

# Department of Health and Human Services

## Part 1. Overview Information

<b>Participating Organization(s)</b>	National Institutes of Health ( <a href="http://www.nih.gov">NIH (http://www.nih.gov)</a> )
<b>Components of Participating Organizations</b>	<p>National Institute of Nursing Research (<a href="http://www.ninr.nih.gov">NINR (http://www.ninr.nih.gov)</a>)</p> <p>National Cancer Institute (<a href="http://www.nci.nih.gov/">NCI (http://www.nci.nih.gov/)</a>)</p> <p>National Institute on Aging (<a href="http://www.nia.nih.gov">NIA (http://www.nia.nih.gov)</a>)</p> <p><i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (<a href="https://www.nichd.nih.gov/">NICHD (https://www.nichd.nih.gov/)</a>)</p> <p>National Institute on Deafness and Other Communication Disorders (<a href="http://www.nidcd.nih.gov">NIDCD (http://www.nidcd.nih.gov)</a>)</p> <p>National Institute on Drug Abuse (<a href="http://www.nida.nih.gov">NIDA (http://www.nida.nih.gov)</a>)</p> <p>National Institute of Mental Health (<a href="http://www.nimh.nih.gov">NIMH (http://www.nimh.nih.gov)</a>)</p> <p>National Institute of Neurological Disorders and Stroke (<a href="http://www.ninds.nih.gov">NINDS (http://www.ninds.nih.gov)</a>)</p> <p>National Heart, Lung, and Blood Institute(<a href="http://www.nhlbi.nih.gov/">NHLBI (http://www.nhlbi.nih.gov/)</a>)</p>
<b>Funding Opportunity Title</b>	<b>Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools (R15 Clinical Trial Required)</b>
<b>Activity Code</b>	<a href="http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r15&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity">R15 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r15&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity)</a> Research Enhancement Award
<b>Announcement Type</b>	New
<b>Related Notices</b>	None
<b>Funding Opportunity Announcement (FOA) Number</b>	<b>PAR-19-135</b>
<b>Companion Funding Opportunity</b>	<a href="https://grants.nih.gov/grants/guide/pa-files/par-19-134.html">PAR-19-134 (https://grants.nih.gov/grants/guide/pa-files/par-19-134.html)</a> , <a href="http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r15&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity">R15 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r15&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity)</a> Research Enhancement Award

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**Number of Applications**See [Section III. 3. Additional Information on Eligibility](#).

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

93.361, 93.393, 93.394, 93.395, 93.399, 93.865, 93.279, 93.173, 93.242, 93.853, 93.866, 93.837, 93.838, 93.839, 93.840, 93.233

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**Funding Opportunity Purpose**

The purpose of the Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools is to stimulate basic and clinical 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. REAP grants create opportunities for scientists and health professional institutions otherwise unlikely to participate extensively in NIH research programs to contribute to the Nation's biomedical and behavioral research effort. REAP grants are intended to support small-scale research projects proposed by faculty members of eligible, domestic institutions, to expose undergraduate and/or graduate students at health professional schools or graduate schools to meritorious research projects, and to strengthen the research environment of the applicant institution.

Eligible institutions (e.g., the university or college) must award NIH-relevant baccalaureate or advanced degrees in health professions and have received less than \$6 million per year of NIH support (total costs) in 4 of the last 7 fiscal years. In this FOA a college is a stand-alone entity and not a component of a university system.

This funding opportunity announcement (FOA) supports investigator-initiated mechanistic and/or minimal risk clinical trials addressing the mission and research interests of the participating NIH institutes. Minimal risk clinical trials are defined as those that do not require FDA oversight, do not intend to formally establish efficacy, and have low risks to potentially cause physical or psychological harm.

## Key Dates

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**Posted Date**

December 21, 2018

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**Open Date (Earliest Submission Date)**

January 25, 2019

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**Letter of Intent Due Date(s)**

Not Applicable

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**Application Due Date(s)**[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11111\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11111)

apply, by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on these dates.

The first standard application due date for this FOA is February 25, 2019

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.

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#### **AIDS Application Due Date(s)**

[Standard AIDS dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11112\)](#) apply by 5:00 PM local time of applicant organization. All [types of AIDS and AIDS-related applications](#) allowed for this funding opportunity announcement are due on these dates.

The first AIDS application due date for this FOA is May 7, 2019.

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.

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#### **Scientific Merit Review**

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113\)](#) (<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa>) apply

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#### **Advisory Council Review**

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113\)](#) (<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa>) apply

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#### **Earliest Start Date**

[Standard dates \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113\)](#) apply

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#### **Expiration Date**

January 8, 2022

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#### **Due Dates for E.O. 12372**

Not Applicable

### **Required Application Instructions**

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](#), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](#)). 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 available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

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 prepare and submit your application to Grants.gov and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-135\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-19-135) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

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## Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

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 institutions 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, known as the Academic Research Enhancement Award (AREA) program that was intended to focus on undergraduate institutions ([PAR-18-714 \(https://grants.nih.gov/grants/guide/pa-files/par-18-714.html\)](https://grants.nih.gov/grants/guide/pa-files/par-18-714.html)). To complement the AREA program, this funding opportunity announcement (FOA) specifically supports eligible health professional schools and

graduate schools, to provide research experiences to undergraduates and graduate students pursuing biomedical or behavioral research. Eligible institutions (e.g., the university or college) must award NIH-relevant baccalaureate or advanced degrees and have received less than \$6 million per year of NIH support (total costs) in 4 of the last 7 fiscal years. Note that all activity codes are included in this calculation except the following: C06, S10, and all activity codes starting with a G. In this FOA a college is a stand-alone entity and not a component of a university system. This new program is called the Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools.

The objectives of the REAP are to provide support for meritorious research, to strengthen the research environment of health professional schools and graduate schools that have not been major recipients of NIH support, and to expose available undergraduate and/or graduate students in such environments to meritorious research.

For the purposes of this FOA, health professional schools and colleges are accredited institutions that provide education and training leading to a health professional degree, including but not limited to: BSN, MSN, DNP, MD, DDS, DO, PharmD, DVM, OD, DPT, DC, ND, DPM, MOT, OTD, DPT, BME, MSEE, MS-SLP, CScD, SLPD, AuD, MSPO, MSAT, and MPH. Eligible health professional schools/colleges may include schools or colleges of nursing, medicine, dentistry, osteopathy, pharmacy, veterinary medicine, public health, optometry, allied health, chiropractic, naturopathy, podiatry, rehabilitation medicine, physical therapy, orthotics & prosthetics, kinesiology, biomedical engineering, occupational therapy and psychology. Accreditation must be provided by a body approved for such purpose by the Secretary of Education.

The REAP 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 REAP will benefit from the opportunity to conduct independent research; that the grantee institution will benefit from a research environment strengthened through REAP grants and that undergraduate and/or graduate students at recipient institutions will benefit from exposure to and participation in scientific research.

The research project must involve undergraduate and/or graduate students in the proposed research. Students' involvement in research may include participation in the design of experiments and controls, collection and analysis of data, execution and troubleshooting of experiments, presentation at meetings, drafting journal articles, collaborative interactions, participation in lab meetings to discuss results and future experiments, etc. The REAP is a research grant program, not a training or fellowship program. As such, applications should not include training plans such as didactic training plans or non-research activities relating to professional development.

A REAP application may include other investigators, such as collaborators or consultants, or other trainees such as high school students, post baccalaureate participants, postdoctoral fellows, or clinical fellows. However, involvement of such individuals does not fulfill the goal to expose undergraduate and/or graduate students in eligible environments to research.

This FOA supports investigator-initiated clinical trials proposing mechanistic and/or low/minimal risk study, with the goal of producing clinical findings that have significant public health impact. The NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15->

[015.html \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html)) A low/minimal risk clinical trial meets the following criteria:

- Does not require FDA oversight such as those requiring Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications. For example, clinical trials involving utilization of a licensed product/device for an approved dose, population, and indication may not require an IND or IDE
- Potential of the intervention to cause physical or psychological harm is low. For example, risks that are no greater than those encountered in routine medical care or procedures
- Intends to gather scientific data/evidence to inform subsequent studies but not aimed or sufficiently powered to directly change health policy or standard of care and is not an NIH defined Phase III Clinical Trial (<https://humansubjects.nih.gov/glossary> (<https://humansubjects.nih.gov/glossary>)).

A mechanistic clinical trial meets the definition of a clinical trial and is designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention.

Proposed studies should be hypothesis-driven and produce research data/evidence that are necessary to inform core scientific, design, implementation and issues essential to advance scientific knowledge.

It is advisable that only one clinical trial be proposed in each R15 clinical trial application. In addition to a clinical trial, basic science and/or other human subjects research may also be included as part of the application. Investigators who are solely proposing basic or non-clinical trial human subjects research (e.g. observational, epidemiological, secondary data analyses), should apply to the [Research Enhancement Award Program \(REAP\) for Health Professional Schools and Graduate Schools \(R15 Clinical Trial Not Allowed\) funding opportunity \(PAR-19-134 \(https://grants.nih.gov/grants/guide/pa-files/par-19-134.html\)\)](https://grants.nih.gov/grants/guide/pa-files/par-19-134.html).

## Research Objectives of the NIH Institutes and Centers

***Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD*** (<https://www.nichd.nih.gov/>)

The NICHD supports biological, behavioral, and clinical research related to conception and pregnancy, normal and abnormal development in childhood, reproductive health, population dynamics across the lifespan, and rehabilitation medicine. <https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/areas-research/Pages/default.aspx> (<https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/areas-research/Pages/default.aspx>).

Research projects considered for funding by NICHD must fall within the scientific missions of the twelve Scientific Branches of the NICHD Division of Extramural Research (DER) or the National Center for Medical Rehabilitation Research (NCMRR). Information about those scientific missions and program staff contacts may be found on the web pages for the DER scientific branches at: <http://www.nichd.nih.gov/about/org/der/branches/Pages/index.aspx> (<http://www.nichd.nih.gov/about/org/der/branches/Pages/index.aspx>) and the NCMRR at: <http://www.nichd.nih.gov/about/org/ncmrr/Pages/overview.aspx> (<http://www.nichd.nih.gov/about/org/ncmrr/Pages/overview.aspx>). Potential applicants are strongly encouraged to read these webpages for any updates in response to recent scientific advances or emerging public health topics.

NICHD encourages applications that address its extramural program priorities and will consider how well research projects align with one or more of those priorities when making award decisions. A detailed list of

NICHD high priority research areas may be found at <https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/areas-research/Pages/priorities.aspx> (<https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/areas-research/Pages/priorities.aspx>)

### ***National Institute on Deafness and Other Communication Disorders (NIDCD)*** (<http://www.nidcd.nih.gov>)

The NIDCD supports biomedical and behavioral research related to the normal and disordered processes of hearing, balance, smell, taste, voice, speech and language. Basic and low risk clinical studies are encouraged of genetic, molecular, cellular, physiological, biochemical, and behavioral aspects of function in health and disease. The NIDCD also supports research concerned with disease prevention, health promotion and the special biomedical and behavioral problems associated with communication impairments and disorders.

### ***National Institute of Drug Abuse (NIDA)***

The projects should address critical issues of neuroscience, genetics, behavior, prevention, treatment, epidemiology, etiology, health services, HIV/AIDS, and co-occurring opportunistic infections (e.g., viral hepatitis C, tuberculosis, sexually transmitted infections) associated consequences in substance abusing populations, medication development, or other research areas relevant to drug abuse. NIDA priorities are further described in the NIDA Strategic Plan (see <https://www.drugabuse.gov/about-nida/2016-2020-nida-strategic-plan> (<https://www.drugabuse.gov/about-nida/2016-2020-nida-strategic-plan>)) and on the NIDA Topics of Interest webpage (see <https://www.drugabuse.gov/funding/funding-priorities/nida-topics-specialcontinuing-interest-dat> (<https://www.drugabuse.gov/funding/funding-priorities/nida-topics-specialcontinuing-interest-dat>)). Applicants are encouraged to contact a program official to discuss the proposed application.

### ***National Institute of Mental Health (NIMH)***

The mission of the National Institute of Mental Health (NIMH) is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. Applications submitted for funding by the NIMH must fall within the areas of priority detailed in the [NIMH Strategic Plan](https://www.nimh.nih.gov/about/strategic-planning-reports/nimh_strategicplanforresearch_508compliant_corrected_final_149979.pdf) ([https://www.nimh.nih.gov/about/strategic-planning-reports/nimh\\_strategicplanforresearch\\_508compliant\\_corrected\\_final\\_149979.pdf](https://www.nimh.nih.gov/about/strategic-planning-reports/nimh_strategicplanforresearch_508compliant_corrected_final_149979.pdf)) and the [NIMH Strategic Research Priorities](https://www.nimh.nih.gov/about/strategic-planning-reports/strategic-research-priorities/index.shtml) (<https://www.nimh.nih.gov/about/strategic-planning-reports/strategic-research-priorities/index.shtml>). Applicants are strongly encouraged to contact the person listed under Agency Contacts (Section VII) prior to submission.

For clinical trials (CTs), NIMH encourages an experimental therapeutics approach to the development and testing of interventions, in which they serve not only as potential treatments, but as probes to generate information about the mechanisms underlying a disorder or the therapeutic effect of the intervention. More information may be found on the [NIMH clinical trials website](https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml) (<https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml>) and in the NIMH CT funding opportunity announcements for pilot/exploratory research (i.e., R61/R33, R33 and R34).

NIMH encourages mechanistic CTs. These studies are designed to provide information about physiological function, target engagement of novel therapeutics, and/or mechanisms of therapeutic responses, all examined in the context of a CT. Further examples of mechanistic clinical trial studies relevant to the NIMH mission are detailed in [NOT-MH-19-006](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-006.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-006.html>).

### ***National Institute of Neurological Diseases and Stroke (NINDS)***

NINDS seeks fundamental knowledge about the brain and nervous system and to use that knowledge to

reduce the burden of neurological disease. NINDS supports basic, translational and clinical research within specifically defined areas of neuroscience. Research projects considered for funding by NINDS must fall within the scientific research mission of the Institute. For this FOA, projects are limited to prospective basic science studies involving human participants that fall within the broad NIH definition of a clinical trial and also meet the definition of basic research as described in [NOT-OD-18-212 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-212.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-212.html). It is critical that applicants with research interests relevant to the NINDS mission contact the person listed under Agency Contacts (Section VII) to confirm that the proposed clinical trial meets NINDS' requirements for this funding opportunity.

### **National Institute of Nursing Research (NINR)**

The National Institute of Nursing Research (NINR) supports clinical, basic, and translational research to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, and enhance palliative and end-of-life care. In doing so, NINR promotes and improves the health of individuals, families, and communities across the lifespan, in a variety of clinical settings and within diverse populations. NINR's goal is to enhance nursing science and health care by integrating the biological and behavioral sciences, applying new technologies, promoting health equity, and developing scientists of the future.

NINR's scientific programs encompass four areas of scientific focus:

- Symptom Science: Promoting Personalized Health Strategies
- Wellness: Promoting Health and Preventing Disease
- Self-Management: Improving Quality of Life for Individuals with Chronic Illness
- End-of-Life and Palliative Care: The Science of Compassion

Two other areas, promoting innovation and developing the nurse scientists of the 21st century, are emphasized in all areas of NINR's research programs.

This FOA supports investigator-initiated basic research, clinical research or clinical trials that address the mission and research interests of NINR. Applicants are encouraged to review [NINR's Strategic Plan. \(https://www.ninr.nih.gov/aboutninr/ninr-mission-and-strategic-plan\)](https://www.ninr.nih.gov/aboutninr/ninr-mission-and-strategic-plan)

NINR will consider clinical trials involving the evaluation of the safety, efficacy, or effectiveness of interventions, and/or clinical management of patients, that are consistent with the NINR's research goals. <http://www.ninr.nih.gov/> (<http://www.ninr.nih.gov/>)

### **Pre-consultation**

Participating NIH Institutes and Centers are listed on the first page of this announcement ("Components of Participating Organizations"). For additional scientific program information and for pre-application guidance, applicants are encouraged to contact the person listed for the participating NIH IC(s) with research interests relevant to the applicant's proposed topic. Consultation with relevant NIH staff prior to the application due date is strongly encouraged for new and resubmission applications. See Section VII for contact information.

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

## **Section II. Award Information**

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### **Funding Instrument**

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>	<p>New</p> <p>Renewal (applications that meet the eligibility criteria in this FOA may be submitted for awards funded through other R15 FOAs)</p> <p>Resubmission (applications that meet the eligibility criteria in this FOA may be resubmitted for applications originally submitted through other R15 FOAs)</p> <p>Revision</p> <p>The <a href="https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116">OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116)</a> and the SF424 (R&amp;R) Application Guide provide details on these application types.</p>
<b>Clinical Trial?</b>	<p>Required: Only accepting applications that propose clinical trials.</p> <p><a href="https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370">Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)</a></p>
<b>Funds Available and Anticipated Number of Awards</b>	<p>The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.</p>
<b>Award Budget</b>	<p>Applicants may request up to \$300,000 in direct cost for the entire project period of up to 3 years.</p>
<b>Award Project Period</b>	<p>The scope of the proposed project should determine the project period. The maximum project period is 3 years.</p>

NIH grants policies as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

##### Higher Education Institutions

- o Public/State Controlled Institutions of Higher Education
- o 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:

- o Hispanic-serving Institutions

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

In addition, all organizations must meet the following two criteria at the time of submission:

- o The applicant organization must be an accredited public or non-profit private school that grants baccalaureate or advanced degrees in health professions (see section below for more details) or advanced degrees in biomedical and behavioral sciences.
- o The applicant institution may not have received research support from the NIH totaling more than \$6 million per year (in both direct and F&A/indirect costs) in 4 of the last 7 years (see Section I. Funding Opportunity Description for definition of "institution"). A year is defined as a federal fiscal year: from October 1 through September 30.
  - o Note that all activity codes are included in this calculation except the following: C06, S10, and all activity codes starting with a G.
- o For this FOA: Only eligible Health Professional Schools (see definition below) or Graduate Schools may apply
- o For this FOA: Non-health professional or non-graduate academic institutions are not eligible to apply
- o For this FOA: A Provost letter will certify that the applicant institution satisfies the eligibility requirements

#### **Definition of Health Professional Schools or Colleges**

For the purposes of this FOA, health professional schools and colleges are accredited institutions that provide education and training leading to a health professional degree, including but not limited to: BSN, MSN, DNP, MD, DDS, DO, PharmD, DVM, OD, DPT, DC, ND, DPM, MOT, OTD, DPT, BME, MSEE, MS-SLP, CScD, SLPD, AuD, MSPO, MSAT, and MPH. Eligible health professional schools/colleges may include schools or colleges of nursing, medicine, dentistry, osteopathy, pharmacy, veterinary medicine, public health, optometry, allied health, chiropractic, naturopathy, podiatry, rehabilitation medicine, physical therapy, orthotics & prosthetics, kinesiology, biomedical engineering, occupational therapy and psychology. Accreditation must be provided by a body approved for such purpose by the Secretary of Education.

For the purposes of this FOA, a graduate school offers advanced degrees, beyond the undergraduate level, in an academic discipline. Advance degrees include M.A., M.S., and Ph.D.

A signed letter is required from the Provost or similar official with institution-wide responsibility verifying the eligibility of the applicant institution at the time of application submission according to the eligibility criteria indicated above. See the application instructions for the Letters of Support attachment on the [PHS 398 Research Plan \(https://grants.nih.gov/grants/guide/pa-files/PAR-18-714.html# PHS 398 Research\)](https://grants.nih.gov/grants/guide/pa-files/PAR-18-714.html#PHS_398_Research) form in Section IV.2 Instructions for Application Submission.

To assist in determining eligibility, organizations are encouraged to use the NIH RePORT website under [NIH Awards by Location & Organization \(http://report.nih.gov/award/index.cfm\)](http://report.nih.gov/award/index.cfm) (<http://projectreporter.nih.gov/reporter.cfm>).

For this FOA: The AREA Ineligibility List does not apply. The Provost letter will certify that the applicant institution satisfies the requirements outlined above.

#### **Additional Eligibility Guidance**

A REAP grant is permitted to have a subcontract to a non-REAP-eligible institution. However, applicants should keep the goals of the REAP in mind when preparing the application, which include strengthening the research environment of eligible institutions and exposing students from eligible institutions to research. It is expected that the majority of the research will be directed by the PD(s)/PI(s) at the grantee institution.

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

Undergraduate-focused institutions with undergraduate enrollment greater than graduate enrollment should apply to [PAR-18-714 \(https://grants.nih.gov/grants/guide/pa-files/par-18-714.html\)](https://grants.nih.gov/grants/guide/pa-files/par-18-714.html), Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15-Clinical Trial Not Allowed) or to [PAR-19-133 \(https://grants.nih.gov/grants/guide/pa-files/PAR-19-133.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-19-133.html), Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15- Clinical Trial Required).

## 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

## 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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) 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 \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - 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 \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) - 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) - Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82300\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) - 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. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. 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 to this FOA, the PD(s)/PI(s) must meet the following additional criteria:

- The PD(s)/PI(s) must have a primary appointment at an eligible institution.
- The PD(s)/PI(s) may not be the PD(s)/PI(s) of an active NIH research grant at the time of award of an R15 grant, although he or she may be one of the Key Personnel for an active NIH grant held by another PD/PI.
- The PD(s)/PI(s) may not be awarded more than one R15 grant at a time, although he or she may hold successive new or renewal 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126))

## **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](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))).

## **Section IV. Application and Submission Information**

## 1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

## 2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=41137\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

### Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11133\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

### 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 & Other Resources:** The following information must be included.

- A profile of the students at the applicant institution and any information or estimate of the number who have obtained an undergraduate or advanced degree in a health professional or graduate discipline and gone on to obtain an academic/professional position 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 REAP grant, where the goals of the REAP 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 health professional, undergraduate and/or graduate students in such environments to research.
- Description of the likely impact of an REAP grant on the PD(s)/PI(s).
- Description of the likely impact of an REAP grant on the research environment of the institution/academic component.

- Description of the likely impact of the REAP grant on the ability of undergraduate and/or graduate students at the institution to gain experience conducting biomedical and behavioral research.
- Although it is expected that the majority of the research will be directed by the PD(s)/PI(s) 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 and access students will need and have to these resources.
- If relevant, a statement of institutional support for the proposed research project (e.g., equipment, supplies, 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 supervising undergraduate and/or graduate students in research in the Personal Statement. The PD(s)/PI(s) should indicate which peer-reviewed publications or other research products involved undergraduate and/or graduate students under his or her supervision.

### **R&R or Modular Budget**

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

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

#### **Modular Budget (direct costs of \$250,000 or less):**

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

##### **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.
- **Budget Justification:**
- *Personnel Justification:* Since a primary objective of the REAP is to expose students to meritorious research, PD(s)/PI(s) must include undergraduate students and/or graduate students from the applicant institution/applicant component 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.

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

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

##### **Budget Period 1: Direct Costs**

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

**Budget Justification:**

- *Personnel Justification:* Since a primary objective of the REAP is to expose students to meritorious research, PD(s)/PI(s) must include undergraduate students and/or graduate students from the applicant institution/applicant component 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.

Justification for phases – PD(s)/PI(s) must include a justification for the allocation of resources during the three proposed phases of the project. See "Research Strategy" below.

**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:

**Research Strategy:** Describe how undergraduate and/or graduate students will be exposed to and supervised conducting hands-on research. Describe how students will participate in research activities such as planning, execution and/or analysis of research. Formal training plans (e.g., non-research activities, didactic training, seminars) should not be provided, although a brief description of activities related to enhancing students' research capabilities and progress (e.g., the use of individual development plans, etc.) is permitted.

A sound rationale should be offered as to why the approach and the research team, including undergraduate and/or graduate students, are appropriate to accomplish the specific aims and to make an important scientific contribution.

**Progress Report Publication List:** For renewals, when listing publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project, note which of these products have included the work of students conducting research supported by the AREA grant.

**Letters of Support:** The Letters of Support attachment must include a signed letter from the Provost or similar official with institution-wide responsibility certifying that the institution has not received support from the NIH totaling more than \$6 million per year (in both direct and F&A/indirect costs) in 4 of the last 7 years, as described in Section III, "Eligible Organization". Finally, the letter must validate that the PD(s)/PI(s) has a primary appointment at the qualifying institution. Applications that do not contain this signed letter will be withdrawn without review.

**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:**

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424

(R&R) Application Guide.

## PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

### Study Record: PHS Human Subjects and Clinical Trials Information

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

### Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

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

## PHS Assignment Request Form

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

## 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 and times. 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. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82380\)](#), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11128\)](#) (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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](#), 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 and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

**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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142). ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142))

## 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11143](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143)).

## 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 [How to Apply – Application Guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) (<https://grants.nih.gov/grants/how-to-apply-application-guide.html>). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) (<https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm>) guidance. For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

### 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11146](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146)) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

### Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82299) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82299](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82299)). Any instructions provided here are in addition to the instructions in the policy.

## Section V. Application Review Information

## 1. Criteria

Only the review criteria described below will be considered in the review process. Application submitted in support of the [NIH mission \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11149\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), 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 health professional, 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.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

### 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 solid and interesting scientific research project that is not by its nature innovative or paradigm-shifting and includes a good plan to engage undergraduates and/or graduate students in primary research may be considered a strong REAP application.

#### Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? 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 award have a substantial effect on the school/academic component in terms of strengthening the research environment and exposing students to research?

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

## Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those 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? Do the PD(s)/PI(s) have suitable experience in supervising students in research?

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

## 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?

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

## Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects? 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 sciences?

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) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

## Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design

adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

#### *Data Management and Statistical Analysis*

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

#### **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?

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

#### **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.

## Study Timeline

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSA, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

## Protections for Human Subjects

For research that involves human subjects but does not involve one of the 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 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11175).

## Inclusion of Women, Minorities, and Individuals Across the Lifespan

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 individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11174).

## Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11150).

## 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](https://grants.nih.gov/grants/guide/redirect.htm?id=11151) ([//grants.nih.gov/grants/guide/redirect.htm?id=11151](https://grants.nih.gov/grants/guide/redirect.htm?id=11151)); (2) [Sharing Model Organisms](https://grants.nih.gov/grants/guide/redirect.htm?id=11152) ([//grants.nih.gov/grants/guide/redirect.htm?id=11152](https://grants.nih.gov/grants/guide/redirect.htm?id=11152)); and (3) [Genomic Data Sharing Plan \(GDS\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11153) ([//grants.nih.gov/grants/guide/redirect.htm?id=11153](https://grants.nih.gov/grants/guide/redirect.htm?id=11153)).

### Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

## Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

## 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](https://grants.nih.gov/grants/guide/redirect.htm?id=11154) ([//grants.nih.gov/grants/guide/redirect.htm?id=11154](https://grants.nih.gov/grants/guide/redirect.htm?id=11154)), 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

## 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

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 terms and conditions found on the [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (<https://register.clinicaltrials.gov>). NIH expects registration of all trials whether required under the law or not. For more information, see [http://grants.nih.gov/ClinicalTrials\\_fdaaa/](http://grants.nih.gov/ClinicalTrials_fdaaa/)

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that the application as well as all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols. Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at [http://grants.nih.gov/grants/policy/hs/data\\_safety.htm](http://grants.nih.gov/grants/policy/hs/data_safety.htm) and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

## 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)) 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* ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157)) and *Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities* ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11159](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159)). More information is provided at *Award Conditions and Information for NIH Grants* ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158)).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html>). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>); and <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>).

[individuals/disability/index.html](https://www.hhs.gov/ocr/about-us/contact-us/index.html)). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

### **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 using the RPPR are posted at <http://grants.nih.gov/grants/policy/myf.htm> (<http://grants.nih.gov/grants/policy/myf.htm>).

A final RPPR, 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](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161) ([http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161)).

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.fsr.gov](http://www.fsr.gov) ([http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11170](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11170)) on all subawards over \$25,000. See the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171) ([http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11171](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171)) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from

all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

## 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 Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

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

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

General Grants Information (Questions regarding application processes and NIH grant resources)

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

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

### Scientific/Research Contact(s)

Michelle R.J. Hamlet, PhD

National Institute of Nursing Research (NINR)

Telephone: 301-496-9623

Email: [hamletm@mail.nih.gov](mailto:hamletm@mail.nih.gov) (<mailto:hamletm@mail.nih.gov>)

Christopher Hatch, Ph.D.

National Cancer Institute (NCI)

Telephone: 240-276-6454

Email: [hatchc@mail.nih.gov](mailto:hatchc@mail.nih.gov) (<mailto:hatchc@mail.nih.gov>)

Rene Etcheberrigaray, M.D.

National Institute of Aging (NIA) Telephone: (301) 451-9798

Email Address: [re4f@nih.gov](mailto:re4f@nih.gov) (<mailto:re4f@nih.gov>)

Mahua Mukhopadhyay, Ph.D.

Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD)

Telephone: 301-435-6886

Email: [mukhopam@mail.nih.gov](mailto:mukhopam@mail.nih.gov) (<mailto:mukhopam@mail.nih.gov>)

Susan L. Sullivan, Ph.D.

National Institute on Deafness and Other Communication Disorders (NIDCD)

Phone: 301-451-3841

Email: [sullivas@nidcd.nih.gov](mailto:sullivas@nidcd.nih.gov) (<mailto:sullivas@nidcd.nih.gov>)

Tracy Waldeck, Ph.D.

National Institute of Drug Abuse (NIDA)

Telephone: (301) 827-5844

Email: [tracy.waldeck@nih.gov](mailto:tracy.waldeck@nih.gov) (<mailto:tracy.waldeck@nih.gov>)

Letitia Weigand, Ph.D.

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-596-4188

Email: [letitia.weigand@nih.gov](mailto:letitia.weigand@nih.gov) (<mailto:letitia.weigand@nih.gov>)

Aaron D. Laposky, PhD

National Heart, Lung, and Blood Institute (NHLBI)

Telephone: 301-827-7837

Email: [laposkya@nhlbi.nih.gov](mailto:laposkya@nhlbi.nih.gov) (<mailto:laposkya@nhlbi.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)**

Ron Wertz

National Institute of Nursing Research (NINR)

Telephone: 301-594-2807

Email: [wertz@mail.nih.gov](mailto:wertz@mail.nih.gov) (<mailto:wertz@mail.nih.gov>)

Crystal Wolfrey

National Cancer Institute (NCI)

Telephone: 240-276-6277

Email: [wolfreyc@mail.nih.gov](mailto:wolfreyc@mail.nih.gov) (<mailto:wolfreyc@mail.nih.gov>)

Traci Lafferty

National Institute of Aging (NIA)

Telephone: 301-496-8987

Email: [laffert@mail.nih.gov](mailto:laffert@mail.nih.gov) (<mailto:laffert@mail.nih.gov>)

Bryan S. Clark, M.B.A

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Telephone: 301-435-6975

Email: [clarkb1@mail.nih.gov](mailto:clarkb1@mail.nih.gov) (<mailto:clarkb1@mail.nih.gov>)

Christopher Myers  
National Institute on Deafness and Other Communication Disorders (NIDCD)  
Telephone: 301-402-0909  
Email: [myersc@mail.nih.gov](mailto:myersc@mail.nih.gov) (<mailto:stones@nidcd.nih.gov>)

Pam Fleming  
National Institute of Drug Abuse (NIDA)  
Telephone: 301-480-1159  
Email: [pfleming@nida.nih.gov](mailto:pfleming@nida.nih.gov) (<mailto:pfleming@nida.nih.gov>)

Tijuanna Decoster, Ph.D.  
National Institute of Neurological Disorders and Stroke (NINDS)  
Telephone: 301-496-9231  
Email: [decostert@ninds.nih.gov](mailto:decostert@ninds.nih.gov) (<mailto:decostert@ninds.nih.gov>)

Anthony Agresti  
National Heart, Lung, and Blood Institute (NHLBI)  
Telephone: 301-435-0186  
Email: [agrestia@nhlbi.nih.gov](mailto:agrestia@nhlbi.nih.gov) (<mailto:agrestia@nhlbi.nih.gov>)

## Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11163](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163)) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11164](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

### 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 Part 75.

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[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?12-21-18) (<http://grants/guide/WeeklyIndex.cfm?12-21-18>)  
[NIH Funding Opportunities and Notices](http://grants/guide/index.html) (<http://grants/guide/index.html>)

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Department of Health  
and Human Services (HHS)



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