

# 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>	National Institute of Mental Health ( <a href="http://www.nimh.nih.gov/">NIMH (http://www.nimh.nih.gov/)</a> )
<b>Funding Opportunity Title</b>	<b>Emotion Regulation, Aging and Mental Disorder (R01 Clinical Trial Not Allowed)</b>
<b>Activity Code</b>	<a href="http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity">R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity)</a> Research Project Grant
<b>Announcement Type</b>	New
<b>Related Notices</b>	None
<b>Funding Opportunity Announcement (FOA) Number</b>	<b>PA-19-094</b>
<b>Companion Funding Opportunity</b>	<a href="https://grants.nih.gov/grants/guide/pa-files/PA-19-095.html">PA-19-095 (https://grants.nih.gov/grants/guide/pa-files/PA-19-095.html)</a> , <a href="http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity">R21 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity)</a> Exploratory/Developmental Grant
<b>Number of Applications</b>	See <a href="#">Section III. 3. Additional Information on Eligibility.</a>
<b>Catalog of Federal Domestic Assistance (CFDA) Number(s)</b>	93.242
<b>Funding Opportunity Purpose</b>	This Funding Opportunity Announcement (FOA) encourages applications for mechanistic research on age-related changes in emotion regulation and how they may contribute to mental disorders in middle-aged and older adults. In particular, research is sought that will advance

understanding of irregularities in the integrative neural-behavioral mechanisms of emotion regulation in adult mood and anxiety disorders, and that will examine whether the irregularities are associated with typical or atypical maturational trajectories of emotion processing. Currently, it is not known whether older adults who suffer episodes of affective dysregulation share the same patterns of improved emotional function with age as have been found to be typical of the older adult population in general. Research that helps to clarify whether they do or do not manifest typical emotion processing trajectories may lead to very different understandings of the irregularities involved in their dysregulation. It is anticipated that such studies may identify novel targets for mental health interventions or prevention efforts, or provide clues as to which available intervention strategies might be optimally applied to normalize emotion dysregulation or to strengthen emotional resilience at particular stages of the adult life cycle.

PA-19-094 uses the R01 grant mechanism while PA-19-095 uses the R21 mechanism. Investigators proposing high risk/high reward projects, projects that lack preliminary data, or studies that utilize existing data may wish to apply using the R21 mechanism, while applicants with preliminary data may wish to apply using the R01 mechanism.

## Key Dates

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### Posted Date

November 29, 2018

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### Open Date (Earliest Submission Date)

January 05, 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.

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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submission process by the due date.

<b>AIDS Application Due Date(s)</b>	Not Applicable
<b>Scientific Merit Review</b>	<a href="http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113">Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)</a> apply
<b>Advisory Council Review</b>	<a href="http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113">Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)</a> apply
<b>Earliest Start Date</b>	<a href="http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113">Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)</a> apply
<b>Expiration Date</b>	January 08, 2022
<b>Due Dates for E.O. 12372</b>	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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](http://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 \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-19-094\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-19-094) 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**

This Funding Opportunity Announcement (FOA) invites applications for mechanistic research on age-related changes in emotion regulation and how such changes contribute to mental disorders in middle-aged and older adults. It will support studies directed at better characterizing and understanding irregularities in the integrative neural-behavioral mechanisms of affect regulation in those who experience mood and anxiety disorders, and at examining whether the irregularities are associated with typical or atypical emotion processing trajectories. It will also support investigations of emotion regulation in those who experience neuropsychiatric symptoms and behavioral disturbances as complications of Alzheimer's disease (AD) or other Alzheimer's disease-related dementias (ADRD). Research is sought that will leverage already established findings about generally improved emotion regulation with aging in order to clarify how maturational shifts (or lack thereof) may relate to affective dysregulation in middle-aged and older adults who experience affective mental disorders. Such studies may identify novel mental health intervention/prevention targets or provide clues as to which available intervention strategies might be optimally applied to normalize emotion dysregulation or to strengthen emotional resilience at different stages of the adult life cycle.

This FOA is intended to support studies aligned with Strategy 2.1 of the NIMH Strategic Plan

(<http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml>

(<http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml>), which calls for research to

“characterize the developmental trajectories of brain maturation and dimensions of behavior to understand the roots of mental illnesses across diverse populations.” In the context of research on emotional processes and their relation to mental illness, the developmental dimension of age-related differences occurring across

the lifespan is to be understood as a major aspect of population diversity.

## Background

Research suggests that, for many adults, normal aging is associated with general trends toward improvements in emotional function, including emotion regulation (e.g., as evidenced by increasing positive and decreasing negative affect, greater emotional stability, higher life satisfaction, a “positivity effect” in information-processing). As compared with younger adults, older adults often show superior emotion regulation capacities, employ different strategies for executive control of emotional information, and recruit different neural networks in performing affective tasks. Such patterns have been variously hypothesized to stem from increased motivation to maintain emotional well-being, learning of more skillful and efficient emotion processing strategies, or compensatory adaptations to age-related brain changes. However, for the most part, such hypotheses remain minimally examined and unconfirmed. Although not all adults demonstrate positive emotion regulation changes in association with aging, the factors that account for individual differences in showing the general maturational shifts remain poorly understood. For example, even though men and women are observed to process emotions differently, to date, evidence remains scarce regarding whether and how sex differences may be modulated during the aging process.

Although mood and anxiety disorders are considered examples of affect dysregulation, knowledge tends to be limited about the specific emotion processing deficits involved. To date, there have been few mechanistic studies employing affective neuroscience methods that have examined how adult maturational changes in emotion regulation may relate to mental disorder in later life. There has been little scientific investigation of the extent to which adults with affective disorders manifest or fail to show the normative maturational shifts, or at what point(s) during the adult lifespan they may begin to show divergent trajectories with respect to their emotion regulation.

In addition, significant gaps remain in our understanding of how age-related cognitive changes may impinge on emotion regulation in adults who experience mental disorders in later life. In the general older adult population, it is considered paradoxical that many aspects of emotional function improve with age even though the cognitive control capacities on which these functions are thought to depend normatively decline with age. Numerous questions remain regarding the role of changes in cognitive control or executive functioning in emotional processes with age, the capacity of older adults to employ alternative strategies to regulate emotion, and the degree to which cognitive changes influence affective dysregulation in those who experience mental disorders with age.

## Research Objectives

This FOA is intended to support research designed to clarify the patterns of emotion processing, at neurobiological as well as behavioral levels of analysis, that are characteristic of middle-aged and older adults who experience affective disorders or manifest other forms of obvious and persistent emotional dysregulation, and to deepen our understanding of the mechanisms and contextual factors involved in their emotion dysregulation. Studies leveraging the concepts, methods, and findings emerging from research on normative adult emotional development, including environmental and life course factors, are of particular interest, so as to investigate variation in emotion processing across a spectrum of older adults, ranging from

those with mood and anxiety disorders to adults without such psychopathology. Research is encouraged that assesses emotional processes dimensionally, integrating across multiple levels of analysis, including brain-level measurements, and employing cutting-edge methodology from such fields as cognitive and affective neuroscience, neuroimaging, neurophysiology, neuroendocrinology, and lifespan developmental psychology. Research is sought that uses psychometrically sound assessment approaches and directly observes emotion processes, such as in response to emotion-evoking stimuli, situations, scenarios or the like. Applicants are encouraged to propose studies that will examine multiple domains of emotion processing so as to address, in aging adults, the key developmental concept of dynamic interactions among differentially maturing brain systems that support successful (or less successful) emotion regulation.

Varied research paradigms may be useful for pursuing the goals outlined above. Use of constructs from NIMH's Research Domain Criteria (RDoC) initiative (<http://www.nimh.nih.gov/research-priorities/rdoc/index.shtml> (<http://www.nimh.nih.gov/research-priorities/rdoc/index.shtml>)), or of RDoC-compatible approaches, in assessing emotion processing, other component aspects of mental disorder, and/or related domains of brain function dimensionally is encouraged. The RDoC initiative has defined a set of [constructs](http://www.nimh.nih.gov/research-priorities/rdoc/development-and-definitions-of-the-rdoc-domains-and-constructs.shtml) (<http://www.nimh.nih.gov/research-priorities/rdoc/development-and-definitions-of-the-rdoc-domains-and-constructs.shtml>) that may be useful in this research. These constructs are organized according to five domains of brain functioning (negative valence systems, positive valence systems, cognitive systems, arousal/regulatory systems, and systems for social processes). Research on RDoC constructs should employ assessment methods appropriate for each construct of interest and the assessment methods are expected to converge on the construct from at least two levels of analysis. RDoC units of analysis (potential levels of measurement) include genes, molecules, cells, circuits, physiology, behavior, and self-report. Details about RDoC constructs and units of analysis can be found [here](http://www.nimh.nih.gov/research-priorities/rdoc/constructs/rdoc-matrix.shtml) (<http://www.nimh.nih.gov/research-priorities/rdoc/constructs/rdoc-matrix.shtml>). Although the structure of the RDoC matrix suggests boundaries among constructs, given the densely integrated and interconnected nature of the brain's circuits, it is understood that the constructs function interactively and that promising empirical approaches to an RDoC-based analysis of emotional functioning and its relationship to psychopathology may involve examining intersections among constructs.

Applicants may propose to examine dimensional constructs that do not appear in the NIMH RDoC matrices as long as there is strong theoretical support for their relevance to a mechanistic understanding of emotional processing. Applicants should be able to cite substantial evidence for the validity of such constructs, and to indicate strong theoretical support that the construct maps onto a specific biological system, such as a brain circuit or physiological pathway, thought to be involved in emotion processing or regulation.

With respect to assessing psychopathology or mental disorder, likewise, an RDoC approach encourages taking a dimensional perspective, and concentrating on aspects of behavior and brain function that span a range from intact to gradations of impairment, independent of diagnosis. Thus, in such an approach, recruitment and eligibility of study participants need not be determined on the basis of traditional diagnostic categories, but should instead be based on criteria that result in a sample that is optimized to study the clinical phenomena of interest over their full range of variability. Such an emphasis on understanding the full dimensionality of neurobehavioral functioning generally precludes simple, dichotomous designs comparing

patients versus controls. Under this FOA, if an RDoC or other dimensional construct is proposed to serve as the primary variable representing psychopathology (as opposed to using a diagnostic characterization), the study design and sampling plan must be such as to assure that an adequate number of individuals assessed as falling within the more severely impaired ranges of that dimension will be included in the study.

If the proposed research involves neuroimaging methods, applicants are encouraged to incorporate use of protocols from the [Human Connectome Project \(http://www.humanconnectomeproject.org/\)](http://www.humanconnectomeproject.org/), assuming that the research addresses constructs that have been previously examined in the Human Connectome Project and that such protocols are available to the investigator.

The particular adult age ranges over which differences in emotion processes (and in maturational changes in them) may be examined are not prespecified and should be determined to fit the specific research questions posed. Applicants are expected to provide compelling rationales for their selections in this regard, such as prior evidence that particular age ranges may represent periods in the life cycle especially critical for observing changes in emotion processing that may, in turn, be associated with the development or recurrence of mental disorder in middle or old age.

Regardless of other variations in sampling and experimental approach, it will be considered scientifically essential that the proposed research attend to sex differences as a central issue. As previously noted, age-related changes in cognitive functioning, particularly with respect to cognitive control or executive functioning, are likely to be an important contributory factor to changes in emotion regulation. Inasmuch as cognitive changes and comorbid medical conditions become increasingly common with advancing age, it will also be critical that the research plans adequately assess or control for differences in cognitive functioning and in medical comorbidity as potential confounding influences on emotional experience in middle-aged and older adults.

Applicants are also strongly encouraged to review the Notice on enhancing the reproducibility of NIH-supported research through rigor and transparency ([NOT-OD-15-103 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-103.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-103.html)), and to incorporate appropriate features into the proposed research plans. NIMH has published guidelines for reporting elements of rigor in experimental design in applications ([NOT-MH-14-004 \(https://grants.nih.gov/grants/guide/notice-files/NOT-MH-14-004.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-14-004.html)), and examples of critical elements for a well-designed study are summarized on the NIMH website (<http://www.nimh.nih.gov/research-priorities/policies/enhancing-the-reliability-of-nimh-supported-research-through-rigorous-study-design-and-reporting.shtml> (<http://www.nimh.nih.gov/research-priorities/policies/enhancing-the-reliability-of-nimh-supported-research-through-rigorous-study-design-and-reporting.shtml>)).

## Specific Areas of Research Interest

Areas of interest include, but are not limited to:

- Research clarifying specific emotion processing irregularities, and their brain-level correlates, characteristic of aging individuals with affective disorders;
- Investigations of whether or to what degree individuals aging with chronic or recurrent affective

- disorders manifest normative maturational shifts in their patterns of emotion regulation, particularly with respect to the underlying mechanistic factors involved;
- Studies identifying trajectories of change in adult affective regulation and associated neurobiological and neurobehavioral factors, and clarifying points in the adult life course at which trajectories may diverge for affectively dysregulated subgroups;
  - Studies evaluating differences in the brain circuits or cortical areas recruited during emotional challenge or task performance as a function of age, sex, and mental disorder, and whether such differences predict resilience against onset or deterioration of course in mental disorders;
  - Studies that examine the impact of early-life adversity, trauma or stress on affect regulation as a central factor in the development of mental disorder in middle or old age;
  - Studies employing efficient multi-cohort designs to estimate adult neurodevelopmental changes relevant to emotion regulation processes and relate these to the risk of developing mental disorders; and,
  - Hypothesis driven research to test putative neural circuits via multiple biological measures.

Examples of studies that will not be supported under this FOA include the following:

- Applications that characterize adults' emotional status solely in terms of diffuse mood states (e.g., only via depression, anxiety or other such scales), lacking assessment of specific emotion processing and/or contextual components essential for a mechanistic understanding of changes or differences in emotion regulation;
- Applications that assess emotion processes and emotion regulatory strategies or processes at only a single level of observation and analysis (i.e., without combining multiple levels/methods such as genetic, cellular, brain circuit, physiological, behavioral, self-report);
- Applications that fail to analyze emotion processing by sex, or if limited to a single sex, that fail to provide justification for how the proposed single-sex approach will be critical to advancing overall understanding of unique aspects of emotion regulation in relationship to mental disorder in middle or old age;
- Applications that propose clinical trials of potential therapies for mental disorders, including tests of interventions intended to impact mental disorders by influencing emotion processing or use of emotion regulation strategies.

Investigators interested in proposing research involving a clinical trial are referred to the [NIMH Clinical Trials website \(http://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml\)](http://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml) (<http://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml>) and to the FOAs indicated there for submitting applications containing clinical trial components.

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.

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**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.

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**Clinical Trial?**

Not Allowed: Only accepting applications that do not propose clinical trials

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

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**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.

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**Award Budget**

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

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**Award Project Period**

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

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

- 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](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11118) ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11118](https://grants.nih.gov/grants/guide/uri_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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176](http://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](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)) - 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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126](http://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 \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/uri_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 \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=41137\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=41137).

#### Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11133\)](https://grants.nih.gov/grants/guide/uri_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 with the following additional instructions:

### **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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11137\)](https://grants.nih.gov/grants/guide/url_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 \(https://grants.nih.gov/grants/guide/url\\_redirect.html?id=82380\)](https://grants.nih.gov/grants/guide/url_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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11144\)](http://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 \(//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](http://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11146\)](http://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82299\)](http://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.

## **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?

### **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?

### **Innovation**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

### **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? 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?

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?

## Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

## Protections for Human Subjects

For research that involves human subjects but does not involve one of the 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150) ([https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11151](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151)); (2) [Sharing Model Organisms](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11152](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152)); and (3) [Genomic Data Sharing Plan \(GDS\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11153](https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11154](https://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.

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 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](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)). 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.

### **2. Administrative and National Policy Requirements**

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://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](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](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://www.fsrs.gov) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11170](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) ([//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, application errors and warnings, documenting system problems that threaten on-time submission, and 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)

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)**

Jovier Evans, PhD

National Institute of Mental Health (NIMH)

Telephone: 301-443-1369

Email: [jevans1@mail.nih.gov](mailto:jevans1@mail.nih.gov) (<mailto:jevans1@mail.nih.gov>)

### Peer Review Contact(s)

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

### Financial/Grants Management Contact(s)

Rita Sisco

National Institute of Mental Health (NIMH)

Telephone: 301-443-2805

Email: [siscor@mail.nih.gov](mailto:siscor@mail.nih.gov) (<mailto:jevans1@mail.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?11-30-18) (<http://grants/guide/WeeklyIndex.cfm?11-30-18>)

[NIH Funding Opportunities and Notices](http://grants/guide/index.html) (<http://grants/guide/index.html>)

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