

Follow the tips in the blue boxes below to help you understand the importance of key pieces of information in funding opportunity announcements (FOA).

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)	Your research has to fit within the mission of one of these participating organizations for your application to be assigned for funding consideration.
Components of Participating Organizations	<p>National Cancer Institute (NCI) National Eye Institute (NEI) National Heart, Lung, and Blood Institute (NHLBI) National Human Genome Research Institute (NHGRI) National Institute on Aging (NIA) National Institute on Alcohol Abuse and Alcoholism (NIAAA) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) National Institute of Biomedical Imaging and Bioengineering (NIBIB) <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NICHD) National Institute on Deafness and Other Communication Disorders (NIDCD) National Institute of Dental and Craniofacial Research (NIDCR) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of General Medical Sciences (NIGMS) National Institute of Mental Health (NIMH) National Institute on Minority Health and Health Disparities (NIMHD) National Institute of Neurological Disorders and Stroke (NINDS) National Institute of Nursing Research (NINR) National Library of Medicine (NLM) National Center for Complementary and Integrative Health (NCCIH formerly NCCAM) Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)</p> <p>Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which</p>	

	ICs participate in this announcement and view their respective areas of research interest at the R01 IC-Specific Scientific Interests and Contact website. ICs that do not participate in this announcement will not consider applications for funding.
Funding Opportunity Title	NIH Research Project Grant (Parent RO1)
Activity Code	R01 Research Project Grant

The activity code tells you the [type of grant program](#) that is being advertised. Talk to a scientific/program contact listed in section VII of the FOA to ensure that you apply to the right grant program for you and your science.

Announcement Type	Reissue of PA-13-302
<p>Related Notices</p> <p>A must-read. The related notices provide updates to instructions after the FOA was issued.</p> <p>Revisit the FOA before submitting your application to check for any new related notices.</p> <p>Information in the notice augments/supersedes the information in the FOA.</p>	<ul style="list-style-type: none"> • March 29, 2017 - NCCIH Policy for Submission of Parent R01 Applications Proposing Clinical Trials. See Notice NOT-AT-17-006. • September 28, 2016 - NIAID Policy: Investigator-Initiated Clinical Trials. See Notice NOT-AI-16-084. • August 25, 2016 - New NHLBI Policy: Investigator-Initiated Single-Site Clinical Trials (Phase II and beyond). See Notice NOT-HL-16-336. • July 20, 2016 - NINDS Policy for Submission of Applications Containing Clinical Trials. See Notice NOT-NS-16-034. • June 14, 2016 - New NHLBI Policy: Investigator-Initiated Multi-Site Clinical Trials. See Notice NOT-HL-16-321. • NOT-AR-16-015 - Update to NIAMS Policy Regarding Submission of Clinical Trials Applications. • NOT-TW-16-001 "Notice of Information: Parallel Funding Initiative for Collaborative Research Between Investigators in the USA and in the State of So Paulo, Brazil" • NOT-DE-15-008 "NIDCR Policy Regarding Acceptance and Peer Review of Investigator-Initiated Clinical Trials and Biomarker Clinical Validation Studies" • NOT-MH-14-007 "NIMH Policy for Submission of Applications Containing Clinical Trials" • NOT-CA-13-012 "Change in NCI Policy: R01 and P01 Activity Codes Will No Longer Be Used to Support Investigator-Initiated Phase III Clinical Trials for Medical Interventions and Cancer Imaging Modalities" • NOT-DK-13-013 "Clarification of NIDDK Policy: Investigator-Initiated Multi-Center Clinical Studies" • NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)

Funding Opportunity Announcement (FOA) Number	PA-16-160	
Companion Funding Opportunity	None	Companion FOAs focus on similar areas of science but use different activity codes
Number of Applications	See Section III. 3. Additional Information on Eligibility .	
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.865; 93.286; 93.846; 93.856; 93.855; 93.853; 93.307; 93.242; 93.351; 93.279; 93.840; 93.233; 93.839; 93.838; 93.837; 93.859; 93.213; 93.173; 93.867; 93.399; 93.396;	

	93.395; 93.394; 93.393; 93.866; 93.273; 93.847; 93.361; 93.121; 93.113; 93.172; 93.879
Funding Opportunity Purpose	The NIH Research Project Grant supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s). The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.

Key Dates

Posted Date	March 31, 2016
Open Date (Earliest Submission Date)	May 5, 2016
Letter of Intent Due Date(s)	Not Applicable Letters of Intent are requested for planning purposes. They are not required.
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Standard AIDS dates apply, by 5:00 PM local time of applicant organization. If your application has a strong focus on AIDS research, special due dates apply. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during submission process by the due date.
Scientific Merit Review	Standard dates apply
Advisory Council Review	Standard dates apply
Earliest Start Date	Standard dates apply
Expiration Date	May 8, 2019 You cannot apply to an expired FOA.
Due Dates for E.O. 12372	Not Applicable Your application may not be accepted for review unless you closely follow the instructions in the FOA and the SF424 (R&R) Application Guide.

Required Application Instructions

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](#), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options to submit your application to the agency through Grants.gov. to NIH and Department of Health and Human Services partners.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to submit your application to Grants.gov and eRA Commons to track your application. Consult with institutional officials regarding availability.

Application forms are specific to each FOA. Access the forms using these buttons in the FOA, then select the submission method that works best for you (ASSIST or downloadable forms). If your institution has its own system-to-system submission method, the system should pull the correct forms for you.

3. [Go to Grants.gov](#) to download an application package to complete the application forms offline or create a Workspace to complete the forms online; submit your application to Grants.gov; and track your application in eRA Commons.

Learn more about the various [submission options](#).

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The NIH Research Project Grant (R01) supports a discrete, specified, circumscribed project in scientific areas that represent the investigators' specific interests and competencies and that fall within the mission of the participating NIH Institutes and Centers (ICs). The R01 is the original, and historically the oldest, grant mechanism used by the NIH to support health-related research and development.

Research grant applications are assigned to an NIH IC based on receipt and referral guidelines and many applications are assigned to multiple ICs with related research interests. Applicants are encouraged to identify a participating IC that supports their area of research via the [R01 IC-Specific Scientific Interests and Contact](#) website and contact Scientific/Research staff from relevant ICs to inquire about their interest in supporting the proposed research project.

For specific information about the mission of each NIH IC, visit the [List of NIH Institutes, Centers, and Offices](#) website.

Applicants should note that some ICs (please see the [Related Notices](#) section above) do not accept applications proposing a clinical trial through this funding opportunity announcement. If the proposed research project includes an NIH-defined [clinical trial](#) that would be assigned to one of these ICs, applicants are advised to contact relevant [Scientific/Research staff](#) to discuss alternative mechanisms of support of these studies.

See [Section VIII. Other Information](#) for award authorities and regulations.

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	<p>New Renewal Resubmission Revision</p> <p>The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.</p>
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	Application budgets are not limited but need to reflect the actual needs of the proposed project.
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is 5 years.

Check the FOA to determine whether renewal, resubmission, and/or revision applications are allowed. See Types of Applications

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Be sure both you and your organization are eligible before applying.

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement](#), **are** allowed.

Required Registrations

Applicant Organizations

All registrations must be complete in order to submit you application. Details on required institutional and investigator registrations may be found on our [Prepare to Apply & Register](#) website.

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible.

The NIH Policy on [Simplifying the NIH Policy for Late Application Submission](#) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](#) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](#) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. 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.
- [NATO Commercial and Government Entity \(NCAGE\) Code](#) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons](#) - Applicants must have an active DUNS number and SAM registration 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) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov](#) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Some of the relevant roles at your organization are described in our [Understanding Your Role](#) website.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account and should work with their organizational officials to either create a new account or to affiliate an existing account with the applicant organization's eRA Commons account. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Individual eligibility requirements apply to the program investigator, not to consultants

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/Pis, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](#).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

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 new (A0) or 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](#)).

Section IV. Application and Submission Information

Section IV provides details of where to put information in your application. Follow these instructions to help ensure a successful submission.

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at [Grants.gov](#).

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](#), including [Supplemental Grant Application Instructions](#) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications](#).

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) must be followed.

Remember to follow the instructions in the application in addition to the instructions listed in this section of the

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Inclusion Enrollment Report

When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the [NIH Grants Policy Statement](#), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award

Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to [Grants.gov](#), the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date. If a Changed/Corrected application is submitted after the deadline, the application will be considered late.

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Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically](#).

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See [Section III](#) of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips](#) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete will not be reviewed.

Requests of \$500,000 or more for direct costs in any year

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a [Scientific/ Research Contact](#) at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

Post Submission Materials

Applicants are required to follow our [Post Submission Application Materials](#) policy.

Section V. Application Review Information

Write your research strategy to respond to the review criteria to ensure reviewers have what they need to properly evaluate the scientific merit of your application.

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific 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? 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?

Investigator(s)

Are the PD(s)/PI(s), 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? 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?

If the project involves humans subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks and 2) the 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 evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

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 review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects](#).

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 the 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, see the [Human Subjects Inclusion Guidelines](#).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

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.

Resubmissions

For Resubmissions, 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.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

For Revisions, 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 consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent 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](#); 2) [Sharing Model Organisms](#); and 3) [Genome Wide Association Studies \(GWAS\)](#).

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.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with [NIH peer review policy and procedures](#), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](#).

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement](#).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding](#)

[Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements as noted on the [Award Conditions and Information for NIH Grants](#) website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](#) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](#). More information is provided at [Award Conditions and Information for NIH Grants](#).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit [the Research Performance Progress Report \(RPPR\)](#) annually and financial statements as required in the [NIH Grants Policy Statement](#).

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement](#).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over \$25,000. See the [NIH Grants Policy Statement](#) for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Use the information in this section to save time by contacting the appropriate help desk to answer your question.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

Finding Help Online: <https://grants.nih.gov/support/> (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Telephone: 301-945-7573

Email: GrantsInfo@nih.gov

Contact the scientific research contact to find out if the FOIA applies to your project, to obtain approval for application for >\$500k/yr, or for a conference grant application

Scientific/Research Contact(s)

Participating NIH Institutes and Centers are listed in “Components of Participating Organizations” in [Part 1. Overview](#). Scientific/Research Contact information is listed on the [R01 IC-Specific Scientific Interests and Contact](#) website.

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Contact the peer review contact (Scientific/Research Contact information appears in the eRA Commons), or to discuss [submission application materials](#)

Financial/Grants Management Contact(s)

Contact grants management contacts for non-scientific questions on grants policy and budgets.

Participating NIH Institutes and Centers are listed in “Components of Participating Organizations” in [Part 1. Overview](#). Financial/Grants Management Contact information is listed on the [R01 IC-Specific Scientific Interests and Contact](#) website.

Section VIII. Other Information

Recently issued trans-NIH [policy notices](#) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](#). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 75.

[Weekly TOC for this Announcement](#)
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