANT: Please select one of the following
Other (Specify):
Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION:
☐ New ☐ Resubmission
☐ Renewal ☐ Continuation ☐ Revision

If Revision, mark appropriate box(es).
☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration
☐ E. Other (specify):

Is this application being submitted to other agencies? Yes ☐ No ☐ What other Agencies?

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:
Start Date | Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

1. Type of Submission

Check one of the Type of Submission boxes. If this submission is to change or correct a previously submitted "New", "Resubmission", "Renewal", or "Revision" application, click the

Changed/Corrected Application box and enter the Grants.gov tracking number in the Previous Grants.gov Tracking ID field.

Unless requested by the agency, applicants may not use this to submit changes after the closing date. This field is required.

Pre-Application: Unless specifically noted in a Funding Opportunity Announcement, the Pre-application option is not used by NIH and other PHS agencies.

Changed/Corrected Application: This box must be used if you need to submit the same application again to correct system validation errors, application assembly problems, or to incorporate other changes. When submitting a Changed/Corrected Application:

- If submitting after the submission date, include an explanation in the Cover Letter attachment.
- Submitting a Changed/Corrected application replaces the previous submission and removes the previous submission from consideration. Once an application has moved forward to agency staff following the two-day application viewing window, subsequent Changed/Corrected applications will not be accepted unless the application is withdrawn. Note that if you are submitting additional grant application materials after the submission date some special guidelines may apply. See NIH Guide Notice NOT-OD-10-115 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html) for the NIH Policy on Post-Submission Application Materials.
- When you check the Changed/Correct Application box the Previous Grants.gov Tracking ID becomes a required field.
- Do **not** use the Changed/Corrected Application box to denote a submission of a resubmission or amended application. That will be indicated in the Type of Application.

SBIR/STTR Phase II applications may be submitted either before or after expiration of the Phase I budget period. However, Phase II grant applications should be submitted no later than the first six submission dates following expiration of the Phase I budget period.

Applicant small business concerns are reminded that Phase II funding is based on the results of Phase I, demonstration of feasibility, scientific, and technical merit, and commercial potential of the Phase II application. *Applicants are cautioned that applications demonstrating insufficient results in Phase I may not receive a score in the peer review process.*

2. Date Submitted and Applicant Identifier

Enter the date the application is submitted to Federal agency (or State if applicable). In the applicant identifier field enter the applicant's control number (if applicable).

Note the Applicant Identifier field is a control number created by the applicant organization, not the Federal agency.

3. Date Received by State and State Application Identifier

Enter the date received by state (if applicable). In the State Application Identifier field, enter the state application identifier, if applicable.

For submissions to NIH and other PHS agencies, leave these fields blank.

4.a. Federal Identifier

When a New Application is being submitted following a Pre-Application, enter the agency-assigned pre-application number, if applicable. If this is a continuation, revision, or renewal application, enter the assigned Federal Identifier number (for example, award number)--even if submitting a Changed/Corrected application.

For submissions to NIH and other PHS agencies, include only the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1). The Federal Identifier is required for Resubmission, Renewal, and Revision applications.

Applicants to NIH and other PHS agencies should complete this field when submitting a resubmission, renewal or revision application. When submitting a "New" application, this field should remain blank

To assist Phase I SBIR contractors or Phase I SBIR/STTR awardees from other agencies applying for SBIR/STTR Phase II or Phase IIB awards, resources are available on the web at: https://sbir.nih.gov/faqs#app-prep-sub26

4.b. Agency Routing Identifier

Enter the agency-assigned routing identifier per the agency-specific instructions. This is an optional field. Unless specifically noted in a program announcement, the Agency Routing Identifier is not used by NIH or other PHS agencies.

4.c. Previous Grants.gov Tracking ID

Enter the previous Grants.gov tracking number, if applicable.

5. Applicant Information

This information is for the Applicant Organization, not a specific individual.

The small business concern is ALWAYS the applicant organization for an SBIR or STTR award (e.g., ABC Incorporated).

Field Name	Instructions
Organizational DUNS	Enter the DUNS or DUNS+4 number of the applicant

Field Name	Instructions
	organization. This field is required. For submission to NIH and other PHS agencies, this DUNS **must** match the number entered in the eRA Commons Institutional Profile for the applicant organization. The applicant AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile (IPF) prior to submitting an application. If your organization does not already have a DUNS number, you will need to go to the Dun & Bradstreet website at http://fedgov.dnb.com/webform to obtain the number. The same DUNS should be used in the eRA Commons IPF, Grants.gov and in the DUNS field in the application.
Legal Name	Enter the legal name of the applicant which will undertake the assistance activity, enter the complete address of the applicant (including county/parish and country), and name, telephone number, e-mail, and fax of the person to contact on matters related to this application.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization that will undertake the assistance activity.
Division	Enter the name of the primary organizational division, office, or major subdivision which will undertake the assistance activity.
Street1	Enter the first line of the street address for the applicant in "Street1" field. This field is required.
Street2	Enter the second line of the street address for the applicant in the "Street2" field. This field is optional.
City	Enter the City for address of the applicant. This field is required.
County/Parish	Enter the county or parish for address of the applicant.
State	Enter the State where the applicant is located. This field is required if the applicant is located in the United States.
Province	Enter the province. If "Country" is not Canada, please leave blank.

Field Name	Instructions
Country	Select the country for the applicant address. For SBIR/STTR applications, the small business concern must be located in the United States.
ZIP Code	Enter the nine-digit postal code (e.g., ZIP code) of applicant. This field is required if the applicant is located in the United States. This field is required if a State is selected; optional for Province.

Person to be contacted on matters involving this application:

This information is for the Administrative or Business Official, not the PD/PI. This person is the individual to be notified if additional information is needed and/or if an award is made. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the AO profile information contained in the eRA Commons.

Field Name	Instructions
Prefix	Enter the prefix (e.g., Mr., Mrs., Rev.) for the person to contact on matters related to this application.
First Name	Enter the first (given) name of the person to contact on matters related to this application. This field is required.
Middle Name	Enter the middle name of the person to contact on matters related to this application.
Last Name	Enter the last (family) name of the person to contact on matters related to this application. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters related to this application.
Phone Number	Enter the daytime phone number for the person to contact on matters related to this application. This field is required
Fax Number	Enter the fax number for the person to contact on matters related to this application.
E-mail	Enter the e-mail address for the person to contact on matters related to this application

6. Employer Identification

Enter either TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the U.S., enter 44-4444444. This field is required.

If you have a 12-digit EIN established for grant awards from NIH or other PHS agencies, **enter all 12 digits (e.g., 1123456789A1); this includes non-U.S. organizations.** For SBIR/STTR applications, the small business must be located in the United States.

7. Type of Applicant

This information is for the Applicant Organization, not a specific individual AOR or PD/PI

Field Name	Instructions
Type of Applicant	Select the appropriate applicant type code. If Small Business is selected as Type of Applicant, then note if the organization is Woman-owned and/or Socially and Economically Disadvantaged. For SBIR/STTR applicant organizations, select R. Small Business. The applicant organization must certify that it will qualify as a small business concern at the time of award.
Other (Specify)	Complete only if "Other" is selected as the Type of Applicant.
Woman Owned	Check if you are a woman-owned small business – a small business that is at least 51% owned by a woman or women, who also control and operate it.
Socially and Economically Disadvantaged	Check if you are a socially and economically disadvantaged small business, as determined by the U.S. Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a).

8. Type of Application

Field Name	Instructions
Type of Application	Select the type from the following list. Check only one. This field is required.

Field Name	Instructions
	• New: An application that is being submitted to an agency for the first time. • Resubmission: An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. • Renewal: An application requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as though the applicant is applying for the first time. • Continuation: A non-competing application for an additional funding/budget period within a previously approved project period. • Revision: 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. • New. Check this option when submitting an application for the first time or in accordance with other submission policies. See also the policy Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code • Resubmission. Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH Policy on Resubmission Applications. Institutions submitting revision or renewal applications **that are also resubmissions** are instructed to select "Resubmission." For additional information, see NIH Guide Notice NOT-OD-10-052, http://grants.nih.gov/grants/guide/notice-files/not-od-10-052.html). • Continuation. For the purposes of NIH and other PHS agencies, the box for Continuation is only used for specific FOAs. • Revision. Used for both competing revisions and non-competing administrative supplements. This field also affects how you complete item 4a.Federal Identifier. If "Type of Application" is "New", you can leave the Federal Identifier field blank on the first submission attempt. However, the Federal Identifier field becomes a required field

Field Name	Instructions
	when submitting a Changed/Corrected application to address errors/warnings. When submitting a Changed/Corrected "New" application, enter the Grants.gov tracking number of the previous submission attempt (e.g. GRANT87654321). If you are unable to find the tracking number, enter "N/A". If "Type of Application" is "Renewal," "Revision," or "Resubmission," enter the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1).
If Revision, mark appropriate box(es)	If Revision, mark appropriate box(es). May select more than one: A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration E. Other If "Other" is selected, please specify in the text box provided. For the purposes of NIH and other PHS agencies, the boxes for options B, C, D, and E will generally not be used and should not be selected unless specifically addressed in a particular FOA.
Other	If "Other" is selected for Revision, add text to explain.
Is this application being submitted to other agencies?	Check applicable box. This field is required. In the field "Is this application being submitted to other agencies?," please check the box "yes" if one or more of the specific aims submitted in your application are also contained in a similar, identical, or essentially identical application submitted to another Federal agency. Indicate the agency or agencies to which the application has been submitted. For additional information, please see NIH Guide Notice NOT-OD-09-100, *Reminder and Clarification of NIH Policies on Similar, Identical, or Essentially Identical Applications, Submission of Applications Following RFA Review, and Submission of Applications with a Changed Activity Code* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html.

Field Name	Instructions
What Other Agencies?	Enter Agency Name.

9. Name of Federal Agency

Name the Federal agency from which assistance is being requested with this application. This field is pre-populated by Grants.gov.

10. Catalog of Federal Domestic Assistance (CFDA) Number and Title (CFDA)

This is the Catalog of Federal Domestic Assistance number of the program under which assistance is requested. This field is pre-populated from the opportunity package.

This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank; the field will not allow any data entry. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate awarding component.

11. Descriptive Title of Applicant's Project

Enter a brief descriptive title of the project. This field is required.

A "new" application must have a different title from any other PHS project submitted for the same application due date. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

A "revision" application must have the same title as the currently funded grant.

NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation. Be sure to only use standard characters in the descriptive title: A through Z, a through z, 0 through 9, and underscore (_).

An SBIR/STTR Phase II application should have the same title as the previously awarded Phase I grant.

12. Proposed Project

Start Date: Enter the proposed start date of the project. This field is required.

Ending Date: Enter the proposed ending date of the project. This field is required.

Phase I: Routinely, SBIR Phase I awards do not exceed six (6) months and STTR Phase I awards do not exceed one year.

Phase II: Routinely, SBIR and STTR Phase II awards do not exceed two years.

Under special circumstances, applicants to NIH may propose longer periods of time for completion of the research project (e.g., feasibility demonstration). Such requests that deviate from the guidelines must be thoroughly justified. Project duration deviations apply to NIH ONLY, as CDC, FDA, and ACF do not make awards for periods longer than the stated guidelines.

13. Congressional District of Applicant

Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.

If outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov Web site.

For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE **Page 2**

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization Name:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested
b. Total Non-Federal Funds
c. Total Federal & Non-Federal Funds
d. Estimated Program Income

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:
b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR
☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious. or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

☐ **I agree**

**The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

Signature of Authorized Representative: Completed on submission to Grants.gov

Date Signed: Completed on submission to Grants.gov

20. Pre-application Add Attachment | Delete Attachment | View Attachment

21. Cover Letter Attachment Add Attachment | Delete Attachment | View Attachment

14. Program Director/Principal Investigator (PD/PI) Contact Information

If submitting an application reflecting Multiple PD/PIs, the individual designated as the Contact PI must be affiliated in the Commons with the applicant organization should be entered here. See Section 4.5 Senior/Key Person Profile Forms for additional instructions for Multiple PD/PIs. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the PD/PI profile information contained in the eRA Commons.

Name the one person responsible to the applicant small business concern for the scientific and technical direction of the project if a single PD/PI application, or the contact PD/PI for a multiple PD/PI application. PHS staff conduct official business only with the named PD/PIs and organizational/institutional officials. A revision/supplemental application must have the same PD/PI as the currently funded grant.

Field Name	Instructions
Prefix	The Project Director/Principal Investigator (PD/PI) is the individual responsible for the overall scientific and technical direction of the project. Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Enter the first name of the PD/PI. This field is required.
Middle Name	Enter the middle name of the PD/PI.
Last Name	Enter the last name of the PD/PI. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) of the PD/PI. Do not use this field to record degrees. Degrees for the PD/PI are requested separately in the Senior/Key Person Profile.
Position/Title	Enter the Position/Title of the PD/PI.
Organization Name	Enter the organization name of the PD/PI.
Department	Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Division	Enter the name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	Enter first line of the street address for the PD/PI in the “Street1” field. This field is required.
Street2	Enter the second line of the street address for the PD/PI in the “Street2” field. This field is optional.

Field Name	Instructions
City	Enter the City for address of the PD/PI. This field is required.
County/Parish	Enter the county/ or parish for address of the PD/PI.
State	Enter the State where the PD/PI is located. This field is required if the PD/PI is located in the United States.
Province	Enter the province for PD/PI. If "Country" is not Canada, please leave blank.
Country	Select the country for the PD/PI address.
ZIP/Postal Code	Enter the postal code (e.g., ZIP code) of the PD/PI. This field is required if the PD/PI is located in the United States.
Phone Number	Enter the daytime phone number for the PD/PI. This field is required
Fax Number	Enter the fax number for the PD/PI.
E-mail	Enter the e-mail address for the PD/PI. This field is required.

Program Director/Principal Investigator Criteria

SBIR

Under the SBIR program, for both Phase I and Phase II, *the primary employment of the PD/PI must be with the small business concern at the time of award and during the conduct of the proposed project*. Primary employment means that more than one half (greater than 50%) of the PD/PI's time is spent in the employ of the small business concern. *Primary employment with a small business concern precludes full-time employment at another organization*. Occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

For Multiple PD/PI applications: The first PI listed must be affiliated with the applicant small business concern organization submitting the application and will serve as the contact PD/PI. For both SBIR Phase I and SBIR Phase II, the primary employment of the "Contact PD/PI" must be with the small business concern at the time of award and during the conduct of the proposed project. As noted above, occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

As defined in 42 CFR 52, the PD/PI(s) is or are the "…individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project." When the proposed PD/PI clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation.

If the application has the likelihood for funding, the awarding component will require documentation to verify the eligibility of the PD/PI, if at the time of submission of the application, the PD/PI is a less-than-full-time employee of the small business concern, is concurrently employed by another organization, or gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

If the PD/PI is employed or appears to be employed by an organization other than the applicant organization in a capacity such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate, a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant small business concern, the PD/PI is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the PD/PI is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

This requirement applies also to those individuals engaged currently as the PD/PI on an active SBIR project. All current employment and all other appointments of the PD/PI must be identified in his or her "Biographical Sketch" required as part of the application. Be certain that correct beginning and ending dates are indicated for each employment record listed.

STTR

For both Phase I and Phase II, the primary employment of the principal investigator must be with the SBC or the research institution at the time of award and during the conduct of the proposed project. Primary employment means that more than one-half (greater than 50%) of the principal investigator's time is spent in the employ of the SBC or the research institution. This precludes full-time employment with another organization aside from the SBC or the research institution. An SBC may replace the principal investigator on an STTR Phase I or Phase II award, subject to approval in writing by the funding agreement officer. For purposes of the STTR Program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee. This is consistent with SBA's size regulations, 13 CFR 121.106—Small Business Size Regulations.

The PD/PI must commit a minimum of 10% (1.2 calendar months) effort to the project and the PD/PI must have a formal appointment with or commitment to the applicant small business concern, which is characterized by an official relationship between the small business concern and that individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the PD/PI's official relationship with the grantee must entail sufficient opportunity for the PD/PI to carry out his or her responsibilities for the overall scientific and technical direction of the project. Documentation (e.g., consortium and contractual arrangements) describing the official relationship of the PD/PI with the applicant small business concern should NOT be submitted with the grant application, but a copy must be furnished upon the request of the NIH awarding component.

For Multiple PD/PI applications: The first PD/PI listed must be affiliated with the applicant small business concern and will serve as the Contact PD/PI. For STTR, the Contact PD/PI may be from either the SBC or the single partnering research institution. Note: the Contact PD/PI 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.

Following is guidance for such documentation, which is required prior to award: The letter should be prepared on the letterhead of the independent PD/PI and addressed to the Small Business Concern (SBC). One page is recommended. At a minimum, each letter should (1) verify the PD/PI's commitment to the project; (2) refer to the specific project by name; and (3) specify what assets or services the PI will contribute (e.g. expertise, number of hours/ percent of effort) as well as the PD/PI's remuneration. The letter should also indicate that the PD/PI and the SBC have reached an agreement on proprietary interests for the project to continue to move forward (e.g., intellectual property).

Signatures of the Authorized Organization Representative (a.k.a. Signing Official) for the applicant organization on the Authorized Representative section of the SF424 (R&R) form and the signature of the duly authorized representative of the research institution certifies, among other things, that the PD/PI has a formal relationship with/commitment to the small business concern when the PD/PI is an employee of the Research Institute (RI).

The following are examples of situations describing the official relationship of the PD/PI with the applicant small business organization:

- PD/PI with a full-time, university appointment may also have appointments with other organizations (with or without salary) and still appropriately consider his or her commitment to the university to be "full-time," consistent with the personnel policies and procedures of the university applied on a routine basis. The PD/PI's commitment to the university and other organizations (including the applicant small business concern) cannot exceed 100% of his or her total professional effort.
- PD/PI with a full-time, 12-month appointment with a small business concern would be considered to have a commitment to the applicant organization of 100% of his or her total professional effort.
- PD/PI who has a part-time appointment with a small business concern and has concurrent commitments or appointments with organizations in addition to the small business concern would deem each commitment as a portion of 100% of his or her total professional effort.

As responsible stewards of funds, the NIH is concerned that the PD/PI has the time available to carry out the proposed STTR research activities. Therefore, it should be clear in the application that the time proposed for the PD/PI on a particular project is reasonable and it should be clear that the PD/PI has sufficient time (minimum 10% effort, which is 1.2 calendar months) from among his or her total professional commitments to devote to this project.

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE **Page 2**

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization Name:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested
b. Total Non-Federal Funds
c. Total Federal & Non-Federal Funds
d. Estimated Program Income

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:
b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR
☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious. or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

☐ **I agree**

**The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

Signature of Authorized Representative: Completed on submission to Grants.gov

Date Signed: Completed on submission to Grants.gov

20. Pre-application Add Attachment | Delete Attachment | View Attachment

21. Cover Letter Attachment Add Attachment | Delete Attachment | View Attachment

15. Estimated Project Funding

Field Name	Instructions
a. Total Federal Funds Requested	Enter the total Federal funds, including Direct Costs, F&A Costs (Indirect Costs), and Fee, requested for the entire project period. According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II, a hard cap). As written in the statute and under appropriate circumstances, NIH can apply for a waiver from SBA to issue an award exceeding $225,000 for Phase I or $1,500,000 for Phase II, if this hard 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. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project. NOTE: CDC, FDA, and ACF do not make awards above these statutory guidelines.
b. Total Non-Federal Funds	Enter total non-Federal funds proposed for the entire project period. For applications to NIH and other PHS agencies, enter "0" in this field unless cost sharing is a requirement for the specific announcement.
c. Total Federal & Non-Federal Funds	Enter total estimated funds for the entire project period, including both Federal and non-Federal funds. This field is required. For NIH and other PHS agencies applicants, this field will be the same as Total Federal Funds Requested above unless the specific announcement indicates that cost sharing is a requirement.
d. Estimated Program Income	Identify any Program Income estimated for this project period, if applicable. This field is required.

16. Is Application Subject to Review by State Executive Order 12372 Process?

If yes, check box. If the announcement indicates that the program is covered under Executive Order 12372, applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372. If no, check appropriate box.

If block 16a is checked, insert date application was submitted to State.

For NIH and other PHS agencies submissions using the SF424 (R&R), applicants should check "No, Program is not covered by E.O. 12372."

17. Certification

Check "I agree" to provide the required certifications and assurances. This field is required.

The list of NIH and other PHS agencies Assurances, Certifications, and other Policies is found in Supplemental Instructions Part III, Policies, Assurances, Definitions, and Other Information.

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

18. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation

If applicable, attach the SFLLL or other explanatory document per agency instructions.

If unable to certify compliance in with the Certification above attach an explanation. Additionally, as applicable, attach the SFLLL (Standard Form LLL, Disclosure of Lobbying Activities) or other documents in this item. A fillable version of the SFLLL form is available at http://www.whitehouse.gov/omb/assets/omb/grants/sflllin.pdf.

19. Authorized Representative

This is equivalent to the individual with the organizational authority to sign for an application; otherwise known as the Authorized Organization Representative or the Signing Official.

Field Name	Instructions
Prefix	Enter the prefix (Mr., Mrs., Rev.) for the name of the Authorized Representative.
First Name	Enter the first (given) name of the Authorized Representative. This field is required.
Middle Name	Enter the middle name of the Authorized Representative.
Last Name	Enter the last (family) name of the Authorized Representative. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the Authorized Representative.
Position/Title	Enter the Title of the name of the Authorized Representative. This field is required.
Organization Name	Enter the name of the organization for the Authorized Representative. This field is required.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the Authorized Representative.
Division	Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative.
Street1	Enter the first line of the street address for the Authorized Representative in the “Street1” field. This field is required.
Street2	Enter the second line of the street address for the Authorized Representative in the “Street2” field. This field is optional.
City	City for address of the Authorized Representative. This field is required.
County/Parish	Enter the county or parish for address of the Authorized Representative.
State	Enter the State where the Authorized Representative is located. This field is required if the Authorized Representative is located in the United States.
Province	Enter the province for the Authorized Representative.

Field Name	Instructions
	If "Country" is not Canada, please leave blank.
Country	Select the country for the Authorized Representative address.
ZIP/Postal Code	Enter Postal Code (e.g., ZIP code) of the Authorized Representative. This field is required if the Authorized Representative is located in the United States. A nine-digit Zip code is required.
Phone Number	Enter the daytime phone number for the Authorized Representative. This field is required
Fax Number	Enter the fax number for the Authorized Representative.
E-mail	Enter the e-mail address for the Authorized Representative. This field is required.
Signature of Authorized Representative	It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov. If this application is submitted through Grants.gov, leave blank. If a hard copy is submitted, the AOR must sign this block.
Date Signed	If this application is submitted through Grants.gov, the system will generate this date. If submitting a hard copy, enter the date the AOR signed the application.

20. Pre-Application

If submitting a pre-application, provide a summary description of the project in accordance with the announcement and/or agency specific instructions, and save the file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.

Unless specifically noted in a Funding Opportunity Announcement, NIH and other PHS agencies do not use Pre-applications and this attachment field should not be used for any other purpose.

21. Cover Letter Attachment

Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the announcement and/or the agency specific instructions.

Applicants are encouraged to include a cover letter with the application. Please attach the cover letter in the correct location, **specifically verify that the cover letter has not been uploaded to the pre-application field which is directly above the cover letter field**. This will ensure the attachment is kept separate from the assembled application in Commons and only made available to appropriate staff.

A cover letter should not be included with post-award submissions such as administrative supplements, change of grantee institution, or successor-in-interest. The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH initiative.
3. Request of an assignment (referral) to a particular awarding component(s) (IC) and SRG.
4. A brief list of individuals (e.g., those with conflicts of interest) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. For late applications (see Late Application policy in Section 2.14) include specific information about the timing and nature of the cause of the delay.
7. When submitting a Changed/Corrected Application **after** the due date, a cover letter is **required** explaining the reason for late submission of the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a late Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
8. Explanation of any subaward budget components that are not active for all periods of the proposed grant.
9. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc. It is recommended that you include the official communication from an NIH official as part of your cover letter.
10. When intending to submit a video as part of the application, the cover letter **must** include information about the intent to submit it; if this is not done, a video will not be accepted. See NOT-OD-12-141 for additional information.
11. Include a statement in the cover letter if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy (NOT-OD-14-11 and NOT-OD-15-027.)

Suggested Cover Letter Format

The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to ICs and to Scientific Review Groups (SRGs). Requests made by

investigators are a valuable source of information in the referral process. To facilitate the use of these requests, applicants are requested to use the following format when assignment requests are contained in a cover letter.

- List one request per line.
- Cite the funding opportunity announcement.
- Place Institute/Center (IC) and SRG review requests (if both are made) on separate lines.
- Place positive and negative requests (if both are made) on separate lines.
- Provide any explanations for each request in a separate paragraph.

Examples:

Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

The reasons for this request are [provide a narrative explanation for the request(s)].

4.3 Project/Performance Site Locations Form

OMB Number: 4040-0010

Project/Performance Site Location(s)

Project/Performance Site Primary Location ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Project/Performance Site Location 1 ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Additional Location(s) Add Attachment Delete Attachment View Attachment

Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location(s) in the blocks provided.

Project/Performance Site Primary Location

Generally, the Primary Location should be that of the applicant organization or identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the Cover Page Supplement Form of the application. If there is more than one performance site, including any Department of Veterans Affairs (VA) facilities and foreign sites, list them in the fields provided for Location 1 - # below. Applicants should also

provide an explanation of resources available from each Project/Performance Site, the Facilities and Resources attachment of the Other Project Information form, and describe any consortium/contractual arrangements in the Consortium/Contractual Arrangements attachment of the PHS 398 Research Plan.

Unless otherwise instructed in the FOA, do **not** check the "I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization" box.

If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR part 46 and other NIH human subject related policies described in Supplemental Instructions Part II of this Application Guide and in the NIH Grants Policy Statement.

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold an OLAW-approved Animal Welfare Assurance. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

For SBIR/STTR applications, one of the performance sites indicated must be that of the applicant small business concern.

For both Phase I and Phase II, the research or R&D project activity must be performed in the United States. However, based on a rare and unique circumstance, for example, if a supply or material or the study design (e.g., patient population) is not available in the United States, NIH may allow that particular portion of the research or R&D work to be performed or obtained in a foreign country. Investigators must thoroughly justify the use of these sites in the application. These rare and unique situations will be considered on a case-by-case basis, and they should be discussed with NIH staff prior to submission of the application. Approval by the funding officer for such specific condition(s) must be in writing prior to issuance of an award. Whenever possible, non-SBIR/STTR funds should be used for other work outside of the United States that is necessary to the overall completion of the project.

The research and analytical work performed by the grantee organization is to be conducted in research space occupied by, available to, and under the control of the SBIR/STTR grantee for the conduct of its portion of the proposed project. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR/STTR awardee has entered into a subcontractual agreement with another institution for a specific, limited portion of the research project.

Whenever a proposed SBIR/STTR project is to be conducted in facilities other than those of the applicant organization, the awarding component will request that the small business concern provide a letter from the organization stating that leasing/rental arrangements have been negotiated for appropriate research space. This letter must be signed by an authorized official of the organization whose facilities are to be used for the SBIR/STTR project and must certify that the small business concern (grantee organization) will have access to and control over the research space. In addition, the letter must include a description of the

facilities and, if appropriate, equipment that will be leased/rented to the grantee organization. (If the letter is included with the application, it is excluded from the page limitations.) Attach this letter to the PHS 398 Research Plan Form, Item 13, Consortium/Contractual Arrangements.

Field Name	Instructions
Organization Name	Indicate the organization name of the primary site where the work will be performed. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.
DUNS Number	Enter the DUNS number associated with the organization where the project will be performed. The DUNS Number is a required field for the Primary Performance Site.
Street1	Enter first line of the street address of the primary performance site location. This field is required.
Street2	Enter second line of the street address of the primary performance site location, if applicable.
City	Enter the city for address of the primary performance site location. This field is required.
County/Parish	Enter the county or parish of the primary performance site location.
State	Select the state of the primary performance site location. This field is not active until USA has been selected for the country. This field is required if the performance site location is in the United States.
Province	Enter the province for the primary performance site location. If “Country” is not Canada, please leave blank.
Country	Select the Country of the Primary Performance Site location. This field is required.
ZIP Code	Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States.

Field Name	Instructions
	A nine-digit Zip code is required.
Project/Performance Site Congressional District	Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district. If all districts in a state are affected, enter "all" for the district number. Example MD-all for all congressional districts in Maryland. If nationwide (all districts in all states), enter US-all. If the program/project is outside the U.S., enter 00-000. To locate your congressional district, visit the Grants.gov Web site. Note it is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application. For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

Project/Performance Site Location 1

Field Name	Instructions
Organization Name	Enter the name of organization of the performance site location. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.
DUNS Number	Enter the DUNS number associated with the organization where the project will be performed.
Street1	Enter first line of the street address of the performance site location. This field is required.
Street2	Enter second line of the street address of the performance site location, if applicable.
City	Enter the city of the performance site location. This field is

Field Name	Instructions
	required
County/Parish	Enter the county or parish of the performance site location.
State	Select the state of the performance site location. This field is not active until USA has been selected for the country. This field is required if the performance site location is in the United States.
Province	Enter the province of the performance site location. If "Country" is not Canada, please leave blank.
Country	Select the country for the performance site location. This field is required.
ZIP Code	Enter the nine-digit postal code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States.
Project/Performance Site Congressional District	Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district. If all districts in a state are affected, enter "all" for the district number. Example MD-all for all congressional districts in Maryland. If nationwide (all districts in all states), enter US-all. If the program/project is outside the U.S., enter 00-000. To locate your congressional district, visit the Grants.gov Web site. Note it is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application. For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.

For additional performance site locations, click **Next Site** to display the fields for Project/Performance Site Locations 2 through 300.

If you need to add more than 300 locations, enter the information in a separate file. In the Additional Locations section at the bottom of the form, click **Add Attachment**, select the file, and then click **Open**. A sample Additional Performance Sites format page for greater than eight locations is found under "Additional Format Pages" at: http://grants.nih.gov/grants/funding/424/index.htm.

4.4 Other Project Information Form

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 6/30/2016

1. Are Human Subjects Involved? ☐ Yes ☐ No
   1.a. If YES to Human Subjects
   Is the Project Exempt from Federal regulations? ☐ Yes ☐ No
   If yes, check appropriate exemption number. ☐1 ☐2 ☐3 ☐4 ☐5 ☐6
   If no, is the IRB review Pending? ☐ Yes ☐ No
   IRB Approval Date:
   Human Subject Assurance Number:
2. Are Vertebrate Animals Used? ☐ Yes ☐ No
   2.a. If YES to Vertebrate Animals
   Is the IACUC review Pending? ☐ Yes ☐ No
   IACUC Approval Date:
   Animal Welfare Assurance Number:
3. Is proprietary/privileged information included in the application? ☐ Yes ☐ No
4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No
4.b. If yes, please explain:
4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No
4.d. If yes, please explain:
5. Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No
5.a. If yes, please explain:
6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No
6.a. If yes, identify countries:
6.b. Optional Explanation:
7. Project Summary/Abstract — Add Attachment | Delete Attachment | View Attachment
8. Project Narrative — Add Attachment | Delete Attachment | View Attachment
9. Bibliography & References Cited — Add Attachment | Delete Attachment | View Attachment
10. Facilities & Other Resources — Add Attachment | Delete Attachment | View Attachment
11. Equipment — Add Attachment | Delete Attachment | View Attachment
12. Other Attachments — Add Attachments | Delete Attachments | View Attachments

1. Are Human Subjects Involved?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check Yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any

time during the proposed project at any performance site, select no and skip the rest of block 1. This field is required.

Applications proposing human subjects research may be required to submit additional information, forms, or attachments with the application, in accordance with NIH and PHS policies covering human subjects research. Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan and Human Subjects Research Policy.

Note that applications involving the use of human biospecimens or data may or may not be considered as research involving human subjects depending on the details of the materials to be used. Applications that involve the use of human materials that check No for human subjects involvement must provide a clear justification about why this use does not constitute human subjects research. For more detail, refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan and Human Subjects Research Policy.

1.a. If YES to Human Subjects

Exemption Number

Is the Project Exempt from Federal Regulations? Yes/No

Yes: If the project is exempt from Federal regulations, check Yes. If yes, check the appropriate exemption number.

No: If the project is not exempt from Federal regulations, check No.

If yes, check appropriate exemption number 1, 2, 3, 4, 5, 6

Select the appropriate exemption number from 1, 2, 3, 4, 5, 6.

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://answers.hhs.gov/ohrp/categories/1564). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

Proposed research may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research. Human subjects research should be designated as exempt if all of the proposed research meets the criteria for one or more of the six exemptions.

If no, is the IRB review Pending? Yes/No

If IRB review is pending, check Yes. If IRB review is not pending, check No.

IRB Approval Date

Enter the latest Institutional Review Board (IRB) approval date (if available). Leave blank if Pending.

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle as a Just-In-Time requirement.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has an FWA number, enter the 8-digit number. Do not enter the FWA before the number.

Insert "None" if the applicant organization does not have an approved FWA on file with OHRP. In this case, the applicant organization, by the signature in the Certification signature section of the SF424 (R&R) form, is declaring that it will comply with 45 CFR part 46 and proceed to obtain an FWA (see http://www.hhs.gov/ohrp). **Do not insert the FWA number of any collaborating institution in the space provided**.

2. Are Vertebrate Animals Used?

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2. This field is required.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals. If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes" and add the Vertebrate Animals attachment to provide an explanation and to indicate when it is anticipated that animals will be used. If an award is made prior to the involvement of animals, the grantee must provide all of the information required by adding a Vertebrate Animals attachment in the Research Plan and verifying an IACUC approval to the awarding component.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

Indicate if an Institutional Animal Care and Use Committee (IACUC) review is pending.

Click Yes if an IACUC review is pending. Click **No**, if no review is pending.

Check "Yes" even if the IACUC review and approval process has not yet begun.

IACUC Approval Date

Enter the latest IACUC approval date (if available). Leave blank if Pending.

IACUC approval must have been granted within three years to be valid. Note that an IACUC Approval Date is not required at the time of submission. NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under Just-In-Time Policy.

Animal Welfare Assurance Number

Enter the Federally approved assurance number, if available.

Enter "None" if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. To determine if the applicant organization holds an Animal Welfare Assurance, see the lists of Domestic and Foreign Assured institutions. **Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution**. When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

3. Is proprietary/privileged information included in the application?

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation." This field is required.

If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. Although the grantee institution and the PD/PI will be consulted about any such disclosure, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). 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.

4. Environmental Questions

Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer 'No' to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the box marked "Yes" should be checked and an explanation provided in field 4.b.

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.

4.a. Does this project have an actual or potential impact on the environment?

Indicate if this project has an actual or potential impact on the environment? Click No here if this is not the case. This field is required.

4.b. If yes, please explain

Explanation of the actual or potential impact on the environment.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

Check yes or no. This field is required.

4.d. If yes, please explain

Enter additional details about the EA or EIS.

5. Is the research performance site designated, or eligible to be designated, as a historic place? Yes/No

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes box and then provide an explanation in the box provided in 5.a. Otherwise, check the No box. This field is required.

5.a. If yes, please explain:

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

6. Does this project involve activities outside of the United States or partnerships with International Collaborators?

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no. This field is required.

Applicants to NIH and other PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component. For a definition of a foreign component, see "Definitions" section of Supplemental Instructions Part III: Policies, Assurances, Definitions, and Other Information.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.

6.b. Optional Explanation

Enter an explanation for involvement with outside entities (optional). If desired, you can provide the information in a separate file, and attach by clicking Add Attachments located to the right of Item 11, Other Attachments.

If you have checked "Yes" to 6, applicants to the NIH and other PHS agencies must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. Provide this information in a separate file, attaching it as Item 12, Other Attachments. In the body of the text, begin the section with a heading indicating "Foreign Justification." When saving this file, please name it "Foreign Justification" as well.

7. Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically

literate lay reader. This Summary must not include any proprietary/confidential information. Please click the **Add Attachment** button to the right of this field to complete this entry.

The **Project Summary** is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at http://report.nih.gov) and will become public information.

The attachment must be in PDF format. (See Section 2.6 for additional information on preparing attachments.)

8. Project Narrative

Provide Project Narrative in accordance with the announcement and/or agency-specific instructions. Please click the **Add Attachment** button to the right of this field to complete this entry.

For NIH and other PHS agencies applications, using no more than two or three sentences, describe the relevance of this research to **public** health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

A separate Research Plan form is required for NIH and other PHS agencies applications. Refer to Section 5.5, Research Plan, for separate file uploads and instructions.

9. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application. To attach a document for Bibliography and References Cited, click **Add Attachment**.

Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly “Literature Cited”) should include any references

cited in the PHS 398 Research Plan form (see Section 5.5 for details on completing that form). When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research

10. Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Please click the **Add Attachment** button to the right of this field to complete this entry.

The research to be performed by the applicant small business concern and its collaborators must be in United States facilities (i.e., foreign sites must be approved by the funding officer) that are available to and under the control of each party for the conduct of each party's portion of the proposed project.

No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support. See http://grants.nih.gov/grants/new_investigators/

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. **Note: Information about select agents must be described in the Research Plan, Section 9 Select Agent Research.**

11. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Please click the **Add Attachment** button to the right of this field to complete this entry.

12. Other Attachments

Attach a file only to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction.

Additional Attachments (When Applicable)

Some FOAs require additional documents or certifications that will need to be uploaded here for research applications.

Authentication of Key Biological and/or Chemical Resources: Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

- Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Save this information in a single file named "Authentication of Key Resources Plan," and attach it as Item 12, Other Attachments, on the Other Project Information form. Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095 and NOT-OD-16-011).

1. SBA Company registry (for both SBIR and STTR)

All applicants to the SBIR and STTR programs are required to register at the SBA Company Registry prior to application submission and attach proof of registration.

Completed registrations will receive a unique SBC Control ID and .pdf file. If applicants have previously registered, you are still required to attach proof of registration. The SBA Company Registry recommends verification with SAM, but a SAM account is not required to complete the registration. In order to be verified with SAM, your email address must match one of the contacts in SAM. If you are unsure what is listed in SAM for your company, you may verify the information on the SAM site. Confirmation of your company's DUNS is necessary to verify your email address in SAM. Follow these steps listed below to register and attach proof of registration to your application.

a. Navigate to the SBA Company Registry.
b. If you are a previous SBIR/STTR awardee from any agency, search for your small business by Company Name, EIN/Tax ID, DUNS, or Existing SBIR/STTR Contract/Grant Number in the search fields provided. Identify your company and click "Proceed to Registration".
c. Fill out the required information on the "Basic Information" and "Eligibility Statement" screens.
d. Press "Complete Registration" on the lower right of the "Eligibility Statement" screen and follow all instructions.
e. Download and save your SBA registry PDF locally. The name will be in the format of SBC_123456789.pdf, where SBC_123456789 (9 digit number) is your firm's SBC Control ID. DO NOT CHANGE OR ALTER THE FILE NAME. Changing the file name may cause delays in the processing of your application.
f. When you are completing the application package, attach this SBA registry PDF as a separate file by clicking Add Attachments located to the right of Other Attachments on the "Research and Related Other Project Information" form.

For questions and for technical assistance concerning the SBA Company Registry, please contact the SBA at http://sbir.gov/feedback?type=reg.

2. NIH and CDC SBIR Only

SBIR Application Certification for small business concerns majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms. Applicant small business concerns that are majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms (e.g. majority VCOC-owned) are required to submit a Certification at time of their application submission per the SBIR Policy Directive. Follow the instructions below.

Applicants small business concerns who are 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 (i.e. NOT majority VCOC-owned) should **NOT** fill out this certification and should **NOT** attach it their application package.

a. Download the "SBIR Application VCOC Certification.pdf" at the NIH SBIR Forms webpage.
b. Answer the 3 questions and check the certification boxes.
c. The authorized business official must sign the certification.

d. Save the certification using the original file name. The file must be named "SBIR Application VCOC Certification.pdf". DO NOT CHANGE OR ALTER THE FILE NAME. Changing the file name may cause delays in the processing of your application.
e. When you are completing the application package, attach this certification as a separate file by clicking Add Attachments located to the right of Other Attachments on the "Research and Related Other Project Information" form.

4.5 Senior/Key Person Profile (Expanded) Form

OMB Number: 4040-0001

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name: Division:
* Street1:
Street2:
* City: County/ Parish:
* State: Province:
* Country: * Zip / Postal Code:
* Phone Number: Fax Number:
* E-Mail:

Credential, e.g., agency login:

*** Project Role:** PD/PI **Other Project Role Category:**

Degree Type:
Degree Year:

***Attach Biographical Sketch** Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

PROFILE - Senior/Key Person 1

Prefix: * First Name: Middle Name:
* Last Name: Suffix:
Position/Title: Department:
Organization Name: Division:
* Street1:
Street2:
* City: County/ Parish:
* State: Province:
* Country: USA: UNITED STATES * Zip / Postal Code:
* Phone Number: Fax Number:
* E-Mail:

Credential, e.g., agency login:

*** Project Role:** **Other Project Role Category:**

Degree Type:
Degree Year:

Attach Biographical Sketch Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

Delete Entry Next Person

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

This form provides the ability to collect structured data for up to 100 senior/key persons. Data must be entered for the first 100 individuals (PD/PI + 99 others) before the Additional Senior/Key Person Form Attachments section becomes available. The information for the PD/PI continues to be pre-populated from the SF424 (R&R) form. See instructions in Section 4.2 SF 424 (R&R) form if these fields are empty.

Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

Multiple PD/PIs

NIH is now accepting applications reflecting Multiple PD/PIs for all grant activity codes using the SF424 (R&R) application. When submitting an application involving Multiple PD/PIs, the Contact PD/PI must be affiliated in the Commons with the applicant organization and should be listed as the PD/PI in the SF424 R&R form (see Section 4.2.14). That information automatically prepopulates the first senior/key person profile record in this form. For the additional PD/PIs, complete all the requested information. **Each PD/PI must be assigned the PD/PI role, even those at subaward/consortium sites when applicable.** (Do **not** use the "Co-PD/PI" or Co-Investigator role.) For more information, please see Section 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium.

Each PD/PI must also be registered in the eRA Commons and must be assigned the PI Role in that system (note other roles such as SO or IAR will not give PD/PIs the appropriate access to the application records). Each PD/PI must include their respective eRA Commons ID in the Credential field. For more information on NIH Implementation of Multiple PD/PIs, see: http://grants.nih.gov/grants/multi_pi/index.htm.

When completing the detailed budget form for either the prime organization or a subaward/consortium organization, the project roles listed in the budget form should be consistent with those used in the Senior/Key Person Form.

Special Note for STTR applicants: The STTR applicant organization must officially affiliate the PD/PI with the small business concern in the Commons if the PD/PI is not an employee of the small business concern. See Section 2.2.2.2 for steps to affiliate a PD/PI to the applicant organization/institution.

Profile - Program Director/Principal Investigator (PD/PI)

Field Name	Instructions
Prefix	Pre-populated from the SF 424 (R&R). The prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Pre-populated from the SF 424 (R&R). The first (given) name of the PD/PI. This field is required.

Field Name	Instructions
Middle Name	Pre-populated from the SF 424 (R&R). The middle name of the PD/PI.
Last Name	Pre-populated from the SF 424 (R&R). The last (family) name of the PD/PI. This field is required.
Suffix	Pre-populated from the SF 424 (R&R). The suffix (e.g., Jr, Sr, PhD) for the name of the PD/PI.
Position/Title	Pre-populated from the SF 424 (R&R). The title of the PD/PI.
Department	Pre-populated from the SF 424 (R&R). The name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Organization Name	Pre-populated from the SF 424 (R&R). The name of organization of the PD/PI.
Division	Pre-populated from the SF 424 (R&R). The name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	Pre-populated from the SF 424 (R&R). The first line of the street address for the PD/PI in the "Street 1" field. This field is required.
Street2	Pre-populated from the SF 424 (R&R). The second line of the street address for the PD/PI in the "Street 2" field. This field is optional.
City	Pre-populated from the SF 424 (R&R). The city for address of PD/PI. This field is required.
County/Parish	Pre-populated from the SF 424 (R&R). The county/parish for address of PD/PI.
State	Pre-populated from the SF 424 (R&R). The state where the PD/PI is located. This field is required if the PD/PI is located in the United States.
Province	Pre-populated from the SF 424 (R&R). The Province where the PD/PI is located. If “Country” is not Canada, this will be blank.
Country	Pre-populated from the SF 424 (R&R). The country for the PD/PI

Field Name	Instructions
	address. This field is required.
ZIP Code	Pre-populated from the SF 424 (R&R). The postal Code (e.g., ZIP code) of PD/PI. This field is required if the PD/PI is located in the United States. A nine-digit Zip code is required.
Phone Number	Pre-populated from the SF 424 (R&R). The daytime phone number for the PD/PI. This field is required.
Fax Number	Pre-populated from the SF 424 (R&R). The fax number for the PD/PI.
E-mail	Pre-populated from the SF 424 (R&R). The e-mail address for the PD/PI. This field is required for PD/PI.
Credential, e.g., agency login	If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank. For NIH and other PHS agencies, registration in the eRA Commons for all PD/PIs is required. **The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here and must have the PI role in eRA Commons. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.** Note for applications reflecting Multiple PD/PIs, the Commons UserName must be provided for all individuals assigned the PD/PI Role on the application.
Project Role	Select one. Use "Other" if a category is not listed in the pick list. Select PD/PI for this person.
Other Project Role Category	Complete if you selected “Other Professional” or “Other” as a project role; e.g., Engineer, Chemist.

Field Name	Instructions
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information.
Attach Biographical Sketch	Provide a biographical sketch for the senior/key person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here. This is required information. Biographical sketches should follow the format described below.
Attach Current & Pending Support	Provide a list of all current and pending support for the PD/PI (even if they receive no salary support from the project(s)) for ongoing projects and pending applications. Show the total award amount for the entire award period (including indirect costs) as well as the number of person-months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of an application to other organizations for simultaneous consideration will not prejudice its review. Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to Other Support in Supplemental Instructions Part III, Policies, Assurances, Definitions and Other Information.

Profile – Senior/Key Person

The remaining senior/key person profiles should be listed in alphabetical order. While alphabetical order is preferred, it is not required. However, be aware that these profiles will appear in the application in the order provided by the applicant. Therefore, peer reviewers

will see them in the order presented. Those with a postdoctoral role should be included if they meet the definition of senior/key personnel.

Also use this section to list any Other Significant Contributors (OSCs), who are those individuals who commit to contribute to the scientific development or execution of the project, but do not commit 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 the OSC definition. OSCs should be listed **after** all senior/key persons.

A biosketch, including Research Support information, will be required all senior/key persons and OSCs as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion. However, if an award is to be made, Other Support information will not be required or accepted for OSCs since considerations of overlap do not apply to these individuals.

Should the level of involvement change for an individual listed as an OSC, requiring measurable effort on the award, the individual should be redesignated as "senior/key personnel." This change should be made before any compensation is charged to the project.

After providing data for each individual senior/key person (the following instructions also apply to OSCs), click the **Next Person** button at the bottom of the form to enter data for the next senior/key person. Continue in this manner until data has been provided for up to 100 senior/key persons. To ensure proper performance of this form, after adding 20 additional senior/key persons please save your application, close the Adobe reader, and reopen it. For applications involving more than 100 senior/key persons, the "Additional Senior/Key Person Profiles" fields will become available once data for the first 100 senior/key persons has been provided.

Field Name	Instructions
Prefix	Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the Senior/Key Person
First Name	Enter the first (given) name of the Senior/Key Person. This field is required.
Middle Name	Enter the middle name of the Senior/Key Person, if applicable.
Last Name	Enter the last (family) name of the Senior/Key Person. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Senior/Key Person.
Position/Title	Enter the title of the Senior/Key Person.
Department	Enter the name of primary organizational department, service,

Field Name	Instructions
	laboratory, or equivalent level within the organization of the Senior/Key Person.
Organization Name	Enter the name of organization of the Senior/Key Person. This is a required field for applications submitted to NIH and other PHS agencies.
Division	Enter the name of primary organizational division, office, or major subdivision of the Senior/Key Person.
Street1	Enter first line of the street address for the Senior/Key Person in the "Street 1" field. This field is required.
Street2	Enter second line of the street address for the Senior/Key Person in the "Street 2" field. This field is optional.
City	City for address of Senior/Key Person. This field is required
County/Parish	County/Parish for address of Senior/Key Person.
State	Enter the State where the Senior/Key Person is located. This field is required if the senior/key person is located in the United States.
Province	Enter the Province where the Senior/Key Person is located. If “Country” is not Canada, please leave blank.
Country	Select the country for the Senior/Key Person address. This field is required.
ZIP Code	Enter the Postal Code (e.g., ZIP code) of Senior/Key Person. This field is required if the Senior/Key Person is located in the United States. A nine-digit Zip code is required.
Phone Number	Enter the daytime telephone number for the Senior/Key Person. This field is required.

Field Name	Instructions
Fax Number	Enter the fax number for the Senior/Key Person.
E-mail	Enter the e-mail address for the Senior/Key Person. This field is required for the Senior/Key Person.
Credential, e.g., agency login	If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank.
Project Role	Select one. Use "Other" if a category is not listed in the pick list. For applications reflecting Multiple PD/PIs, all such individuals must be assigned the PD/PI role, even those at organizations other than the applicant organization. The role of “Co-PD/PI” is not currently used by NIH and other PHS agencies. Assigning an individual(s) the role of "Co-PD/PI" will not identify the application as a Multiple PD/PI application. If applicants wish to use a different role, select “Other” for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field. If including individuals classified as “Other Significant Contributors (OSCs),” use the “Other” category and indicate “Other Significant Contributor” as the role in the “Other Project Role Category.” OSCs should be listed last after all other senior/key persons have been listed.
Other Project Role Category	Complete if you selected “Other Professional” or “Other” as a project role; e.g., Engineer, Chemist.
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information. Applicants should ensure that their degree information is current in their Commons Profile.
Attach Biographical Sketch	Provide a biographical sketch for the senior/key person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and

Field Name	Instructions
	attach here. This field is required. Biographical sketches should follow the format described below.
Attach Current & Pending Support	Provide a list of all current and pending support for the senior/key person (even if they receive no salary support from the project(s)) for ongoing projects and pending proposals. Show the total award amount for the entire award period (including indirect costs) as well as the number of person-months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of a proposal to other organizations will not prejudice its review. Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs refer to Other Support in Supplemental Instructions Part III, Policies, Assurances, Definitions and Other Information.

Additional Senior/Key Person Profile(s)

If more than 99 senior/key person profiles are proposed, enter the information in a separate file and attach it here.

A sample Additional Senior/Key Person Profiles format page for greater than 100 profiles is found under "Additional Format Pages" at: http://grants.nih.gov/grants/funding/424/index.htm.

Additional Biographical Sketch(es) (Senior/Key Person)

Provide a biographical sketch for each senior/key person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here.

Biographical Sketches should follow the format described below.

Additional Current and Pending Support

Provide a list of all current and pending support for the PD/PI and each senior/key person (even if they receive no salary support from the project(s) for ongoing projects and pending proposals). Show the total award amount for the entire award period (including indirect costs) as well as the number of person months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of a proposal to other organizations will not prejudice its review.

Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, refer to Other Support in Supplemental Instructions Part III, Policies, Assurances, Definitions, and Other Information.

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

Use the sample *format* on the Biographical Sketch Format Page to prepare this section for **all** (modular *and* other) grant applications. Include biographical sketches of all **senior/key personnel and Other Significant Contributors**. The Biographical Sketch may not exceed five pages per person. This 5-page limit includes the table at the top of the first page. See the sample of a completed Biographical Sketch.

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI but is currently optional for all other senior/key persons. In other federal forms this information is referred to as "Credential, e.g., agency login." For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.

Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the Field of Study should reflect the area of residency.

Following the educational block, complete sections A, B, C, and D as described below.

A. **Personal Statement.** Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.
B. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. **Contributions to Science.** Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central findng(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can list audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

D. **Research Support**. List both selected ongoing and completed research projects for the past three years (Federal or non-Federal support). *Begin with the projects that are most relevant to the research proposed in the application*. Briefly indicate the overall goals of the projects and responsibilities of the senior/key person identified on the Biographical Sketch. *Do not include number of person months or direct costs*.

   Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

4.6 (Reserved)

4.7 R&R Budget Form

The R&R Budget form includes three separate data entry screens: (1) Sections A and B; (2) Sections C through E; and (3) Sections F through K. To navigate between the various screens, use the **Previous** and **Next** buttons at the top of the form or use the scroll bar on the side of the screen. Complete the R&R Budget form following the instructions provided. You must complete a separate detailed budget for each year of support requested. The form will generate a cumulative budget for the total project period. If no funds are requested for a required field, enter "0."

While the dollar fields allow cents to be entered, all dollar fields should be presented in whole numbers. Please round to the nearest whole number.

NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at:

http://grants.nih.gov/grants/policy/person_months_faqs.htm. Frequently asked questions and a conversion calculator are available.

If funds are being requested for more than one budget period, click the **Next Period** button at the top of the third budget screen (Sections F through K) to navigate to screens for the next budget period.

Revision (Supplemental) Application. For a Revision application, show only those items for which additional funds are requested. If the initial budget period of the Revision application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

4.7.1 Sections A and B

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001

ORGANIZATIONAL DUNS: Enter name of Organization:

Budget Type: Project Subaward/Consortium Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)

Project Role:

Additional Senior Key Persons: Add Attachment Delete Attachment View Attachment

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

B. Other Personnel

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B)

Organizational DUNS

Enter the DUNS or DUNS+4 number of the applicant organization. For project applicant, this field is pre-populated from the SF 424 (R&R) form. For subaward applicants, this field is a required enterable field.

Enter name of Organization

Pre-populated from the SF 424 (R&R) form. Enter the name of the organization.

Budget Type

Project, Subaward/Consortium: Check the appropriate block. This field is required.

Project: The budget requested for the primary applicant organization.

Subaward/Consortium: The budget requested for subawardee/consortium organization(s). Note, separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

If creating Subaward Budget, use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget Attachment(s) form.

If you are preparing an application that includes a subaward/consortium, see Section 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium.

Start Date

Pre-populated from the SF424 (R&R). Enter the requested/proposed start date of each budget period. This field is required.

End Date

Enter the requested/proposed end date of each budget period. This field is required.

Budget Period

Identify the specific budget period (for example, 1, 2, 3, 4, 5). If submitting through Grants.gov, the system will automatically generate a cumulative budget for the total project period. This is a required field.

(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the form.)

A. Senior/Key Person

This section should include the names of all senior/key persons at the applicant organization who are involved on the project in a particular budget year. Include all collaborating investigators, and other individuals meeting the senior/key person definition if they are from the applicant organization. Details of collaborators at other institutions will be provided in the Subaward budget for each subaward/consortium organization. Personnel listed as Other Significant Contributors who are not committing any specific measurable effort to the project should not be included in the Personnel section of the budget since no associated salary and/or fringe benefits should be requested for their contribution. Consultants designated as senior/key persons in the Senior/Key Person Profile Form can be included in Budget Section A only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in Consultant Services.

Field Name	Instructions
Prefix	Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of each Senior/Key Person.
First Name	Enter the first (given) name of each senior/key person.
Middle Name	Enter the middle name of each Senior/Key Person, if applicable.
Last Name	Enter the last (family) name of each Senior/Key Person. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., PhD) of each Senior/Key Person.
Base Salary ($)	Enter the annual compensation paid by the employer for each Senior/Key Person. This includes all activities such as research, teaching, patient care, or other. You may choose to leave this column blank. An applicant organization may choose to leave this blank; however, PHS staff will request this information prior to award.
Cal. Months	Identify the number of months devoted to the project for each senior/key person (i.e., calendar, academic, summer). If effort does not change throughout the year, it is OK to use only the calendar months column. However, you may use both academic and summer months columns if your institutional business process requires noting each separately even if effort remains constant. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns. Please use either calendar months OR a combination of academic and summer months. Some measurable effort is required for every Senior/Key Person entry.
Acad. Months	Identify the number of months devoted to the project for each senior/key person (for example, calendar, academic, summer). If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification. Some measurable effort is required for every Senior/Key Person entry.

Field Name	Instructions
Sum. Months	Identify the number of months devoted to the project for each senior/key person (for example, calendar, academic, summer). If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification. Some measurable effort is required for every Senior/Key Person entry.
Requested Salary ($)	Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each senior/key person. This field is required. Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award; therefore requested salary should be based on institutional base salary at the time the application is submitted and not adjusted for any limitation. For guidance on current salary limitations, see the Salary Cap Summary on the NIH grants website or contact your office of sponsored programs. NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.
Fringe Benefits ($)	Enter applicable fringe benefits, if any, for each senior/key person.
Funds Requested ($)	The requested salary and fringe benefits for each senior/key person. This field is auto-calculated.
Project Role	Identify the project role of each senior/key person in this section. This section could also include such roles as Co-PD/PI, Postdoctoral Associates, and Other Professionals. Roles should correspond to the roles included on the Senior/Key Person Profile (Expanded) Form.

Field Name	Instructions
Additional Senior/Key Persons	If funds are requested for more than eight senior/key persons, include all pertinent budget information as identified in this section and attach as a file here. Enter the total funds requested for all additional senior/key persons in line 9 of Section A. This attachment is required if funds are entered in line 9 of Section A. Use the same format as the budget form and include all required information.
Total Funds requested for all persons in the attached file	Enter the total funds requested for all senior/key persons. This is required information.
Total Senior/Key Persons	The total funds requested for all senior/key persons.

Special Instructions: Joint University and Department of Veterans Affairs (V.A.) Appointments

Individuals with joint university and V.A. appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the V.A.; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding components.

B. Other Personnel

Field Name	Instructions
Number of Personnel	For each project role category identify the number of personnel proposed. In most circumstances, the salaries of administrative or clerical staff at educational institutions and nonprofit organizations are included as part of indirect costs. Examples, however, of situations where direct charging of administrative or clerical staff salaries may be appropriate may be found at: http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html#exc. The circumstances for requiring direct charging of these services must be clearly described in the budget justification.

Field Name	Instructions
	For all Postdoctoral Associates and Graduate Students not already named in Section A. Senior/Key Person, individually list names, roles (e.g., PostDoc or Graduate Student), associated months, and salary & fringe benefits requested in the Budget Justification. The salaries of administrative and clerical personnel should normally be treated as F&A costs. Inclusion of such 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 or have prior written approval of the Federal awarding agency; and 4. The costs are not also recovered as indirect costs. Requests for direct charging or Secretarial/Clerical Personnel (i.e., administrative and clerical staff) must be appropriately justified in the Budget Justification.
Project Role	For each project role category identify the number of personnel proposed. List any additional project role(s) in the blank(s) provided, e.g., Engineer, IT Professionals, etc. Do not include consultants in this section. Consultants are included below in Section F. Other Direct Costs.
Cal. Months	Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer).
Acad. Months	Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer).

Field Name	Instructions
	If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification.
Sum. Months	Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer). If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification.
Requested Salary ($)	Regardless of the number of months being devoted to the project, indicate only the amount of salary/wages being requested for each project role. Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For guidance on current salary limitations, see the Salary Cap Summary on the NIH grants website or contact your office of sponsored programs. NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.
Fringe Benefits ($)	Enter applicable fringe benefits, if any, for this project role category.
Funds Requested ($)	This field is auto-calculated.
Total Number of Other Personnel	This total will auto-calculate. Total Number of Personnel.
Total Other Personnel	Total Funds requested for all other Personnel.
Total Salary, Wages and	Total Funds requested for all Senior/Key persons and all Other

Field Name	Instructions
Fringe Benefits (A+B)	Personnel. This total will auto-calculate.

To navigate to the next page (Sections C through E), click the **Next** button at the top of the form or use the scroll bar on the left-hand side of the screen.

4.7.2 Sections C through E

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item | Funds Requested ($)

Additional Equipment: | Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel | Funds Requested ($)

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)
2. Foreign Travel Costs

Total Travel Cost

E. Participant/Trainee Support Costs | Funds Requested ($)

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other

Number of Participants/Trainees | Total Participant/Trainee Support Costs

C. Equipment Description

List of items and dollar amount for each item exceeding $5,000.

Field Name	Instructions
Equipment Item	Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. List each item of equipment separately and justify each in the budget justification section. Allowable items ordinarily will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual

Field Name	Instructions
	conduct of scientific research.
Funds Requested	List the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. This is required information.
Additional Equipment	If this section cannot accommodate all the equipment proposed, attach a file in the block provided. List each additional item and the funds requested. For all additional items in the attached file, list the total funds requested in the following field
Total funds requested for all equipment listed in the attached file	Total funds requested for all equipment listed in the attached file. Dollar amount for each item should exceed $5000.
Total Equipment	Total Funds requested for all equipment.

D. Travel

Field Name	Instructions
Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	Identify the total funds requested for domestic travel. Domestic travel includes Canada, Mexico, and U.S. possessions. In the budget justification section, include the purpose, destination, dates of travel (if known), and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).
Foreign Travel Costs	Identify the total funds requested for foreign travel. Foreign travel includes any travel outside of North America and/or U.S. possessions. In the budget justification section, include the purpose, destination, dates of travel (if known) and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).
Total Travel Cost	Total Funds requested for all travel.

E. Participant/Trainee Support Costs

Unless specifically stated otherwise in an announcement, NIH and other PHS agencies applicants should leave blank Section E. Note: Tuition remission for graduate students should continue to be included in Section F. Other Direct Costs when applicable.

Field Name	Instructions
Tuition/Fees/Health Insurance	List total funds requested for Participant/Trainee Tuition / Fees / Health insurance.
Stipends	List total funds requested for Participant/Trainee stipends.
Travel	List total funds requested for Participant/Trainee travel.
Subsistence	List total funds requested for Participant/Trainee subsistence.
Other	Describe any other participant trainee funds requested. List total funds requested for any other Participant/Trainee costs described.
Number of Participants/Trainees	List total number of proposed Participants/Trainees.
Total Participant/Trainee Support Costs	Total Funds requested for all trainee costs.

4.7.3 Sections F through K

F. Other Direct Costs — Funds Requested ($)

1. Materials and Supplies
2. Publication Costs
3. Consultant Services
4. ADP/Computer Services
5. Subawards/Consortium/Contractual Costs
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations
8.
9.
10.

Total Other Direct Costs

G. Direct Costs — Funds Requested ($)

Total Direct Costs (A thru F)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)

Total Indirect Costs

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs — Funds Requested ($)

Total Direct and Indirect Institutional Costs (G + H)

J. Fee — Funds Requested ($)

K. Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel — **Funds Requested ($)**

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)
2. Foreign Travel Costs

Total Travel Cost

E. Participant/Trainee Support Costs — **Funds Requested ($)**

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other

Number of Participants/Trainees **Total Participant/Trainee Support Costs**

F. Other Direct Costs

Field Name	Instructions
1. Materials and Supplies	List total funds requested for materials and supplies. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than $1,000 are not required to be itemized.
2. Publication Costs	List the total publication funds requested. The proposal budget may request funds for the costs of documenting, preparing, publishing, or otherwise making available to others the findings and products of the work conducted under the award. In the budget justification include supporting information.
3. Consultant Services	List the total costs for all consultant services. In the budget justification, identify each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs.

Field Name	Instructions
	In the budget justification also provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed.
4. ADP/Computer Services	List total funds requested for ADP/computer services. The cost of computer services, including computer-based retrieval of scientific, technical and education information may be requested. In the budget justification, include the established computer service rates at the proposing organization if applicable.
5. Subawards/Consortium/ Contractual Costs	List total funds requested for 1) all subaward/consortium organization(s) proposed for the project and 2) any other contractual costs proposed for the project. This line item should include both direct and indirect costs for all subaward/consortium organizations. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of the budget justification. NIH policy provides for exclusion of consortium/contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. Please see the Supplemental Instructions, Part III, Section 1.1 for additional information regarding this exclusion Policy
6. Equipment or Facility Rental/User Fees	List total funds requested for equipment or facility Rental/Use fees. In the budget justification, identify each rental user fee and justify.
7. Alterations and Renovations	List total funds requested for alterations and renovations. In the budget justification, itemize by category and justify the costs of alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.

Field Name	Instructions
	Under certain circumstances the public policy requirements that apply to construction activities may also apply to A&R activities. Please refer to the NIH Grants Policy Statement section on "Construction Grants – Public Policy Requirements and Objectives" for more information. Note, costs for any Alterations and Renovations (A&R) were previously unallowable on domestic applications with foreign subawards. However, an HHS policy change now allows for minor A&R (≤$500,000) on these applications. When requesting minor A&R costs under this policy, please provide detailed information on the planned A&R in the budget justification.
8-10 Other	Add text to describe any "other" direct costs not requested above. Use the budget justification to further itemize and justify. List total funds requested for items 8-10 "Other." Use lines 8-10 for such costs as SBIR/STTR technical assistance, patient care and tuition remission. If requesting patient care costs, request inpatient and outpatient costs separately using lines 8 and 9.
Total Other Direct Costs	Total Funds requested for all other direct costs.

Special Instructions for Technical Assistance Costs

NIH offers distinct technical assistance programs to SBIR and STTR Phase I and Phase II awardees. These programs offer specialized, strategic business training and provide access to a vast network of industry experts possible through the efficiencies of scale that under a contract deliver the best value to the government and the intended small businesses seeking such assistance. If you wish to utilize your own technical assistance provider, you are required to include this as a consultant in your budget and to provide a detailed budget justification. You may request up to $5,000 for assistance. Reimbursement is limited to services received that comply with 15 U.S.C. § 638(q):

To provide small business concerns engaged in SBIR or STTR projects with technical assistance services, such as access to a network of scientists and engineers engaged in a

wide range of technologies, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns in:

A. Making better technical decisions concerning such projects;
B. Solving technical problems which arise during the conduct of such projects;
C. Minimizing technical risks associated with such projects; and
D. Developing and commercializing new commercial products and processes resulting from such projects.

To request technical assistance from your own provider:

1. Label the requested cost of up to $5,000 "Technical Assistance" on lines 8-10.
2. Include a detailed description of the services your vendor will provide in the Budget Justification.

G. Total Direct Costs (A through F)

Total funds requested for all direct costs.

H. Indirect Costs

Indirect costs are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. If the applicant small business concern has a currently effective negotiated indirect cost rate with a Federal agency, that rate should be used when calculating proposed indirect costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services [HHS].)

If applicable, indicate your organization's most recent indirect cost rate established with the Division of financial Advisory Services (DFAS), NIH, or with another Federal agency. If your applicant organization is in the process of negotiating or renegotiating a rate, use that rate in the application.

If the applicant organization does not have a current negotiated rate, it should develop a provisional rate for application purposes. If the applicant organization has a current negotiated rate with another Federal agency, the negotiated rate must be adjusted to treat any independent research and development (IR&D) costs in accordance with HHS policy.

In accordance with the Small Business Innovation Development Act of 1982 and the Small Business Technology Transfer Act of 1992, irrespective of the time period in which the costs are incurred, no SBIR/STTR funds can be used to "support" any commercialization (Phase III activities). "Support" in this case includes both direct and indirect costs.

The Small Business Administration's SBIR and STTR Program Policy Directives defined terms:

SBIR agencies must establish an SBIR Program by reserving, in each fiscal year, not less than 2.9 percent (FY 2015) of its extramural budget for awards to SBCs for R/R&D. "R&D activities" include any activities directed toward reducing the technical risk of the technology.

- Commercialization. The process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to government or commercial markets.
- Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace. No SBIR funds support this phase. The small business must find funding in the private sector or other non-SBIR Federal agency funding.

Based on this position, when NIH is negotiating indirect costs with SBIR/STTR grantees/contractors, we are disallowing all indirect costs applicable to commercialization activities related to SBIR/STTR awards.

Note: Below is a list of cost categories NIH considers to be commercialization. In addition, these items include labor costs for the Marketing Director and Director of Business Development, as well as sales and marketing staff who are grantee/contractor employees or contractors hired for those purposes.

Commercialization cost categories: market and sales; market research; business development/product development/market plans; legal fees, travel and other costs relating to license agreements and partnerships.

You are encouraged to visit the following Division of Financial Advisory Services (DFAS) Web sites or call the DFAS staff at 301-496-2444 for guidance: Main DFAS website, FAQS.

Listing of unallowable and unallocable costs and the related Federal Acquisition Regulation (FAR) citation for each, http://oamp.od.nih.gov/dfas/indirect-cost-branch/indirect-cost-submission/unallowableunallocable-costs

Field Name	Instructions
Indirect Cost Type	Indicate the type of cost (e.g., Salary & Wages, Modified Total Direct Costs, or Other [explain]). Also indicate if Off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect rate(s) approved by a Federal agency, indicate, “None--will negotiate” and include information for a proposed rate. Use the budget justification if additional space is needed.
Indirect Cost Rate (%)	Indicate the most recent indirect cost rate(s) (also known as Facilities & Administrative Costs [F&A]) established with the cognizant Federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you have a cognizant/oversight agency and are selected for an award, you must submit your indirect rate proposal to that office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency.

Field Name	Instructions
	If this field does not allow a figure greater than 100% to be entered, use two lines to show the entire calculation. This field should be entered using a rate such as "55.5." SBIR and STTR Phase I Applicants: If your organization does not have a currently effective negotiated F&A cost rate with a Federal agency, then propose estimated F&A costs at a rate not to exceed 40% of the total direct costs. If awarded at a rate of 40% or less of total direct costs the rate used to charge actual F&A costs to projects cannot exceed the awarded rate. NIH will not negotiate F&A rates for Phase I awards. SBIR and STTR Phase II Applicants: SBIR and STTR applicants who propose in the application an F&A rate of **40 percent** of total direct costs or less will not be required to provide further justification at the time of award, and F&A costs will be awarded at the requested rate. However, DFAS will retain the authority to require well-documented proposals for F&A rates on an ad hoc basis. 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.) 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 will negotiate F&A/IDC rates for SBCs receiving Phase II awards if the requested rate is greater than 40 percent of total direct costs. For more detailed information, see NIH Guide Notice: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-038.html.
Indirect Cost Base ($)	Enter the amount of the base for each indirect cost type.
Funds Requested	Enter funds requested for each indirect cost type.
Total Indirect Costs	Total funds requested for indirect costs.
Cognizant Federal Agency	Enter the name of the cognizant Federal Agency, name and phone number of the individual responsible for negotiating your rate. If no cognizant agency is known, enter "None."

I. Total Direct and Indirect Institutional Costs (G + H)

Total Funds requested for direct and indirect costs.

Ensure that the direct costs and the indirect costs (G+H) on Section F-K EQUAL the Total Direct and Indirect Costs (G+H) on the Cumulative Budget page.

According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II, a hard cap). As written in the statute and under appropriate circumstances, NIH can apply for a waiver from SBA to issue an award exceeding $225,000 for Phase I or $1,500,000 for Phase II, if this hard 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. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

The ability to deviate from the statutory guidelines applies to NIH ONLY –

SBIR Phase I applications to CDC, FDA, and ACF are limited to a total cost of $150,000.

SBIR Phase II applications to CDC, FDA, and ACF are limited to a total cost of $1,000,000.

J. Fee

A reasonable fee, not to exceed 7% of total costs (direct and indirect) for each Phase (I and II) of the project, is available to small business concerns receiving awards under the SBIR/STTR program. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work.

Explain the basis and the amount requested for the fee in the budget justification. The amount requested for the fee should be based on the following guidelines: (1) it must be consistent with that paid under contracts by the PHS for similar research conducted under similar conditions of risk; (2) it must take into account the complexity and innovativeness of the research to be conducted under the SBIR/STTR project; and (3) it must recognize the extent of the expenditures for the grant project for equipment and for performance by other than the grantee organization through consultant and subaward agreements.

The fee is not a direct or indirect "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee applies solely to the small business concern receiving the award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

Note: The electronic system automatically rounds up. If you get an error "The fee must be less than 7%," try using 6.99% as the rate.

K. Budget Justification

Use the budget justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support and other direct cost categories. Only one file may be attached.

Use this section to list the names, role (e.g., PostDoc or Graduate Student), associated months, salary and fringe benefits for all Postdoctoral Associates and Graduate Students included in Budget Section B. Other Personnel.

The salaries of administrative and clerical personnel should normally be treated as F&A costs. Inclusion of such 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 or have prior written approval of the Federal awarding agency; and
4. The costs are not also recovered as indirect costs.

For all individuals classified as administrative/secretarial/clerical, provide a justification documenting how they meet all four conditions. NIH ICs may request additional information for these positions in order to assess allowability.

Include a justification for any significant increases or decreases from the initial year budget. Justify budgets with more than a standard escalation from the initial to the future year(s) of support. Also use this section to explain any exclusions applied to the F&A base calculation.

If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget. See Section 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium.

Completing Budget Periods 2-5

If funds are being requested for more than one budget period, you must complete a separate detailed budget for each year of support requested. To navigate to screens for the next budget period, click the **Next Period** button at the top of the 3rd budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted and outlined in red) and/or confirm/update any pre-populated information before the **Next Period** button is activated. If no funds are requested for a required field, enter "0." Note the Budget Justification is also a required item and must be attached before the **Next Period** button is activated.

Supplemental/Revision Application

For a supplemental/revision application, show only those items for which additional funds are requested. If the initial budget period of the supplemental/revision application is less

than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

When authorized or requested by the appropriate NIH IC, applicants may submit applications with more than 5 budget periods. In these situations complete the detailed budget for periods 1-5 as usual. However, include the same level of detail for Period 6 in the Budget Justification along with an explanation of the situation. Also, be sure to include a cover letter that addresses these extra budget periods, and include the IC Program Official's preapproval as part of the Cover Letter PDF.

4.7.4 Cumulative Budget

All values on this form are calculated automatically. They present the summations of the amounts that you have entered previously, under Sections A through K, for each of the individual budget periods. Therefore, no data entry is allowed or required, in order to complete this "Cumulative Budget" section.

If any of the amounts displayed on this form appears to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such adjustments, you will need to revisit the appropriate budget period form(s), to enter corrected values.

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

4.8 Special Instructions for Preparing Applications with a Subaward/Consortium

SBIR

In Phase I, normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern. The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 33% of the total amount requested (direct, F&A/indirect, and fee).

If the application is selected for an award, the Authorized Organization Representative (AOR) will need to certify that the applicant and all proposed consortium participants understand and agree to 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.

In Phase II, normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. The total amount of consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct and F&A/indirect).

The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct and F&A/indirect) attributable to each party, unless otherwise described and justified in Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research Plan form.

STTR

In Phase I and Phase II, at least 40% of the work must be performed by the small business concern and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct and F&A/indirect) attributable to each party, unless otherwise described and justified in Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research Plan form.

The single "partnering" research institution must provide a letter to the applicant small business concern certifying that at least 30% of the work of the STTR project will be performed by the research institution. The small business concern will include this letter as an attachment upload in Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research Plan form.

In addition, a small business concern must negotiate a written agreement between the small business and the research institution allocating intellectual property rights to carry out follow-on research, development or commercialization. See Model Agreement for the Allocation of Rights. This agreement is required to receive support under the STTR program but is NOT submitted with the application. A copy of the Agreement must be furnished upon request of the NIH awarding component.

A small business concern may subcontract a portion of its SBIR or STTR award to a Federal laboratory within the limits above. A Federal laboratory, as defined in 15 U.S.C. § 3703, means

any laboratory, any federally funded research and development center, or any center established under 15 U.S.C. §§ 3705 & 3707 that is owned, leased, or otherwise used by a Federal agency and funded by the Federal Government, whether operated by the Government or by a contractor. A small business concern may subcontract a portion of its STTR award to a Federally Funded Research and Development Center (FFRDC), either in its capacity as the Research Institution or as a participant in the STTR project in another capacity. **However, STTR funds may not be used to pay for laboratory resources of non-FFRDCs, and no STTR funds may be used to pay for subcontracting any portion of the STTR award back to the issuing agency or to any other Federal government unit unless a waiver is granted by the Small Business Administration.**

OMB Number: 4040-0001
Expiration Date: 6/30/2016

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1		Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2		Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3		Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4		Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5		Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6		Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7		Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8		Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9		Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10		Add Attachment	Delete Attachment	View Attachment
11) Please attach Attachment 11		Add Attachment	Delete Attachment	View Attachment
12) Please attach Attachment 12		Add Attachment	Delete Attachment	View Attachment
13) Please attach Attachment 13		Add Attachment	Delete Attachment	View Attachment
14) Please attach Attachment 14		Add Attachment	Delete Attachment	View Attachment
15) Please attach Attachment 15		Add Attachment	Delete Attachment	View Attachment
16) Please attach Attachment 16		Add Attachment	Delete Attachment	View Attachment
17) Please attach Attachment 17		Add Attachment	Delete Attachment	View Attachment
18) Please attach Attachment 18		Add Attachment	Delete Attachment	View Attachment
19) Please attach Attachment 19		Add Attachment	Delete Attachment	View Attachment
20) Please attach Attachment 20		Add Attachment	Delete Attachment	View Attachment
21) Please attach Attachment 21		Add Attachment	Delete Attachment	View Attachment
22) Please attach Attachment 22		Add Attachment	Delete Attachment	View Attachment
23) Please attach Attachment 23		Add Attachment	Delete Attachment	View Attachment
24) Please attach Attachment 24		Add Attachment	Delete Attachment	View Attachment
25) Please attach Attachment 25		Add Attachment	Delete Attachment	View Attachment
26) Please attach Attachment 26		Add Attachment	Delete Attachment	View Attachment
27) Please attach Attachment 27		Add Attachment	Delete Attachment	View Attachment
28) Please attach Attachment 28		Add Attachment	Delete Attachment	View Attachment
29) Please attach Attachment 29		Add Attachment	Delete Attachment	View Attachment
30) Please attach Attachment 30		Add Attachment	Delete Attachment	View Attachment

A complete subaward/consortium budget form (including the budget justification section) should be completed by each consortium grantee organization. Separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

Note, a complete subaward/consortium budget form is only required when the prime grantee is submitting a detailed budget using the R&R Budget Form.

For any subaward or consortium sites, it is appropriate and expected that someone may be designated as the consortium lead investigator responsible for ensuring proper conduct of the project or program at that site. However, when completing the Project Role for the consortium lead investigator, the project role of "PD/PI" should only be used if the entire application is being submitted under the Multiple PI policy. Otherwise, this individual should be assigned some other project role in the senior/key personnel section of the application. Also, the role of Co-PD/PI is not currently used by NIH and other PHS agencies. Assigning an individual(s) the role of "Co-PD/PI" will not identify the application as a Multiple PD/PI application. Although NIH now recognizes the role of "Co-Investigator," if applicants wish to use the role of "Consortium PI" or some other similar role, select "Other" for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field.

NIH continues to support the policy established in April 2004, (revised in November 2004) regarding applications that involve consortium/contractual F&A costs (See NOT-OD-05-004). This policy allows applicants to exclude consortium/contractual F&A costs when determining compliance for any application where a direct cost limit applies. The use of the SF424 (R&R) application with separately submitted subaward/consortium budgets allows NIH to take advantage of a system validation for this policy. When an application is submitted in response to a program with a direct cost limit, the eRA system will perform the calculation by taking the total direct costs requested by the prime/parent organization in their detailed budget, and subtracting all subaward/consortium F&A from each and every subaward budget attached. When the validation calculation equals or exceeds the respective direct cost limit, the application will receive a warning.

This form accommodates a set number of separate subaward budgets (30). If you are submitting an application with more subaward budgets than the form allows, the remaining budgets should be converted to PDF and included as part of Section K. Budget Justification of the parent budget. **Reminder, the sum of all subaward budgets; e.g., those attached separately and those provided as part of the budget justification, must be included in Line F.5 Subawards/Consortium/Contractual Costs of the project budget.**

To start the process, the applicant organization should:

- Select the Subaward Budget Attachment Form from the Optional Documents in the Grant Application Package.
- Open the form, and click the **Click here to extract the R&R Subaward Budget Attachment** button in the middle of the form. A "SAVE" dialog box appears.
- Save the file locally using the first ten letters of the consortium organization's name and use ".pdf" as the file extension. (The extracted file is an Adobe PDF file.) Once you have saved the file there is no need to extract another budget attachment. Doing so may cause you to lose any data already stored in the saved file.
- E-mail the extracted, saved form to the consortium grantee. Note: consortium grantees must have installed a compatible version of Adobe Reader before they can complete the form. The consortium grantee should complete all the budget information as instructed in the R&R Budget form instructions in Section 4.7. The Budget Type should be set to Subaward/Consortium. Organizational DUNS and Name of Organization fields must reflect that of the subaward/consortium grantee.

- The consortium grantee must complete the budget form and e-mail it back to the applicant organization.
- A fee cannot be entered for a subaward/consortium budget. Fee is allowable only for the small business applicant organization budget page.
- Return to the Subaward Budget Attachment Form and attach the consortium grantee's budget to one of the blocks provided on the form.

STTR: If more than one Subaward is included in the STTR application, identify the single, partnering research institution on the RI Subaward budget justification page.

Submitting Subaward Budgets that are not Active for all Periods of the Prime Grant

When submitting subaward budgets that are not active for all periods of the prime grant, fill out the subaward R&R Budget form and include only the number of periods for which the subaward is active. The budget period start/end dates reflected in each period should reflect the corresponding prime budget period start/end dates. This approach is the most workable solution to the limitations in existing forms that do not allow an "empty" budget period and do not allow submission of a subaward budget with zero effort to skip a budget period.

For example, suppose the prime has filled out a budget form with the following periods:

- period 1 - Jan 1, 2015 – Dec 31, 2015
- period 2 - Jan 1, 2016 – Dec 31, 2016
- period 3 - Jan 1, 2017 – Dec 31, 2017
- period 4 - Jan 1, 2018 – Dec 31, 2018
- period 5 - Jan 1, 2019 – Dec 31, 2019

Now, suppose there is a subaward that performs in support year 1 and does not become active again until support year 4. The subaward can fill out the first two periods of their budget form as follows:

- period 1 - Jan 1, 2015 – Dec 31, 2015 (dates correspond to prime period 1)
- period 2 - Jan 1, 2018 – Dec 31, 2018 (dates correspond to prime period 4)

It is not necessary that the budget period numbers between the prime and subaward match; the correlation is reflected in the dates. Do be careful, however, that the dates exactly match what is listed for the period in the prime budget.

Note this approach may cause a validation warning regarding the NIH $500,000 per year limit on direct costs, therefore you should document in both the cover letter and the subaward budget justification that the subaward is only active for specific periods of the prime. Appropriate NIH staff has access to the cover letter and reviewers have access to the budget justification. This documentation will make the date correlation immediately apparent and will help avoid any confusion.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document

name to select it and then click the Move Form to Delete button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

4.9 SBIR/STTR Information Form

In conjunction with the other SF424 (R&R) forms and PHS 398 forms, NIH, CDC, FDA, and ACF SBIR/STTR grant applicants must also complete and submit the "SBIR/STTR Information" form.

SBIR/STTR Information

OMB Number: 4040-0001
Expiration date: 06/30/2011

*** Program Type (select only one)**

☐ SBIR ☐ STTR
☐ Both *(See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)*

*** SBIR/STTR Type (select only one)**

☐ Phase I ☐ Phase II
☐ Fast-Track *(See agency-specific instructions to determine whether a particular agency participates in Fast-Track)*

Questions 1-7 must be completed by all SBIR and STTR Applicants:

☐ Yes ☐ No	* 1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?
	* 1b. Anticipated Number of personnel to be employed at your organization at the time of award.
☐ Yes ☐ No	* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? * If yes, insert the names of the Federal laboratories/agencies:
☐ Yes ☐ No	* 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov
☐ Yes ☐ No	* 4. Will all research and development on the project be performed in its entirety in the United States? If no, provide an explanation in an attached file. * Explanation: Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? * If yes, insert the names of the other Federal agencies:
☐ Yes ☐ No	* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?
	* 7. Commercialization Plan: If you are submitting a Phase II or Phase I/Phase II Fast-Track Application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. * Attach File: Add Attachment Delete Attachment View Attachment

Program Type (select only one): SBIR / STTR / Both

If you are applying under the SBIR program, check the SBIR box. If you are applying under the STTR program, check the STTR box. If a particular agency allows a single submission for both

STTR & SBIR, check the Both box. A selection is required. Note HHS does not accept 'Both' as a choice.

SBIR/STTR Type (select only one): Phase I / Phase II / Fast-Track

If you are submitting a Phase I application, check the Phase I box. If you are submitting a Phase II application, check the Phase II box. When submitting a Phase II application, please include the Phase I SBIR/STTR grant number in Item #4a (Federal Identifier) on the SF424 (R&R) form. If you are submitting a Fast-Track application, check the Fast-Track box. A selection is required.

1a. Certification of Small Business Eligibility

If you certify that at the time of award, your organization will meet the eligibility criteria for a small business as defined in the FOA, check the Yes box. Otherwise, check the No box. A selection is required.

1b. Anticipated Number of personnel to be employed at your organization at the time of award.

Enter the number of personnel anticipated to be employed by the small business at the time of award.

2. Does this application include subcontracts with Federal laboratories or any other Federal government agencies?

If this application includes subcontracts with Federal laboratories or any other Federal Government agencies, check the Yes box and insert the name of the Federal laboratories/agencies in the space provided. Otherwise, check the No box. A selection is required.

3. Are you located in a HUBZone?

If you are located in a HUBZone, check the Yes box. To find out if your business is in a HUBZONE, use the mapping utility provided by the Small Business Administration at its Web site: http://www.sba.gov. Otherwise, check the No box. A selection is required.

4. Will all research and development on the project be performed in its entirety in the United States?

If all research and development on the project will be performed in its entirety in the United States, check the Yes box. Otherwise, check the No box and use the **Add Attachment** button below, to attach an explanation. A selection is required.

If you have answered "no" to question 4 above, please prepare an explanation of the research and development that is being performed outside the United States, in a separate file. Then use the **Add Attachment** button to the right of this field to attach the file and complete this entry. When you click **Add Attachment**, browse to where you saved the file, select the appropriate file and then click **Open** to complete the action.

5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work?

If the applicant and/or PD/PI has submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work, check the Yes box and insert the names of the other Federal agencies in the space provided. Otherwise, check the No box. A selection is required.

6. Disclosure Permission Statement

If this application does not result in an award, and the Government is permitted to disclose the title of your proposed project, and the name, address, telephone number, and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment), check the Yes box. Otherwise check the No box. A selection is required.

Your response will not affect any peer review or funding decisions.

7. Commercialization Plan

(Applicable to all Phase II and Phase IIB Applications and Phase I/Phase II Fast-Track Applications.)

If you are submitting a Phase II, Phase IIB or Phase I/Phase II Fast-Track application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. To attach a Commercialization Plan file, click the **Add Attachment** button to the right of this field, browse to where you saved the file, select the file, and then click **Open**.

All Phase II, Phase IIB and Fast-Track applications must include a succinct Commercialization Plan. The Commercialization Plan is limited to 12 pages. Be succinct. There is no requirement for applicants to use the maximum allowable pages allotted to the Commercialization Plan.

Create a document entitled, "Commercialization Plan," and provide a description in each of the following areas:

a. ***Value of the SBIR/STTR Project, Expected Outcomes, and Impact.*** Describe, in layperson's terms, the proposed project and its key technology objectives. State the product, process, or service to be developed in Phase III. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.

b. ***Company.*** Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

c. ***Market, Customer, and Competition.*** Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation.

   Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product.

   Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. *(It is very important that you understand and know the competition.)*

d. ***Intellectual Property (IP) Protection***. Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

e. ***Finance Plan.*** Describe the necessary financing you will require to commercialize the product, process, or service, and when it will be required. Describe your plans to raise the requisite financing to launch your innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

   Letter of commitment of funding.

   Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.

   Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.

   Specific steps you are going to take to secure Phase III funding.

f. ***Production and Marketing Plan***. Describe how the production of your product/process/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/process/service. For example, explain plans for licensing, Internet sales, etc.

g. ***Revenue Stream.*** Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the

SBIR/STTR grant. Place relevant letters following letters from consultants and collaborators in Item 12, Letters of Support in the PHS 398 Research Plan Form.

Your Phase III funding may be from any of a number of different sources including, but not limited to: SBIR/STTR firm itself; private investors or "angels"; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; state finance programs; non SBIR-funded R&D or production commitments from a Federal agency with the intention that the results will be used by the United States government; or other industrial firms.

SBIR/STTR Information

SBIR-Specific Questions: ***Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.***	
☐ Yes ☐ No	* 8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment. * Attach File: [ ] Add Attachment Delete Attachment View Attachment
☐ Yes ☐ No	* 9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

STTR-Specific Questions: ***Questions 10 and 11 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 and 11 blank.***	
☐ Yes ☐ No	* 10. Please indicate whether the answer to BOTH of the following questions is TRUE: (1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND (2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?
☐ Yes ☐ No	* 11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

SBIR-Specific Questions:

8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a commercialization history in accordance with agency-specific instructions

If you have received SBIR Phase II awards from the Federal Government, check the Yes box and use the **Add Attachment** button below to attach a company commercialization history in accordance with agency-specific instructions. Otherwise check the No box.

If the applicant small business has received an SBIR Phase II awards issued by NIH or any other Federal Government agency, attach a file that includes either: (1) a statement indicating that the applicant small business has not received more than 15 SBIR Phase II awards from the Federal Government during the preceding five fiscal years; or (2) a company commercialization history if the applicant small business has received more than 15 Phase II SBIR awards from the Federal Government during the preceding five fiscal years. The history must document the extent to which the company was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards, and for each Phase II award the history must include: (1) name of awarding agency; (2) award number

and date; (3) amount of award; (4) title of project; (5) source, date, and amount of Phase III funding agreement; and (6) commercialization status of each Phase II award.

9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

If the PD/PI will have his/her primary employment with the small business at the time of award, check the Yes box. Otherwise, check the No box.

A selection is required for SBIR applications only.

STTR-Specific Questions:

10. Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process, AND will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?

Check the Yes box only if both of the following conditions is true:

1. The PD/PI has a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; and
2. The PD/PI will devote at least 10% effort to the proposed project.

Check the No box if either of these two conditions (or both) is false.

11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

If in the joint research and development proposed in this project, the small business performs at least 40% of the work and the research institution named in the application performs at least 30% of the work, check the Yes box. Otherwise, check the No box.

Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

5. Completing PHS 398 Forms

5.1 Overview

In conjunction with the SF424 (R&R) forms, NIH and other PHS agencies grants applicants should also complete and submit additional forms titled "PHS 398." Note the PHS 398 forms include additional data required by the agency for a complete application. While these are not identical to the PHS 398 application form pages, the PHS 398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) forms. A complete application to NIH and other PHS agencies will include SF424 (R&R) and PHS 398 forms. The PHS 398 forms include:

- PHS 398 Cover Page Supplement (this supplements the data requirements in the SF 424 R&R form)
- PHS 398 Research Plan Form
- Planned Enrollment Report
- PHS 398 Cumulative Inclusion Enrollment Report

Complete each form using the instructions provided below.

5.2 (Reserved)

5.3 Cover Page Supplement Form

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix:
*First Name:
Middle Name:
*Last Name:
Suffix:

2. Human Subjects

Clinical Trial? ☐ No ☐ Yes

*Agency-Defined Phase III Clinical Trial? ☐ No ☐ Yes

3. *Disclosure Permission Statement

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

☐ Yes ☐ No

4. *Program Income

*Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☐ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

1. Program Director/Principal Investigator (PD/PI)

Field Name	Instructions
Prefix	Pre-populated from the SF424 (R&R). The prefix (for example, Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Pre-populated from the SF424 (R&R). The first (given) name of the PD/PI. This field is required.
Middle Name	Pre-populated from the SF424 (R&R). The middle name of the PD/PI.
Last Name	Pre-populated from the SF424 (R&R). The last (family) name of the PD/PI. This field is required.
Suffix	Pre-populated from the SF424 (R&R). The suffix (for example, Jr., Sr., PhD) for the name of the PD/PI.

2. Human Subjects

Field Name	Instructions
Clinical Trial?	Check "yes" or "no" to indicate whether the project includes a clinical trial. See Supplemental Grant Application Instructions, Part III.3 for the specific definition.
Agency-Defined Phase III Clinical Trial	Check “Yes” or “No” to indicate whether the project is an NIH-defined Phase III clinical trial. An NIH-defined Phase III clinical trial is 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.

3. *Disclosure Permission Statement

Field Name	Instructions
If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?	Select "yes" or "no" to indicate whether disclosure permission is granted. This field is required. Your response will not affect any peer review or funding decisions.

4. Program Income

Field Name	Instructions
Is program income anticipated during the periods for which the grant support is requested?	If program income is anticipated during the periods for which the grant support is requested, check “Yes,” and then complete the section below. If no program income is anticipated, check “No” and leave the following section blank.
Budget Period	If program income is anticipated, enter the budget periods in this column. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income.
Anticipated Amount ($)	If program income is anticipated, enter the amount anticipated for each budget period listed.
Source(s)	If program income is anticipated, enter the source for each budget period listed.

PHS 398 Cover Page Supplement

5. Human Embryonic Stem Cells

*Does the proposed project involve human embryonic stem cells? ☐ No ☐ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): ☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

*Inventions and Patents: Yes ☐ No ☐

If the answer is "Yes" then please answer the following:

*Previously Reported: Yes ☐ No ☐

5. Human Embryonic Stem Cells

Field Name	Instructions
Does the proposed project involve human embryonic stem cells?	If the proposed project involves human embryonic stem cells, check Yes and complete the section below. If the proposed project does not involve human embryonic stem cells, check No.
Specific stem cell line cannot be referenced at this time. One from the registry will be used.	If a specific line cannot be referenced at the time of application submission, check this box. Additionally, provide a strong justification for why an appropriate cell line is not available from the Registry at this time. The justification should be included as

Field Name	Instructions
	part of the Research Strategy or Program Plan as appropriate.
Cell Line(s)	List in this section the 4-digit registration number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry (e.g. 0123)

6. Inventions and Patents (For renewal applications only)

Field Name	Instructions
Inventions and Patents	This block need only be completed if submitting an R&R "Renewal" application or a Resubmission of a Renewal application. If no inventions were conceived or reduced to practice during the course of work under this project, check "No." The remaining parts of the item are then not applicable. If any inventions were conceived or first actually reduced to practice during the previous period of support, check "Yes." Note: NIH recipient organizations must promptly report inventions to the Division of Extramural Inventions and Technology Resources (DEITR) Branch of the Office of Policy for Extramural Research Administration (OPERA), OER, NIH, Bethesda, MD 20892-2750, (301) 435-1986. Invention reporting compliance according to regulations at 37 CFR 401.14 is described at http://www.iedison.gov. The grantee is required to submit reports electronically using Interagency Edison (http://www.iedison.gov). See NOT-OD-15-080.
Previously Reported	If the item above is checked "Yes", indicate whether this information has been reported previously to the PHS or to the applicant organization official responsible for patent matters.

7. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:
*First Name:
Middle Name:
*Last Name:
Suffix:

☐ Change of Grantee Institution

*Name of former institution:

7. Change of Investigator/Change of Institution Questions

Field Name	Instructions
Change of Program Director/Principal Investigator	Check here, if this application reflects a change in principal investigator/program director from that indicated on a previous application. Attach a relinquishing letter from the previous applicant institution as part of the Cover Letter. See instructions in Cover Letter Attachment.
Prefix	If this application reflects a change in PD/PI, enter the name prefix (for example, Mr., Mrs., Rev.) of the former PD/PI.
First Name	If this application reflects a change in PD/PI, enter the first name of the former PD/PI.
Middle Name	If this application reflects a change in PD/PI, enter the middle name of the former PD/PI.
Last Name	If this application reflects a change in PD/PI, enter the last name of the former PD/PI.
Suffix	If this application reflects a change in PD/PI, provide the suffix (for example, Jr., Sr., PhD) of the former PD/PI.
Change of Grantee Institution	Check here, if this application reflects a change in grantee institution from that indicated on a previous application. This is not generally applicable to a "New" application.
Name of Former Institution	If this application reflects a change in grantee institution, insert

Field Name	Instructions
	the name of the former institution here.

5.4 (Reserved)

5.5 PHS 398 Research Plan Form

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment
Human Subjects Sections				
5. Protection of Human Subjects		Add Attachment	Delete Attachment	View Attachment
6. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Children		Add Attachment	Delete Attachment	View Attachment
Other Research Plan Sections				
8. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
9. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
10. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
11. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
12. Letters of Support		Add Attachment	Delete Attachment	View Attachment
13. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
Appendix (if applicable)				
14. Appendix		Add Attachments	Remove Attachments	View Attachments

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

Your SBIR/STTR application should represent a sound approach to the investigation of an important biomedical research, behavioral research, technological, engineering or scientific question, and be worthy of support under the stated criteria of this program solicitation. It should be self-contained and written with the care and thoroughness accorded to papers for publication. Review the application carefully to ensure that information essential for evaluation is included. The scientific and technical merit of the proposed research is the primary concern for all research supported by NIH, CDC, FDA, and ACF.

You are strongly encouraged to contact agency program staff for pre-application guidance and/or for more specific information on the research topics described in this solicitation.

A firm must not propose market research, patent applications, or litigation. The research may be carried out through construction and evaluation of a laboratory prototype, where necessary.

Research Plan Attachments (see also Section 2.3.2 Creating PDFs for Text Attachments)

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. In addition, be sure to save files with descriptive file names.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Digital images of material such as electron micrographs or gels must only be included within the page limits of the Research Strategy. The maximum size of images to be included should be approximately 1200 x 1500 pixels using 256 colors. Figures must be readable as printed on an 8.5 x 11 inch page at normal (100%) scale.

Investigators must use image compression such as JPEG or PNG. Do not include figures or photographs as separate attachments either in the Appendix or elsewhere in the application.

Separate Attachments

Separate attachments have been designed for the Research Plan sections to maximize automatic validations conducted by the eRA system. When the application is received by the agency, all of the Research Plan sections will be concatenated in the appropriate order so that reviewers and agency staff will see a single cohesive Research Plan.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you **must** delete the previous attachment and then

reattach the revised document to the application form. Use the **View Attachment** button to determine if the correct version has been attached.

Page Limits

Applicants must observe the page numbers given in the detailed Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless the FOA specifies otherwise. All tables, graphs, figures, diagrams, and charts must be included within the Research Strategy page limit. If PAs or RFAs contain specific page limits, those instructions always supersede the instructions in this application guide.

All applications and proposals for NIH funding must be self-contained within specified page limits. Agency validations will include checks for page limits. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may be delayed in the review process. Unless otherwise specified in an NIH solicitation, Internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are not obligated to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access a website (except to review publications cited in the Biographical Sketch or Progress Report publication list) as it could compromise their anonymity.

Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html.

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, make sure you have checked the “Yes” box of question #3 in the “Other Project Information” form.

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. However, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government’s right to use the information if it is obtained without restriction from another source.

Although the grantee institution and the PD/PI will be consulted about any such release, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). 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.

Begin each text section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc).

Field Name	Instructions
1. Introduction to Application (for Resubmission or Revision only)	Use only if Type of Application is Resubmission or Revision. See specific instructions in Section 2.7, Resubmission Applications and Section 2.8, Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction unless specified in the FOA. The Introduction is a required attachment for Resubmissions and Revisions. Follow the page limits for the Introduction in the Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless otherwise specified in the FOA. **Introductions for ALL SBIR or STTR applications are limited to one (1) page**. This includes Phase I, Phase II, Fast-Track, and Phase IIB Competing Renewals applications. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
2. Specific Aims	State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. The Specific Aims attachment is required unless otherwise specified in the FOA. Follow the page limits for the Specific Aims in the Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless specified otherwise in the FOA. The Specific Aims attachment is required unless otherwise specified in the FOA. **Phase I Applications:** State the specific objectives of the Phase I research and development effort, including the technical questions you will try to answer to determine the Phase I feasibility of the proposed approach and the impact that the results of the proposed research will exert on the research field(s) involved. State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process or service to ultimately be developed. Include milestones for each of the aims as these will be used in the evaluation process. **Phase II and Phase IIB Applications:** State the specific objectives of the

Field Name	Instructions
	Phase II research and development effort including the impact that the results of the proposed research will exert on the research field(s). State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process or service to ultimately be developed. Include milestones for each of the aims as these will be used in the evaluation process. **Fast-Track Applications:** Create a heading titled "Phase I Specific Aims", and follow the instructions above for "Phase I Applications." Next, create a heading titled "Phase II Specific Aims" and follow the instructions above for "Phase II Applications." **"Specific Aims" for ALL SBIR or STTR applications are limited to one (1) page.** This includes Phase I, Phase II, Fast-Track, and Phase IIB Competing Renewals. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
3. Research Strategy	Organize the Research Strategy in the specified order and using the instructions provided below, or as stated in the Funding Opportunity Announcement. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Section 4.4.9). Follow the page limits for the Research Strategy in the table of page limits http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file. 1. *Significance* • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application. • Explain the project's potential to lead to a marketable product, process or service. • For Phase II, Fast-Track, and Phase IIB Competing Renewals, explain how the commercialization plan demonstrates a high probability of commercialization.

Field Name	Instructions
	2. *Innovation* • Explain how the application challenges and seeks to shift current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. • Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. 3. *Approach* • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Provide a tentative sequence or timetable for the project. Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. • Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. • If your study(s) involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample. • Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

Field Name	Instructions
	• Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in Item 11, below. • If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time. If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively. **As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.** **Preliminary Studies for Phase I Applications:** Preliminary data are not required for Phase I applications; however, such results may assist reviewers in assessing the likelihood of success of the proposed project and may be included in the Research Strategy section. **Progress Report for Phase II and Phase IIB Competing Renewal and Revision Applications.** For Phase II and Phase IIB Competing Renewal and Revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the previous specific aims and any new directions including changes resulting from significant budget reductions. Describe the technology developed from this SBIR/STTR, its intended use and who will use it. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed on IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved). For any studies meeting the NIH definition for clinical research, discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children etc.) as part of the progress report, particularly if relevant to studies proposed in the renewal or revision application. You should **not** submit a Cumulative Inclusion Enrollment Report form unless the enrollment is part of the renewal or revision application. A list of publications, patents, and other printed materials should be

Field Name	Instructions
	included in Item 5 (Progress Report Publication List); do not include that information here. **Progress Report for Fast-Track Applications.** For Fast-Track applications, the Phase I Final Report is submitted to the awarding component after the Phase I research is completed so is not included in a Fast-Track application. Refer to your Notice of Award for instructions for preparing and submitting a Phase I Final Progress Report.
4. Progress Report Publication List (Renewal Applications Only)	**Phase II and Phase IIB Applications:** List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the Phase I or describe patent status, trade secrets or other demonstration of IP protection, and other printed materials that have resulted from the Phase I effort. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material).

Human Subjects Sections

Field Name	Instructions
5. Protection of Human Subjects	Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan and Human Subjects Research Policy. Complete this section if you answered "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the question but your proposed research involves human specimens and/or data from subjects you must provide a justification in this section for your claim that no human subjects are involved. Follow the instructions provided in the Application Guide and the FOA regarding the Protection of Human Subject attachment. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

Field Name	Instructions
	Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
6. Inclusion of Women and Minorities	Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan and Human Subjects Research Policy. This section is required if you answered "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form and the research does not fall under Exemption 4. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**. Also, please refer to Section 5.8 of these instructions as well as the Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan and Human Subjects Research Policy (Section 4.3) for more information on submitting Planned and/or Cumulative Inclusion Enrollment Report forms as part of your application.
7. Inclusion of Children	Refer to Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan and Human Subjects Research Policy, Sections 4.4 and 5.8. Complete this section if you answered "Yes" to the question "Are human subjects involved" on the R&R Other Project Information Form and the research does not fall under Exemption 4. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.

Other Research Plan Sections

Field Name	Instructions
8. Vertebrate Animals	Complete this section if you answered "yes" to the question "Are Vertebrate Animals Used?" on the R&R Other Project Information Form. If Vertebrate Animals are involved in the project, address each of the criteria below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the criteria below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites

Field Name	Instructions
	and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following criteria will result in the application being designated as incomplete and it will not be considered. If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, the grantee must submit to the NIH awarding office detailed information as required in the criteria below and verification of IACUC approval prior to the involvement of animals. If the grantee does not have an Animal Welfare Assurance, then an applicable Animal Welfare Assurance will be required (see Part III, Section 2.2 Vertebrate Animals for more information). The criteria are as follows: 1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals. 2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro). 3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury. 4. Euthanasia: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification. For additional information, see http://grants.nih.gov/grants/olaw/VASchecklist.pdf. Do not use the Vertebrate Animals section to circumvent the page limits of the Research Strategy. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.

Field Name	Instructions
9. Select Agent Research	Select agents are hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See http://www.selectagents.gov/. If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The list of exclusions is available at http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html. If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion. If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct. 1. Identify the select agent(s) to be used in the proposed research. 2. Provide the registration status of all entities* where select agent(s) will be used. • If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed. *An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity." 3. Provide a description of all facilities where the select agent (s) will be used. • Describe the procedures that will be used to monitor possession, use and transfer of select agent(s).

Field Name	Instructions
	• Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s). • Describe the biocontainment resources available at all performance sites. If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA. Reviewers will assess the information provided in this Section, and any questions associated with select agent research will need to be addressed prior to award. Save this file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
10. Multiple PD/PI Leadership Plan	For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. A rationale for choosing a multiple PD/PI approach should be described. 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 and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award. Save this file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
11.Consortium/Contractual Arrangements	Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&R) form (Item 17)

Field Name	Instructions
	signifies that the applicant and all proposed consortium participants understand and agree to the following statement: The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy. **SBIR** **Phase I SBIR Applications:** Normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern. The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 33% of the total amount requested (direct, F&A/indirect, and fee). **Phase II and Phase IIB SBIR Applications:** Normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. The total amount of consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct, F&A/indirect, and fee). The basis for determining the percentage of work to be performed by each of the cooperative parties in Phase I or Phase II will be the total requested costs attributable to each party, unless otherwise described and justified in Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research Plan form. **Fast-Track SBIR Applications**: Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements", and complete the sections following the instructions provided above for each phase. **STTR** **Phase I, Phase II and Phase IIB STTR Applications:** At least 40% of the work must be performed by the small business concern and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct and F&A/indirect costs and fee) attributable to each party, unless otherwise described and justified in Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research

Field Name	Instructions
	Plan form. Certification showing the cooperative R&D arrangement between the small business concern and the research institution will be requested prior to an award. The single partnering research institution must certify at the time of application that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution." The requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution must be included in a letter stating: "The small business concern and the research institution certify jointly that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project. If the research institution is a contractor-operated Federally Funded Research and Development Center (FFRDC), the duly authorized representative of the contractor-operated Federally funded research and development center certifies, additionally, that it: (4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein." The applicant small business concern should convert the letter from the partnering research institution into a PDF attachment, and include it as part of Item 13, Consortium/Contractual Arrangements, of the PHS 398 Research Plan form.

Field Name	Instructions
	Fast-Track STTR Applications: Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements", and complete the sections following the instructions provided above for each phase. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
12. Letters of Support (e.g., Consultants)	Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service. Do not place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section. **Phase I, Phase II, Phase IIB, and Fast-Track SBIR/STTR Applications:** Involvement of consultants and collaborators in the planning and research stages of the project is permitted. Include with the application letters from each individual and/or collaborator confirming their role(s) in the project. Following is guidance for such documentation: The letter(s) should be prepared on the consultant or collaborator's letterhead and addressed to the Small Business Concern (SBC). *One page is recommended.* At a minimum, each consultant and collaborator letter should (1) verify their commitment to the project; (2) refer to the specific project by name, acknowledging the PD/PI as the lead on the project; and (3) specify what services /tasks the consultant or collaborator will contribute (e.g. expertise, number of hours/ percent of effort, summary of tasks to be completed). For consultants, the letter should also include the rate/charge for consulting services. Also include biographical sketches for each consultant.

Field Name	Instructions
	For STTR projects, the single "partnering" research institution must provide a letter to the applicant small business concern certifying that at least 30% of the work of the STTR project will be performed by the research institution. Letters of interest from potential commercial partners or investors and letters of commitment of funds or other resources that will enhance the likelihood of commercialization should be placed following the letters of support for consultants and collaborators. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
13. Resource Sharing Plan(s)	NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources. 1. *Data Sharing Plan:* Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.). Specific funding opportunity announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html. 2. *Sharing Model Organisms:* Regardless of the amount requested, 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 organisms or state why such sharing is restricted or not possible. See Sharing Model Organisms in Part III, 1.5.2, and NIH Guide NOT-OD-04-042.

Field Name	Instructions
	3. *Genomic Data Sharing:* Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data in the Resource Sharing Plan section of the funding application. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH Genomic Data Sharing policy (GDS), provides examples of genomic research projects that are subject to the Policy. For further information see the NIH GDS Policy, NIH Guide NOT-OD-14-124, and the GDS website at http://gds.nih.gov/. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**. Note that, for proposed studies generating human genomic data under the scope of the GDS Policy, an Institutional Certification may be submitted at the time of application submission, but it is not required at that time; the Institutional Certification however, will be requested as Just-in-Time (JIT) information prior to award. The Institutional Certification, or in some cases, a Provisional Institutional Certification, must be submitted and accepted before the award can be issued.
14. Appendix	Only one copy of appendix material is necessary. Use the **Add Attachments** button to the right of this field to complete this entry. A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. When allowed there is a limit of 3 publications that are not publicly available (see below for further details **and check the FOA** for any specific instructions), though not all grant activity codes allow publications to be included in the appendix. Do not use the appendix to circumvent the page limits of the research Strategy or any other section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html. Appendix material may not appear in the assembled application in

Field Name	Instructions

	the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements may be delayed in the review process.
	
	New, resubmission, renewal, and revision applications may include the following materials in the Appendix :
	
	• **Publications – No longer allowed as appendix materials except in the circumstances noted below.** Applicants may submit up to 3 of the following types of publications:
	  • **Manuscripts and/or abstracts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment.
	  • **Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:** The entire article should be submitted as a PDF attachment.
	  • **Patents directly relevant to the project:** The entire document should be submitted as a PDF attachment.
	
	Do not include unpublished theses, or abstracts/manuscripts **submitted** (but not yet accepted) for publication.
	
	• Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.
	
	• For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.
	
	Items that must **not** be included in the appendix:
	
	• Digital photographs or color images of gels, micrographs, etc. **are no longer accepted as Appendix material**. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.
	
	Publications that are publicly accessible. For such publications, the

Field Name	Instructions
	URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section. **Phase I SBIR/STTR Applications:** Do not include appendices unless specifically solicited by NIH.

Once all data have been entered, use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a form from your application, uncheck the box next to the form name in the Optional document section.

5.6 (Reserved)

5.7 (Reserved)

5.8 Planned Enrollment Report and Cumulative Inclusion Enrollment Report

NOTE: These report formats should NOT be used for collecting data from study participants. To ensure proper performance, please save frequently.

See below for the forms descriptions and please refer to Part II (Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subject Research Policy) for additional guidance on how and when to use the Planned Enrollment Report (s) and/or Cumulative Inclusion Enrollment Report(s).

5.8.1 Planned Enrollment Report

Planned Enrollment Report OMB Number: 0925-0002

This report format should NOT be used for collecting data from study participants.

Study Title:

Domestic/Foreign:

Comments:

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Study 1 of 1

To ensure proper performance, please save frequently.

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. If there is more than one study, provide a separate Study Title for each. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.
Domestic/Foreign	Select whether the participants described in the planned enrollment report are domestic or foreign. At a minimum, domestic and foreign participants must be reported separately even if for the same study. This is a required field.
Comments	Enter information you wish to provide about this planned enrollment report. This includes but is not limited to addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied and/or a study that will have a delayed onset. Maximum 500 characters.
American Indian/Alaska Native	Enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino. These are required fields.
Asian	Enter the expected number of females and males (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Asian and Hispanic or Latino. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino. These are required fields.
Black or African American	Enter the expected number of females and males (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; Enter the expected number of females and males (in the respective fields) who are Black or African American and Hispanic or Latino. These are required fields.
White	Enter the expected number of females and males (in the respective fields) who are White and Not Hispanic or Latino,

Field Name	Instructions
	and; enter the expected number of females and males (in the respective fields) who are White and Hispanic or Latino. These are required fields.
More than One Race	Enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Hispanic or Latino. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females and males who are Not Hispanic or Latino and all racial categories for females and males who are Hispanic or Latino. The total fields at the right are auto-calculated to total all males and females of both Not Hispanic or Latino and Hispanic or Latino ethnicity in each racial category.

5.8.2 Cumulative Inclusion Enrollment Report

Cumulative Inclusion Enrollment Report OMB Number: 0925-0002

This report format should NOT be used for collecting data from study participants.

Study Title:

Comments:

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Study 1 of 1

To ensure proper performance, please save frequently.

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. The title should be the same as submitted on the original Planned Enrollment form for this study. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.
Comments	Enter information you wish to provide about this Cumulative Inclusion Enrollment Report. This includes but is not limited to information if distinctive subpopulations are relevant to the scientific hypotheses being studied. Maximum 500 characters.
American Indian/Alaska Native	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino,

Field Name	Instructions
	and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and of unknown/not reported ethnicity. These are required fields.
Asian	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and of unknown/not reported ethnicity. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and of unknown/not reported ethnicity. These are required fields.
Black or African American	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and of unknown/not reported ethnicity. These are required fields.
White	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Hispanic or Latino; and enter the number of females, males, and

Field Name	Instructions
	individuals of unknown/not reported sex/gender (in the respective fields) who are White and of unknown/not reported ethnicity. These are required fields.
More than One Race	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and of unknown/not reported ethnicity. These are required fields.
Unknown or Not Reported	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are of unknown/not reported race and of unknown/not reported ethnicity. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino; all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino, and all racial categories for females, males, and individuals of unknown/not reported sex/gender who are of unknown/not reported ethnicity. The total fields at the right are auto-calculated to total all individuals in a given racial category.

6. Peer Review Process

Overview

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 free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects" (42 CFR part 52h).

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils composed of both scientific and lay members are chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council (or the IC in the case of fellowships) are considered for funding. Only the NIH Institute or Center may make funding decisions.

A detailed description of what happens to a research project grant application at NIH after it is received for peer review can be found at the following location: http://grants.nih.gov/grants/peer_review_process.htm.

Additional information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate Institute, Center, or Office. Information on CDC review procedures is located at http://www.cdc.gov/phpr/science/erp_policies.htm.

Streamlining

The initial scientific peer review of most applications will also include a process in which only those applications deemed by the reviewers to have the highest scientific and technical merit, generally the better half of the applications under review, will be discussed at the SRG meeting, assigned an impact score, and receive a second level review. Applications in the lower half are reviewed by SRG members but they are not discussed or assigned overall impact scores at the SRG meeting. This process allows the reviewers to focus their discussion on the most meritorious applications.

Before the review meeting, each reviewer and discussant assigned to an application will give a separate score for each of (at least) five review criteria and a preliminary impact score for that application (see below). The preliminary impact scores help the SRG to determine which applications will be discussed.

Scoring

Each FOA specifies all of the review criteria and considerations that will used in the evaluation of applications submitted for that FOA; RFAs and other types of funding opportunities (e.g., for construction or fellowship applications) may include different and/or additional review criteria and considerations. SRG members are instructed to evaluate research applications by addressing the scored review criteria (see below) and additional review criteria as applicable for the application.

For each application that is discussed, a final overall impact/priority score will be given by each eligible committee member (without conflicts of interest) following the panel discussion. Each member's impact score will reflect his/her evaluation of the potential overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's scores given to each criterion. The final impact score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' impact scores, and multiplying the average by 10.

As part of the initial merit review, and regardless of whether an application is discussed or not discussed (streamlined), all applicants will receive a written critique, called a Summary Statement. Unless stated otherwise in the FOA, the Summary Statement represents a combination of the reviewers' written comments and scores for individual criteria. The Summary Statement for discussed applications includes the Scientific Review Officer's summary of the members' discussion during the SRG meeting; the final impact score; the recommendations of the SRG, including budget recommendations; and administrative notes of special considerations. For applications that are not discussed by the full committee, the scores of the assigned reviewers and discussants for the five scored criteria will be reported individually on the Summary Statement. Final, numerical impact scores are not given for applications that are not discussed.

Research Project Evaluation Criteria

Overall Impact: Reviewers will provide an overall impact/priority 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 following five scored review criteria, and additional review criteria (as applicable for the project proposed).

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. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Does the proposed project have commercial potential to lead to a marketable product, process or service? (In the case of Phase II, Fast-Track, and Phase IIB Competing Renewals, does the Commercialization Plan demonstrate a high probability of commercialization?)

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new

application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans for (1) Protections for Human Subjects, and (2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

> ***For Phase II and Phase IIB Applications Only.*** When reviewing Phase II applications, how well did the applicant demonstrate progress toward meeting the Phase I objectives, demonstrating feasibility, and providing a solid foundation for the proposed Phase II activity?
>
> ***For Phase I/Phase II Fast-Track Applications Only.*** When reviewing Phase I/Phase II Fast-Track applications, reviewers will consider the following:
>
> 1. Does the Phase I application specify clear, appropriate, measurable goals (milestones) that should be achieved prior to initiating Phase II?
> 2. To what extent was the applicant able to obtain letters of interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources that would enhance the likelihood for commercialization?
>
> ***Protections for Human Subjects.*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits to the subjects and others, (4) importance of the knowledge to be gained, and (5) data and safety monitoring for clinical trials.
>
> For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate: (1) the justification for the exemption, (2) human subjects involvement and characteristics, and (3) sources of materials. For additional information on the review of the Human Subjects section, please refer to the Human Subjects Protection Guidelines.

Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion.

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of procedures involving animals including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information, see http://grants.nih.gov/grants/olaw/VASchecklist.pdf.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission Applications. When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

Revision Applications. When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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/priority score.

Select Agents Research. Reviewers will assess the information provided in this section of the application, including 1) the select agent(s) to be used in the proposed research, 2) the registration status of all entities where select agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of select agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the select agent(s).

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms

(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and 3) Genomic Data Sharing (GDS) Plan (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html.) For AHRQ applicants, reviewers will evaluate data management plans for merit while considering the values of long-term preservation, access, and the associated cost, and administrative burden.

Authentication of Key Biological and/or Chemical Resources: For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Dual-Level Peer Review

The second level of review will usually be performed by the Advisory Council or Board of the potential awarding component (Institute, Center, or other unit). Council or Board recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study to an Institute/Center's mission, programs and priorities.