### Department of Health and Human Services

**Part 1. Overview Information**

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<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
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<tr>
<td><strong>Components of Participating Organizations</strong></td>
<td>National Cancer Institute (NCI)</td>
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<td>National Eye Institute (NEI)</td>
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<td>National Heart, Lung, and Blood Institute (NHLBI)</td>
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<td>National Human Genome Research Institute (NHGRI)</td>
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<td>National Institute on Aging (NIA)</td>
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<td>National Institute on Alcohol Abuse and Alcoholism (NIAAA)</td>
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<td>National Institute of Allergy and Infectious Diseases (NIAID)</td>
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<td>National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)</td>
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<td>National Institute of Biomedical Imaging and Bioengineering (NIBIB)</td>
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<td><em>Eunice Kennedy Shriver</em> National Institute of Child Health and Human Development (NICHD)</td>
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<td>National Institute on Deafness and Other Communication Disorders (NIDCD)</td>
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<td>National Institute of Dental and Craniofacial Research (NIDCR)</td>
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<td>National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</td>
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<td>National Institute on Drug Abuse (NIDA)</td>
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<td>National Institute of Environmental Health Sciences (NIEHS)</td>
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<td>National Center for Complementary and Alternative Medicine (NCCAM)</td>
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<td>Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)</td>
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**Funding Opportunity Title**

Academic Research Enhancement Award (Parent R15)

**Activity Code**

R15 Academic Research Enhancement Award (AREA)

**Announcement Type**

Reissue of PA-12-006

**Related Notices**

None

**Funding Opportunity Announcement (FOA) Number**

PA-13-313

**Companion Funding Opportunity**

None

**Number of Applications**

See Section III. 3. Additional Information on Eligibility.

**Catalog of Federal Domestic Assistance (CFDA) Number(s)**

93.361; 93.233; 93.839; 93.838; 93.837; 93.865; 93.113; 93.273; 93.286; 93.859; 93.173; 93.866; 93.351; 93.853; 93.856; 93.855; 93.847; 93.121; 93.172; 93.867; 93.846; 93.279; 93.213; 93.242; 93.399; 93.396; 93.395; 93.394; 93.393; 93.879

**Funding Opportunity Purpose**

The purpose of the Academic Research Enhancement Award (AREA) program is to stimulate research in educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support. AREA grants create opportunities for scientists and institutions, otherwise unlikely to participate extensively in NIH research programs, to contribute to the Nation's biomedical and behavioral research effort. AREA grants are intended to support small-scale research projects proposed by faculty members of eligible, domestic institutions.
Key Dates

<table>
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<tr>
<th>Key Date</th>
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<tr>
<td>Posted Date</td>
<td>September 11, 2013</td>
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<tr>
<td>Open Date (Earliest Submission Date)</td>
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<td>AIDS Application Due Date(s)</td>
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<td>Advisory Council Review</td>
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<td>Earliest Start Date</td>
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<tr>
<td>Expiration Date</td>
<td>September 8, 2016</td>
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<tr>
<td>Due Dates for E.O. 12372</td>
<td>Not Applicable</td>
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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.

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  Section VI. Award Administration Information
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Part 2. Full Text of Announcement
Section I. Funding Opportunity Description

Purpose

The National Institutes of Health (NIH) is continuing to make a special effort to stimulate research at educational institutions that provide baccalaureate and/or advanced degrees for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support. Since Fiscal Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, which NIH has implemented through the Academic Research Enhancement Award (AREA) program. Based on the expectation that funds will continue to be available each year, the NIH invites applications for AREA (R15) grants through this Funding Opportunity Announcement (FOA). AREA funds are intended to support new and renewal biomedical and behavioral research projects proposed by faculty members of eligible colleges, universities, schools, and components of domestic institutions.

The AREA program will enable qualified scientists to receive support for small-scale research projects. These grants are intended to create a research opportunity for scientists and institutions otherwise unlikely to participate extensively in NIH programs that support the Nation's biomedical and behavioral research effort. It is anticipated that investigators supported under the AREA program will benefit from the opportunity to conduct independent research; that the grantee institution will benefit from a research environment strengthened through AREA grants and furthered by participation in the diverse extramural programs of the NIH; and that students at recipient institutions will benefit from exposure to and participation in scientific research in the biomedical and behavioral sciences.

The application should include plans to involve undergraduate or graduate students in the proposed research. However, the AREA program is a research grant program, not a training or fellowship program. The application should include plans to expose students to hands-on research and should not include training plans.

Research Objectives of the NIH Institutes and Centers

The AREA program website provides information about each of the participating Institutes and Centers (ICs), including each IC's AREA-specific research interests and staff contacts. For additional scientific program information and for pre-application guidance, a potential applicant is encouraged to contact the person listed for the particular NIH IC(s) with research interests relevant to the applicant's proposed topic.

In addition, applicants are encouraged to consult the Frequently Asked Questions website for more information about this program.

Section II. Award Information

<table>
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<tr>
<th>Funding Instrument</th>
<th>Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.</th>
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| Application Types Allowed | New
Renewal
Resubmission
Revision |
| 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 | Applicants may request up to $300,000 in direct costs plus applicable Facilities & Administrative (F&A) for the entire project period of up to 3 years. Note when a consortium is involved, the $300,000 direct cost limit is exclusive of consortium F&A costs. These can be requested in addition to the $300,000 direct costs limit. |
| Award Project Period | The scope of the proposed project should determine the project period. The maximum project period is 3 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

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)

In addition, all organizations must meet the following two criteria:

- The applicant organization must offer baccalaureate or advanced degrees in the biomedical or behavioral sciences
- The applicant organization may not receive research support from the NIH totaling more than $6 million per year (in both direct and F&A/indirect costs) in each of 4 of the last 7 years.
- Note that the following activity codes are excluded: C06, S10, and all activity codes starting with a G.

Institutions with Multiple Schools or Colleges

For institutions composed of multiple schools or colleges, the criterion of financial eligibility is based on the amount of NIH support received, not by the institution (university or college) as a whole, but by the individual school/college or aggregation of "other academic components" (as defined in this section) where the PD(s)/PI(s) has a primary appointment (e.g., School of Medicine, College of Nursing, etc.). Thus, each of the following should be considered independently when determining the financial eligibility of the applicant organization.

- Health professional school/college: Accredited public or non-profit private school that provides a terminal degree related to the health sciences granted by that school (e.g., PhD, MD, DDS, MPT, DC, ND, BSN). The term "accredited" means a school or program that is accredited by a recognized body or bodies approved for such purposes by the Secretary of Education.
- Includes schools or colleges of medicine, dentistry, osteopathy, pharmacy, nursing, veterinary medicine, public health, optometry, allied health, chiropractic, naturopathy and podiatry
- Other academic components: Once the health professional schools have been excluded, "other academic components" refers to all remaining schools, colleges, and free-standing institutes of the institution taken as a single component.

Additional Eligibility Guidance

To determine the eligibility of an institution, applicants should consult the list of ineligible institutions on the AREA program website. If the name of the institution does not appear on the list, it is likely eligible to apply for AREA grants. Applicants should check with their own institutions if unsure.

An AREA grant is permitted to have a subcontract to a non-AREA-eligible institution. However, applicants should keep the goals of the AREA program in mind when preparing the application, which include strengthening the research environment of the institution and exposing students to research.

Although foreign institutions are not eligible, applications may include a foreign collaboration, component, or consortium.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, are allowable.
Required Registrations

Applicant Organizations

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.

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 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.

To be eligible for an AREA grant, the PD(s)/PI(s) must meet the following additional criteria.

- The PD(s)/PI(s) must have a primary appointment at an AREA eligible institution.
- The PD(s)/PI(s) may not be the PD(s)/PI(s) of any active NIH research grant, including another AREA grant, at the time of an AREA award (although he or she may be one of the project personnel for an active NIH grant held by another PD/PI).
- The PD(s)/PI(s) may not be awarded more than one AREA grant at a time, although he or she may hold successive new or renewal AREA grants.

Note: These eligibility criteria only apply to the PD(s)/PI(s) of the application, not to other key personnel such as collaborators and consultants.

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

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.

Required and Optional Components

The forms package associated with this FOA includes all applicable components, required and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

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.

Facilities and Other Resources: Include the following information:

- A profile of the students of the applicant institution/academic component and any information or estimate of the number who have obtained a baccalaureate degree and gone on to obtain an academic or professional doctoral degree in the health-related sciences during the last five years.
- A description of the special characteristics of the institution/academic component that make it appropriate for an AREA grant, where the goals of the AREA program are to: (1) provide support for meritorious research; (2) strengthen the research environment of schools that have not been major recipients of NIH support; and (3) expose available undergraduate and/or graduate students in such environments to research. Include a description of the likely impact of an AREA grant on the PD(s)/PI(s) and the research environment of the institution/academic component.
- Although it is expected that the majority of the research will be directed by the applicant investigator and
conducted at the grantee institution, limited use of special facilities or equipment at another institution is permitted. For any proposed research sites other than the applicant institution, provide a brief description of the resources.

- If relevant, a statement of institutional support for the proposed research project (e.g., equipment, laboratory space, release time, matching funds, etc.).

**SF424(R&R) Senior/Key Person Profile**

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

**Biographical Sketch:** The PD(s)/PI(s) should include a summary of his or her previous and/or current experience in supervising students in research in the Personal Statement. The PD(s)/PI(s) also should indicate which peer-reviewed publications involved students under his or her supervision.

**R&R or Modular Budget**

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

The total budget for all years of the proposed project must be requested in Budget Period 1. Do not complete Budget Periods 2 or 3. They are not required and will not be accepted with the application.

Complete only Budget Period 1 of either the PHS398 Modular Budget form or the R&R Budget form.

- Applicants submitting an application with direct costs of $250,000 or less (total for all years, excluding consortium Facilities and Administrative [F&A] costs) must use the PHS398 Modular Budget form.
- Applicants submitting an application with direct costs of $250,001 - $300,000 (total for all years) must use the R&R Budget form.

**PHS 398 Modular Budget (direct costs of $250,000 or less):**

Follow all instructions in the SF 424 (R&R) Application Guide, noting the following specifications for R15 applications.

**Budget Period 1: Direct Costs**

*Direct Costs less Consortium F&A:* Select the appropriate dollar amount from the drop-down list. This number must not exceed $250,000.

*Consortium F&A:* If applicable, enter the actual consortium F&A (e.g., $3,271).

*Total Direct Costs:* This field auto-calculates so no data entry is required.

**Budget Period 1: Indirect Costs**

If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs.

If the F&A rate has not been established, enter "None-will negotiate" and include information for a proposed rate. Use the budget justification if additional space is needed.

**Budget Justification:** Attach the Personnel Justification and Consortium Justification. If the requested budget requires any additional justification, attach an Additional Narrative Justification.

**Personnel Justification:** Follow all instructions in the SF 424 (R&R) Application Guide. Since a primary objective of the AREA program is to expose students to meritorious research, PD(s)/PI(s) must include undergraduate (preferably, if available) and/or graduate students in the proposed research. Indicate aspects of the proposed research in which students will participate. If participating students have not yet been individually identified, the number and academic level of those to be involved should be provided. If there are any Collaborators or Consultants for the project, provide their names, organizational affiliations, and the services they will perform.

**Consortium Justification:** Follow all instructions in the SF 424 (R&R) Application Guide, but note that the Letter of Intent to establish a consortium must also be included in the Consortium Justification attachment.

**R&R Budget (direct costs of $250,001 to $300,000):**

Follow all instructions in the SF424 (R&R) Application Guide, noting the following specifications for R15 applications.
Budget Period 1: Direct Costs

*Total Direct Costs less Consortium F&A:* This number must not exceed $300,000.

Budget Period 1: Indirect Costs

If the F&A rate agreement has been established, indicate the type of agreement. All appropriate exclusions must be applied in the calculation of the F&A costs.

If the F&A rate has not been established, enter "None-will negotiate" and include information for a proposed rate. Use the budget justification if additional space is needed.

**Budget Justification:** Follow all instructions in the SF424 (R&R) Application Guide. Since a primary objective of the AREA program is to expose students to meritorious research, PD(s)/PI(s) must include undergraduate (preferably, if available) and/or graduate students in the proposed research. Indicate aspects of the proposed research in which students will participate. If participating students have not yet been individually identified, the number and academic level of those to be involved should be provided. If there are any Collaborators or Consultants for the project, provide their names, organizational affiliations, and the services they will perform.

**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.

**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 due date. If a Changed/Corrected application is submitted after the deadline, the application will be considered late.

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.

**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.

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.

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

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.

For this particular announcement, note the following:

The objectives of the R15 program are to (1) provide support for meritorious research, (2) strengthen the research environment of schools that have not been major recipients of NIH support, and (3) expose available undergraduate and graduate students in such environments to meritorious research. Preliminary data are not required for an R15 application; however, they may be included if available.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to make an important scientific contribution to the research field(s) involved, to provide research opportunities to students, and to strengthen the research environment of the institution, 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 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? If funded, will the AREA award have a substantial effect on the school/academic component in terms of strengthening the research environment and exposing students to research?

**Investigator(s)**

Are the PD(s)/P(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(s)/P(s), do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Do the PD(s)/P(s) have suitable experience in supervising students in research?

**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? Does the application provide sufficient evidence that the project can stimulate the interests of students so that they consider a career in the biomedical or behavioral science?

If the project involves human 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**

Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Does the application demonstrate the likely availability of well-qualified students to participate in the research project? Does the application provide sufficient evidence that students have in the past or are likely to pursue careers in the biomedical or behavioral sciences?

**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](http://grants.nih.gov/grants/guide/pa-files/PA-13-313.html).

**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

Not Applicable

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

Progress reports for multi-year funded awards are due annually on or before the anniversary of the budget/project period start date of award. The reporting period for multi-year funded award progress report is the calendar year preceding the anniversary date of the award. Information on the content of the progress report and instructions on how to submit the report are posted at http://grants.nih.gov/grants/policy/myf.htm.

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.

Application Submission Contacts

eRA Commons Help Desk (Questions regarding 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

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

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Telephone: 301-435-0714
TTY: 301-451-5936
Email: GrantsInfo@nih.gov

Scientific/Research Contact(s)

Program Guidelines and other information related to the AREA program are available on the AREA Program website.

Questions regarding eligibility, policies, procedures, and other administrative aspects of the NIH AREA program should be referred first to the Office of Sponsored Programs at the educational institution.

All programmatic and scientific questions should be directed to NIH Institutes and Centers (ICs) sponsoring the AREA program. See AREA contacts.

For NIH-wide policy and other questions about the AREA program, please contact the R15 mailbox at R151@mail.nih.gov.

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)

All financial and grants management questions should be directed to NIH Institutes and Centers (ICs) sponsoring the AREA program. See AREA contacts.

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.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.