

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

|   |   |   |
|---|---|---|
| <p><b>Participating Organization(s)</b></p>             | <p>National Institutes of Health (<a href="#">NIH</a>)</p>  | <p>Your research has to fit within the mission of one of these participating organizations for your application to be <a href="#">assigned</a> for funding consideration.</p> |
| <p><b>Components of Participating Organizations</b></p> | <p>National Cancer Institute (<a href="#">NCI</a>)<br/> National Eye Institute (<a href="#">NEI</a>)<br/> National Heart, Lung, and Blood Institute (<a href="#">NHLBI</a>)<br/> National Human Genome Research Institute (<a href="#">NHGRI</a>)<br/> National Institute on Aging (<a href="#">NIA</a>)<br/> National Institute on Alcohol Abuse and Alcoholism (<a href="#">NIAAA</a>)<br/> National Institute of Allergy and Infectious Diseases (<a href="#">NIAID</a>)<br/> National Institute of Arthritis and Musculoskeletal and Skin Diseases (<a href="#">NIAMS</a>)<br/> National Institute of Biomedical Imaging and Bioengineering (<a href="#">NIBIB</a>)<br/> <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (<a href="#">NICHD</a>)<br/> National Institute on Deafness and Other Communication Disorders (<a href="#">NIDCD</a>)<br/> National Institute of Dental and Craniofacial Research (<a href="#">NIDCR</a>)<br/> National Institute of Diabetes and Digestive and Kidney Diseases (<a href="#">NIDDK</a>)<br/> National Institute on Drug Abuse (<a href="#">NIDA</a>)<br/> National Institute of Environmental Health Sciences (<a href="#">NIEHS</a>)<br/> National Institute of General Medical Sciences (<a href="#">NIGMS</a>)<br/> National Institute of Mental Health (<a href="#">NIMH</a>)<br/> National Institute on Minority Health and Health Disparities (<a href="#">NIMHD</a>)<br/> National Institute of Neurological Disorders and Stroke (<a href="#">NINDS</a>)<br/> National Institute of Nursing Research (<a href="#">NINR</a>)<br/> National Library of Medicine (<a href="#">NLM</a>)<br/> National Center for Complementary and Integrative Health (<a href="#">NCCIH</a> formerly <a href="#">NCCAM</a>)<br/> Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (<a href="#">ORIP</a>)</p> |   |
| <p><b>Funding Opportunity Title</b></p>                 | <p><b>Research Project Grant (Parent R01)</b></p>   |   |
| <p><b>Activity Code</b></p>                             | <p><a href="#">R01</a> Research Project Grant</p>   |   |

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.

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| <p><b>Announcement Type</b></p>  | <p>Reissue of <a href="#">PA-11-260</a></p>  |
| <p><b>Related Notices</b></p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <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> </div> | <ul style="list-style-type: none"> <li>• <a href="#">NOT-OD-16-004</a> - NIH &amp; AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)</li> <li>• <a href="#">NOT-OD-16-006</a> - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015)</li> <li>• <a href="#">NOT-OD-16-011</a> - Implementing Rigor and Transparency in NIH &amp; AHRQ Research Grant Applications (November 18, 2015)</li> <li>• <a href="#">April 16, 2015</a> - Notice of Information: NIMH High-Priority Areas for Research on Women's Mental Health During Pregnancy and the Postpartum Period . See Notice <a href="#">NOT-MH-15-013</a>.</li> <li>• <a href="#">September 25, 2014</a> - See Notice <a href="#">NOT-MH-14-033</a>. Notice of Information on High-Priority Research Areas to Understand and Reduce Mental Health Disparities.</li> <li>• <a href="#">September 4, 2014</a> - Notice Announcing Updates to NHLBI Topics of Special Interest (TOSI). See Notice <a href="#">NOT-HL-14-236</a>.</li> <li>• <a href="#">August 29, 2014</a> - See Notice <a href="#">NOT-AR-14-021</a>. NIAMS Policy for Submission of Applications Containing Clinical Trials.</li> <li>• <a href="#">August 06, 2014</a> - See Notice NOT-MH-14-007. Notice of change to application requirements.</li> <li>• <a href="#">July 10, 2014</a> - Notice of National Institute on Minority Health and Health Disparities (NIMHD) Participation in PA-13-302. See Notice NOT-MD-14-003.</li> <li>• <a href="#">June 10, 2014</a> - Notice of NICHD's Interest in Supporting Research on Contraception, Long-Term Outcomes of Assisted Reproductive Technologies, and Intrauterine Assessment of Placental and Fetal Function. See Notice NOT-HD-14-020.</li> <li>• <a href="#">June 4, 2014</a> - Notice <a href="#">NOT-14-074</a> supersedes instructions in Section III.3 regarding applications that are essentially the same.</li> <li>• <a href="#">November 25, 2013</a> - See Notice NOT-HL-13-201. Notice Announcing NHLBI Topics of Special Interest (TOSI).</li> <li>• August 21, 2013: Removed reference to ASSIST in section IV.3, since ASSIST is currently only available for multi-project applications.</li> <li>• <a href="#">NOT-DK-13-013</a> "Clarification of NIDDK Policy: Investigator-Initiated Multi-Center Clinical Studies"</li> <li>• August 7, 2013 - Use this funding opportunity announcement for due dates of September 25, 2013 and beyond.</li> </ul> |
| <p><b>Funding</b></p>  | <p><b>PA-13-302</b></p>  |

|  |  |
|--|--|
| <b>Opportunity Announcement (FOA) Number</b>                   |  |
| <b>Companion Funding Opportunity</b>                           | None <span style="border: 1px solid black; padding: 2px;">Companion FOAs focus on similar areas of science but use different activity codes</span>   |
| <b>Number of Applications</b>                                  | See <a href="#">Section III. 3. Additional Information on Eligibility.</a>   |
| <b>Catalog of Federal Domestic Assistance (CFDA) Number(s)</b> | 93.361, 93.233, 93.839, 93.838, 93.837, 93.113, 93.859, 93.879, 93.286, 93.273, 93.172, 93.173, 93.866, 93.853, 93.847, 93.856, 93.855, 93.121, 93.351, 93.867, 93.213, 93.242, 93.846, 93.865, 93.399, 93.307, 93.396, 93.395, 93.394, 93.393, 93.279   |
| <b>Funding Opportunity Purpose</b>                             | The Research Project Grant (R01) supports a discrete, specified, circumscribed project to be performed by the named investigator(s) 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 descriptions of their programs. <span style="border: 1px solid black; padding: 2px;">Goals of the FOA.</span> |

## Key Dates

|   |  |
|---|--|
| <b>Posted Date</b>                          | August 2, 2013   |
| <b>Open Date (Earliest Submission Date)</b> | August 7, 2013   |
| <b>Letter of Intent Due Date(s)</b>         | Not Applicable <span style="border: 1px solid black; padding: 2px;">Letters of Intent are requested for planning purposes. They are not required.</span>   |
| <b>Application Due Date(s)</b>              | <a href="#">Standard dates</a> apply, by 5:00 PM local time of applicant organization.<br><br>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.  |
| <b>AIDS Application Due Date(s)</b>         | <a href="#">Standard AIDS dates</a> apply, by 5:00 PM local time of applicant organization.<br><br><span style="border: 1px solid black; padding: 2px;">If your application has a strong focus on AIDS research, special due dates apply.</span> 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. |
| <b>Scientific Merit</b>                     | <a href="#">Standard dates</a> apply   |

|                                 |                                      |
|---------------------------------|--------------------------------------|
| <b>Review</b>                   |                                      |
| <b>Advisory Council Review</b>  | <a href="#">Standard dates</a> apply |
| <b>Earliest Start Date</b>      | <a href="#">Standard dates</a> apply |
| <b>Expiration Date</b>          | September 8, 2016                    |
| <b>Due Dates for E.O. 12372</b> | Not Applicable                       |

You cannot apply to an expired FOA.

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. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. [Learn more.](#)

Apply Online Using ASSIST

Apply Using Downloadable Forms

Problems accessing or using ASSIST should be directed to [Grants.gov](#)  
 Problems downloading forms should be directed to [Grants.gov](#)

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.

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## Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

The 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.

Each IC maintains a web site with funding opportunities and areas of interest. Contacting an [IC representative](#) may help focus the proposed research based on an understanding of the mission of the IC. For specific information about the mission of each NIH IC, see <http://www.nih.gov/icd>, which provides a brief summary of the research interests in each IC and access to individual IC websites.

### Section II. Award Information

|  |  |  |  |
|--|--|--|--|
| <b>Funding Instrument</b>                  | Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.  |  |  |
| <b>Application Types Allowed</b>           | <table border="1"><tr><td>New<br/>Renewal<br/>Resubmission<br/>Revision</td><td>Check the FOA to determine whether renewal, resubmission, and/or revision applications are allowed. See <b>Types of Applications</b></td></tr></table> <p>The <a href="#">OER Glossary</a> and the SF424 (R&amp;R) Application Guide provide details on these application types.</p> | New<br>Renewal<br>Resubmission<br>Revision | Check the FOA to determine whether renewal, resubmission, and/or revision applications are allowed. See <b>Types of Applications</b> |
| New<br>Renewal<br>Resubmission<br>Revision | Check the FOA to determine whether renewal, resubmission, and/or revision applications are allowed. See <b>Types of Applications</b>   |  |  |

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|---|---|
| <b>Funds Available and Anticipated Number of Awards</b> | The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. |
| <b>Award Budget</b>                                     | Application budgets are not limited but need to reflect the actual needs of the proposed project.                                 |
| <b>Award Project Period</b>                             | The scope of the proposed project should determine the project period. The maximum project period is 5 years.                     |

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 your 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 Late Submission of Grant Applications](#) 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.

### **Eligible Individuals (Program Director/Principal Investigator)**

Any individual(s) with the skills, knowledge, and resources necessary to conduct research as the Program Director(s)/Principal Investigator(s) with his/her organization to develop an application for support of research in underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

Individual eligibility requirements only apply to the program director/principal investigator, not to collaborators or consultants

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.

NIH will not accept any application that is essentially the same as one already reviewed within the past thirty-seven months (as described in the [NIH Grants Policy Statement](#)), except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

## Section IV. Application and Submission Information

### 1. Requesting an Application Package

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

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](#), 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.

#### Instructions for Application Submission

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

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.

## 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 (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) 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.

## Planned Enrollment Report

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

## PHS 398 Cumulative Inclusion Enrollment Report

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

## 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. 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 deadline. If a Changed/Corrected application is submitted after the deadline, the application is considered late.

All system-detected errors in your application must be addressed by the application deadline to be considered an on-time application.

**Applicants are responsible for viewing their application before the 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.

### 4. Intergovernmental Review (E.O. 12372)

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

### 5. 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](#).

## 6. 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 [NIH program staff](#) 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 the instructions for post-submission materials, as described in [NOT-OD-13-030](#).

## Section V. Application Review Information

**NEW Important Update:** Write your research strategy to respond to the review criteria to ensure reviewers applications for due dates 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, see the [Human Subjects Protections 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 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 annual Non-Competing Progress Report ([PHS 2590](#) or [RPPR](#)) 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](http://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.

### Application Submission Contacts

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

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)

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

Web ticketing system: <https://public.era.nih.gov/commonshelp>

TTY: 301-451-5939

Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)

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

Contact Center Telephone: 800-518-4726

Web ticketing system: <https://grants-portal.psc.gov/ContactUs.aspx>

Email: [support@grants.gov](mailto:support@grants.gov)

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

Telephone: 301-435-0714

TTY: 301-451-5936

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)

Contact the scientific research (program staff) contact to find out if the FOA is right for you and your project, to obtain approval to submit an application for >\$500k/yr, or before submitting a conference grant application.

### Scientific/Research Contact(s)

Participating NIH Institutes and Centers are listed on the first page of this announcement ("Components of Participating Organizations"). Scientific/Research Contact information is listed in the table at [http://grants.nih.gov/grants/guide/contacts/parent\\_R01.html](http://grants.nih.gov/grants/guide/contacts/parent_R01.html).

### 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 Review Officer) for questions about your review assignment (after the information appears in the eRA Commons), or to discuss submission of [post submission application materials](#).

## Financial/Grants Management Contact

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

Participating NIH Institutes and Centers are listed on the first page of this announcement ("Components of Participating Organizations"). Financial/Grants Management Contact information is listed in the table at [http://grants.nih.gov/grants/guide/contacts/parent\\_R01.html](http://grants.nih.gov/grants/guide/contacts/parent_R01.html).

## 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 74 and 92.

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[Weekly TOC for this Announcement](#)  
[NIH Funding Opportunities and Notices](#)

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**Note:** For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](#).