

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

Components of Participating Organizations

National Institute of Neurological Disorders and Stroke ([NINDS \(http://www.ninds.nih.gov/\)](http://www.ninds.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism ([NIAAA \(http://www.niaaa.nih.gov/\)](http://www.niaaa.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS \(http://www.niams.nih.gov/\)](http://www.niams.nih.gov/))

National Institute of Dental and Craniofacial Research ([NIDCR \(http://www.nidcr.nih.gov/\)](http://www.nidcr.nih.gov/))

National Institute of Nursing Research ([NINR \(http://www.ninr.nih.gov/\)](http://www.ninr.nih.gov/))

National Center for Complementary and Integrative Health ([NCCIH \(http://www.nccam.nih.gov/\)](http://www.nccam.nih.gov/))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Behavioral and Social Sciences Research ([OBSSR \(http://obssr.od.nih.gov/\)](http://obssr.od.nih.gov/))

Office of Research on Women's Health ([ORWH \(http://orwh.od.nih.gov/\)](http://orwh.od.nih.gov/))

Funding Opportunity Title

Research on Chronic Overlapping Pain Conditions (R01 Clinical Trial Optional)

Activity Code

[R01 \(//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity)
Research Project Grant

Announcement Type

Reissue of PA-14-244 (<https://grants.nih.gov/grants/guide/pa-files/pa-14-244.html>)

Related Notices	None
Funding Opportunity Announcement (FOA) Number	PA-18-937
Companion Funding Opportunity	PA-18-939 (//grants.nih.gov/grants/guide/pa-files/pa-18-939.html), R21 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Grant
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.853, 93.273, 93.846, 83.361, 93.213, 93.313, 93.121
Funding Opportunity Purpose	<p>The purpose of this Funding Opportunity Announcement (FOA) is to encourage epidemiological, clinical and translational research that will increase our understanding of the natural history, prevalence, biological mechanisms, psychological variables, and clinical risk factors responsible for the presence of multiple chronic pain conditions in people with pain. Recent clinical findings suggest that substantial overlap may exist between chronic pain conditions. Individuals diagnosed with one disorder often exhibit characteristics of additional chronic painful conditions or transition to other diagnostic categories. A better understanding is needed of the prevalence of overlapping pain conditions, the underlying etiologies, the progression of these conditions, the evolution of these overlaps, and the therapeutic approaches best suited for treating subjects with these conditions. The main objective of this FOA is the formation of research groups with interests bridging expertise in pain mechanisms with translational and clinical expertise to address important unresolved questions about overlapping pain conditions. Applicants are encouraged to leverage existing and develop new resources pertinent to the study of these conditions. Applicants are encouraged to include researchers with complementary expertise from outside the pain field in their research teams who will enhance the breadth of research and understanding of comorbid chronic pain conditions.</p>

Key Dates

Posted Date	September 16, 2018
Open Date (Earliest Submission Date)	January 5, 2019
Letter of Intent Due Date(s)	Not applicable
Application Due Date(s)	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) , 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. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Not applicable
Scientific Merit Review	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Advisory Council Review	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Earliest Start Date	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Expiration Date	January 8, 2022
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in 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 to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](https://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.
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
3. [Go to Grants.gov \(https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-18-505.html#\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-18-505.html#) to download an application package to complete the application forms offline or create a Workspace to complete the forms online; submit your application to Grants.gov; and track your application in eRA Commons.

Learn more about the various [submission options \(//grants.nih.gov/grants/ElectronicReceipt/preparing.htm#2\)](https://grants.nih.gov/grants/ElectronicReceipt/preparing.htm#2).

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 \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-18-937\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-18-937) 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

Purpose

The purpose of this FOA is to encourage epidemiological, clinical and translational research that will increase our understanding of the presence of multiple chronic pain conditions in subjects with pain.

Recent findings suggest substantial overlap may exist between chronic pain conditions. Individuals diagnosed with one disorder often exhibit characteristics of additional chronic painful conditions or transition to other diagnostic categories. A better understanding is needed of the prevalence of overlapping pain conditions, their underlying etiologies, the evolution of these overlaps, and the therapeutic approaches best suited for treating subjects with these conditions. The main objective of this FOA is the formation of research groups with research interests bridging expertise in pain mechanisms and translational and clinical expertise to address important unresolved questions about overlapping pain conditions.

Background

Chronic pain affects approximately 100 million Americans and exacts large economic, social and personal costs. It is a major public health challenge that needs to be addressed at multiple levels including the generation of new scientific knowledge that will enhance our understanding of these conditions. Current research efforts in chronic pain conditions have focused on single disorders or types of pain such as neuropathic and inflammatory pain. These research efforts have generated a substantial body of information advancing our discovery and understanding of the underlying mechanisms of pain onset and development, the transition from acute to chronic pain, and promising therapeutic targets for treating acute and chronic pain. Over the past twenty years sporadic reports have documented the presence of more than one chronic pain condition in subjects with pain. Studies have identified overlap between a number of chronic pain conditions, including temporomandibular joint disorder (TMD), fibromyalgia (FM), vulvodynia, functional gastrointestinal disorders such as irritable bowel syndrome (IBS), migraine, and urologic chronic pelvic pain syndromes (UCPPS). These results suggest that chronic pain conditions may not be localized conditions, but may share symptoms and mechanisms that involve a general central nervous system dysfunction as well as disorder-specific symptoms. More recent evidence is supportive of the idea that chronic pain conditions are complex disorders consistent with a biopsychosocial model of pain, and exhibit substantial overlap. Therefore, this may be an opportune time to encourage research efforts that focus, not on single pain conditions, but on subjects with multiple chronic pain disorders.

Chronic pain conditions represent a complex set of painful disorders that lack a firm mechanistic understanding, and are in need of hypothesis-driven research efforts. A new focus on overlapping pain conditions is warranted to develop therapies to prevent and treat these overlapping disorders and to develop approaches to better manage pain that can be disabling. A workshop sponsored by the NIH Pain Consortium was held in the summer of 2012 titled "A Workshop on Chronic Overlapping Pain Conditions". It brought together researchers with expertise in various pain conditions and other relevant expertise to discuss these conditions and to develop a forward-thinking research agenda. The workshop focused on our current understanding of chronic overlapping pain conditions, their etiology, risk factors, mechanisms of

disease, outcome measures, and diagnosis. Topics of discussion included epidemiology of chronic overlapping pain conditions, risk factors and mechanisms of disease, leveraging of current data sets, and new scientific approaches incorporating systems biology. The recommendations derived from this workshop have, in part, informed the development of this FOA.

Some of the overlapping pain conditions under consideration include, but are not limited to: chronic headache, migraine headache, temporomandibular joint disorder, generalized pain conditions, functional gastrointestinal disorders such as irritable bowel syndrome, endometriosis, urologic chronic pelvic pain, vulvodynia, fibromyalgia, chronic fatigue syndrome, and osteoarthritis.

Research Objectives

Specific areas of research that are important for this FOA include but are not limited to:

- Longitudinal studies and natural history of disease development, disease progression and remission
- Studies related to common and disorder-specific mechanisms of disease, such as central and peripheral drivers of pain hypersensitivity
- Nervous system interactions with the immune and endocrine systems, and the microbiome
- Development of phenotypes relevant to basic and clinical studies of overlapping conditions
- Genetic and epigenetic factors linked to these conditions

Note: Applications that propose a clinical trial or any other study designed to test and administer an intervention are not appropriate for this FOA. Applicants interested in this approach are encouraged to contact Program Staff at individual Institutes for details on how to apply for grants to support clinical trials.

Types of research and experimental approaches that are being sought to achieve the objectives:

- Determine common genetic factors that link these conditions
- Develop an understanding of shared mechanisms of disease, especially with regard to pain modulatory circuits.
- Explore mechanisms of central sensitization and clarify the role of peripheral and central nervous system hypersensitivity in these conditions
- Identify whether biological pathways or markers can be defined that are associated with specific chronic pain subclusters
- Identify the key environmental, behavioral and psychological risk factors and their potential interaction with genetic factors that predict the onset and lead to chronic pain, remission, and recurrence
- Identification of biopsychosocial mechanisms that represent potential targets for therapeutic intervention
- Develop/refine diagnostic approaches for overlapping conditions with existing or novel phenotypes and biological markers
- Compare validity of general clinical measures such as PROMIS or NeuroQoL with disease-specific instruments
- Identify early childhood exposures leading to increased risk for developing chronic pain conditions
- Identification of hormonal, sex and gender risk factors for chronic pain conditions
- Examine patterns of sleep and physical activity in subjects with chronic overlapping conditions
- Examine effects of alcohol and other psychoactive compounds on these pain conditions

- Collection of longitudinal data to analyze co-modifiers of pain such as depression, anxiety and other psychopathological conditions that elucidate underlying neurobiological and behavioral mechanisms linking pain and psychopathology
- Collection of longitudinal data to analyze co-occurrence of other complex conditions such as cardiovascular disease, diabetes, hypertension, respiratory conditions, etc.
- Use of a lifetime approach to identify individual and environmental risk factors including measures of somatic awareness and dieExplore the role of complementary approaches (e.g. natural products, mind-body approaches) for pain relief and functional restoration in patients with chronic overlapping pain conditions
- Explore the role of complementary approaches (e.g. natural products, mind-body approaches) for pain relief and functional restoration in patients with chronic overlapping pain conditions
- Identify mechanisms underlying the responsiveness to complementary approaches for chronic overlapping pain conditions in relevant model organisms or human subjects

Investigators interested in submitting an application as an Ancillary Study to the MAPP Research Network are asked to contact the NIDDK prior to submission to secure permissions to access samples/data. In addition, it is highly recommended any proposed study focused on UCPPS be discussed with the NIDDK prior to submission to assess potential overlap with ongoing or completed MAPP Network efforts.

NIH Institute and Center Interests and Guidance

National Center for Complementary and Integrative Health (NCCIH)

The National Center for Complementary and Integrative Health (NCCIH) will support research that explores the the mechanisms by which natural products (including botanicals, probiotics, dietary supplements, and special diets) and mind and body approaches (such as acupuncture, meditation, spinal manipulation, yoga, massage, hypnosis) affect the outcomes of chronic overlapping pain condition. NCCIH will not fund research proposing efficacy or effectiveness clinical trials through this FOA (please see [NCCIH Clinical Trial Funding Opportunities \(https://nccih.nih.gov/grants/funding/clinicaltrials\)](https://nccih.nih.gov/grants/funding/clinicaltrials) instead). Investigators are strongly encouraged to discuss their research plans with NCCIH program staff prior to submitting their application.

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

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal
Resubmission
Revision

The [OER Glossary \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11116\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on

these application types.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s)
[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

Award Project Period

The maximum project period is 5 years.

NIH grants policies as described in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/uri_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

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

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

Other

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

Foreign Institutions

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

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

Foreign components, as [defined in the NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11118](http://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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html](http://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/>) (formerly CCR) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

- [NATO Commercial and Government Entity \(NCAGE\) Code](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) ([//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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//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 – 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.

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

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms 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 instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](#) 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=41137\)](#).

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11133\)](#) 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.

SF424(R&R) Senior/Key Person Profile

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

R&R or Modular Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

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

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

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

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.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/uri_redirect.htm?id=11137\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates 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 \(https://grants.nih.gov/grants/guide/uri_redirect.html?id=82380\)](#), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](https://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://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. \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11142\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11143\)](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 [Applying Electronically \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11144\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Guidelines for Applicants Experiencing System Issues \(//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](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.

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

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

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](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. As part 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), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Specific to applications involving clinical trials

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 exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? 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?

In addition, for applications involving clinical trials

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?

In addition, for applications involving clinical trials

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?

In addition, for applications involving clinical trials

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?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

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? 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 agents(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 ? 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?

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?>

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific

environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials

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

Specific to applications involving clinical trials

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/url_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/url_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/url_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

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

U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11151](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151)); (2) [Sharing Model Organisms](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11152](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152)); and (3) [Genomic Data Sharing Plan \(GDS\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11153](http://grants.nih.gov/grants/guide/url_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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11154](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154)), using the stated [review criteria](#).

Assignment to a Scientific Review Group will be shown in the eRA Commons.

- 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.

[//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html)

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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](http://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11156\)](http://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](http://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](http://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/

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 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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) ([//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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159) ([//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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) ([//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.

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 (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, 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.

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 <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html>. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>); and <http://www.hhs.gov/ocr/civilrights/understanding/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see

<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html> (<http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.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>).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\)](http://grants.nih.gov/grants/rppr/index.htm) (<http://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161). (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

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/url_redirect.htm?id=11161) (http://grants.nih.gov/grants/guide/url_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.fsrs.gov (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) (http://grants.nih.gov/grants/guide/url_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 registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

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

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

[Grants.gov Customer Support](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82301](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301)) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

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

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

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

Telephone: 301-710-0267

Scientific/Research Contact(s)

Michael L. Oshinsky, Ph.D.

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-496-9964

Email: michael.oshinsky@nih.gov (<mailto:michael.oshinsky@nih.gov>)

Soundar Regunathan

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Telephone: 301-443-1192

Email: regunathans@mail.nih.gov (<mailto:regunathans@mail.nih.gov>)

Gayle Lester

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS](http://www.niams.nih.gov/) (<http://www.niams.nih.gov/>))

Telephone: 301-594-3511

Email: lester1@mail.nih.gov (<mailto:lester1@mail.nih.gov>)

Tonse Raju

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

Telephone: 301-402-1872

Email: tr146h@nih.gov (<mailto:tr146h@nih.gov>)

Mary Ellen Michel

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

Telephone: 301-496-5289

Email: mary.michel@nih.gov (<mailto:mary.michel@nih.gov>)

John Kusiak
National Institute of Dental and Craniofacial Research (NIDCR)
Telephone: 301-594-7984
Email: kusiakj@mail.nih.gov (<mailto:kusiakj@mail.nih.gov>)

Christopher Mullins
National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK)
Telephone: 301-451-4902
Email: mullinsc@mail.nih.gov (<mailto:mullinsc@mail.nih.gov>)

Martha Matocha, PhD
National Institute of Nursing Research (NINR)
Telephone: 301-594-2775
Email: matocham@mail.nih.gov (<mailto:matocham@mail.nih.gov>)

Wen Chen, PhD
National Center for Complementary and Integrative Health (NCCIH)
Telephone: 301-451-3989
Email: Wen.Chen@nih.gov (<mailto:Wen.Chen@nih.gov>)

Wendy Smith
Office of Behavioral and Social Science Research (OBSSR)
Telephone: 301-594-5515
Email: smithwe@mail.nih.gov (<mailto:smithwe@mail.nih.gov>)

Terri Cornelison
Office of Research on Women's Health (ORWH)
Telephone: 301-402-1770
Email: terri.cornelison@nih.gov (<mailto:terri.cornelison@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)

Tijuanna DeCoster
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-9231
Email: decostert@mail.nih.gov (<mailto:decostert@mail.nih.gov>)

Judy Fox
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Telephone: 301-443-4704
Email: jfox@mail.nih.gov (<mailto:jfox@mail.nih.gov>)

Steve Austin
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NAIMS)

Telephone: 301-594-3504

Email: austins2@mail.nih.gov (<mailto:austins2@mail.nih.gov>)

Bryan Clark

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>)

Diana Rutberg

National Institute of Dental and Craniofacial Research (NIDCR)

Telephone: 301-594-4798

Email: rutbergd@mail.nih.gov (<mailto:rutbergd@mail.nih.gov>)

Pamela Love

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Telephone: 301-435-6198

Email: lovepa@mail.nih.gov (<mailto:lovepa@mail.nih.gov>)

Ronald Wertz

National Institute of Nursing Research (NINR)

Telephone: 301-594-2807

Email: wertzr@mail.nih.gov (<mailto:wertzr@mail.nih.gov>)

Shelley Carow

National Center for Complementary and Integrative Health (NCCIH) (Previously NCCAM)

Telephone: 301-594-3788

Email: CarowS@mail.nih.gov (<mailto:CarowS@MAIL.NIH.GOV>)

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