

# Department of Health and Human Services

## Part 1. Overview Information

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### Participating Organization(s)

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

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### Components of Participating Organizations

National Institute of Mental Health ([NIMH \(https://www.nimh.nih.gov/index.shtml\)](https://www.nimh.nih.gov/index.shtml))

National Eye Institute ([NEI \(https://www.nei.nih.gov/\)](https://www.nei.nih.gov/))

National Institute on Aging ([NIA \(https://www.nia.nih.gov/\)](https://www.nia.nih.gov/))

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

National Institute of Biomedical Imaging and Bioengineering ([NIBIB \(https://www.nibib.nih.gov/\)](https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development ([NICHD \(https://www.nichd.nih.gov/\)](https://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders ([NIDCD \(https://www.nidcd.nih.gov/\)](https://www.nidcd.nih.gov/))

National Institute on Drug Abuse ([NIDA \(https://www.drugabuse.gov/\)](https://www.drugabuse.gov/))

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

National Center for Complementary and Integrative Health ([NCCIH \(https://nccih.nih.gov/\)](https://nccih.nih.gov/))

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### Funding Opportunity Title

## BRAIN Initiative: Non-Invasive Neuromodulation - New Tools and Techniques for Spatiotemporal Precision (R01 Clinical Trial Optional)

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### Activity Code

[R01 \(/grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r01&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

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### Announcement Type

Reissue of [RFA-MH-17-240 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-240.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-240.html)

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### Related Notices

- **August 23, 2019** - Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice [NOT-OD-19-137 \(/grants/guide/notice-files/NOT-OD-19-137.html\)](https://grants/guide/notice-files/NOT-OD-19-137.html).
- **July 26, 2019** - Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice [NOT-OD-19-128 \(/grants/guide/notice-files/NOT-OD-19-128.html\)](https://grants/guide/notice-files/NOT-OD-19-128.html).

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**Funding Opportunity Announcement (FOA) Number****RFA-MH-20-310**

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**Companion Funding Opportunity**

None

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

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

93.242, 93.213, 93.867, 93.866, 93.273, 93.286, 93.865, 93.279, 93.173, 93.853

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**Funding Opportunity Purpose**

This Funding Opportunity Announcement (FOA) solicits grant applications in two related but distinct areas. The first area is in the development and testing of novel tools and methods of neuromodulation that go beyond the existing forms of neural stimulation. The second distinct area that this FOA seeks to encourage is the optimization of existing stimulation methods.

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**Key Dates**

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**Posted Date**

June 27, 2019

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**Open Date (Earliest Submission Date)**

August 03, 2019

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

August 03, 2019

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**Application Due Date(s)**

September 03, 2019 and February 14, 2020, by 5:00 PM local time of applicant organization. All [types of non-AIDS applications \(https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-19-136.html#Application Types Allowed\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-19-136.html#Application Types Allowed) allowed for this funding opportunity announcement are due on these dates.

No late applications will be accepted for this Funding Opportunity Announcement.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

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**AIDS Application Due Date(s)**

Not Applicable

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**Scientific Merit Review**

November 2019 and July 2020

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### Advisory Council Review

January 2020 and August 2020

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### Earliest Start Date

April 2020 and September 2020

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### Expiration Date

February 15, 2020

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### 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 \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](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.

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 \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-MH-20-310\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-MH-20-310) 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

#### Background

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® is aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies, researchers will be able to produce a new dynamic picture of the brain that, for the first time, will show how individual cells and complex neural circuits interact in both time and space. It is expected that the application of these new tools and technologies will ultimately lead to new ways to treat and prevent brain disorders.

NIH is one of several federal agencies involved in the BRAIN Initiative. Planning for the NIH component of the BRAIN initiative is guided by the long-term scientific plan, "[BRAIN 2025: A Scientific Vision \(http://braininitiative.nih.gov/pdf/BRAIN2025\\_508C.pdf\)](http://braininitiative.nih.gov/pdf/BRAIN2025_508C.pdf)," which details seven high-priority research areas and calls for a sustained federal commitment of \$4.5 billion over 12 years. This Funding Opportunity Announcement (FOA) and other FOAs issued in Fiscal Year 2020 are based on careful consideration by the NIH of the recommendations of the BRAIN 2025 Report, and input from the NIH BRAIN Multi-Council Working Group. Videocasts of the NIH BRAIN Multi-council Working Group are available at <http://www.braininitiative.nih.gov/about/mcwg.htm> (<http://www.braininitiative.nih.gov/about/mcwg.htm>).

To enable rapid progress in development of new technologies as well as in theory and data analysis, the BRAIN Initiative encourages collaborations between neurobiologists and scientists from statistics, physics, mathematics, engineering, and computer and information sciences; and NIH welcomes applications from investigators in these disciplines.

NIH encourages BRAIN Initiative applications from investigators that are underrepresented in the biomedical, behavioral, or clinical research workforce (see data at <http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27> (<http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27>) and the most recent report on [Women, Minorities, and Persons with Disabilities in Science and Engineering \(http://www.nsf.gov/statistics/women/\)](http://www.nsf.gov/statistics/women/)). Such individuals include those from underrepresented racial and ethnic groups, those with disabilities, and those from disadvantaged backgrounds.

NIH also encourages businesses to participate in the BRAIN Initiative. It is possible for companies to submit applications directly to BRAIN Initiative program announcements or to collaborate with academic researchers in joint submissions. Small businesses should consider applying to one of the BRAIN Initiative small business FOAs (<http://braininitiative.nih.gov/funding/index.htm> (<http://braininitiative.nih.gov/funding/index.htm>)).

In addition to the BRAIN Initiative, the NIH continues to have a substantial annual investment in neuroscience research. The Institutes and Centers contributing to the NIH BRAIN Initiative (<http://braininitiative.nih.gov/> (<http://braininitiative.nih.gov/%20>)) support those research efforts through investigator-initiated applications as well as through specific FOAs. Potential applicants to this FOA are strongly encouraged to contact Scientific/Program staff if they have any questions about the best FOA for their research.

The BRAIN Initiative will require a high level of coordination and sharing between investigators. While this FOA does not use a cooperative agreement mechanism, it is expected that BRAIN Initiative awardees will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings and in other activities.

This FOA is related to the Recommendations in Sections III.4 and III.6 of the Final Report (<http://www.nih.gov/science/brain/2025/index.htm> (<http://www.nih.gov/science/brain/2025/index.htm>)) of the BRAIN working group. Specifically, this FOA solicits applications that will address the recommendations on "Demonstrating Causality" and "Advancing Human Neuroscience" in Section III.

## Research Objectives

Non-invasive neuromodulation devices are rapidly becoming one of the classes of tools considered for the treatment and diagnosis of brain disorders and could become an alternative or an adjunct to neurological, neuropsychopharmacological, rehabilitative, or cognitive behavioral therapies. Non-invasive devices can be defined as those that do not require surgery and do not penetrate the brain parenchyma. These devices include, but are not limited to, those used for focused ultrasound stimulation, magnetic seizure therapy, electroconvulsive therapy, static magnets, transcranial alternating current stimulation, transcranial direct current stimulation, and transcranial magnetic stimulation. Applications involving devices that require surgery or penetrate the brain parenchyma will be deemed nonresponsive and will not be reviewed.

This FOA solicits grant applications in two related but distinct areas.

The first area is in the development and testing of novel tools and methods of neuromodulation that go beyond the existing stimulation methods. The rationale for this objective is that existing magnetic and electrical stimulation methods have limited spatial and temporal precision. To overcome these obstacles and move beyond incremental advances in the field, collaborations between physicists, engineers, neuroscientists, and clinicians are encouraged. The fresh perspective of such integrative teams would enable the development and testing of novel approaches that leverage other types of energy in a way that can lead to novel tools for scientific discovery and for therapeutic brain stimulation with high spatial and temporal resolution. This type of application may be in the initial stages and may therefore still be in the animal testing phase; however, the proposed tools and methods must be adaptable for use in humans. In recognition of the fact that these methods might be in early stages of development, work with human volunteers can, but does not need to, be included.

The second distinct area that this FOA seeks to encourage is the significant improvement of existing stimulation methods. Applications should propose technology improvements and testing methods in areas such as, but not limited to: (1) substantial improvement of the focality and depth of penetration of the stimulus, (2) prevention of extraneous stimulation (e.g. auditory clicking, scalp sensation, stimulation of non-target brain regions), (3) integration with endogenous rhythmic activity and advancing closed-loop stimulation capabilities, (4) use in natural ambulatory settings such as home or community settings, (5) improved sham and control conditions, and (6) [development](#) of multi-modal non-invasive recording plus brain stimulating devices.

These six topics are discussed below in greater detail. They are not meant to be an exhaustive list, but provide examples of the types of improvements that are needed in this field.

- The first type of improvement is related to improving the focality and depth of the stimulation signal. The issue of focality is compounded for deep brain areas where existing non-invasive devices and protocols do not adequately provide both depth of penetration and target resolution. Advances toward noninvasive devices that allow deep and focal stimulation of the brain are strongly desired. Devices that could specifically stimulate more than one site are of interest.
- A second type of improvement involves the elimination of unintended extraneous stimulation. Current noninvasive techniques generally stimulate large regions of the brain. This is due both to the lack of focality of the stimulation signal as well as extraneous mechanical effects associated with device operation that independently stimulate auditory and somatosensory systems, thereby confounding experimental protocols. These extraneous effects can be a significant confound in trying to deliver precise stimulation.
- A third type of improvement entails enhanced control of the temporal component of the delivered stimulation dose. Such temporal control can apply both to the stimulation signal itself as well as the interaction of the stimulation with dynamic brain processes. Applications could focus on developing closed-loop devices that are sensitive and responsive to dynamic neural activity recorded from the brain, but this is not a requirement. Improvements that enable an exploration of the frequency of the stimulation, the duration, number, or shape of pulses that are delivered during the stimulation, or the shape of the pulse of the delivered stimulation would allow the research community to understand how those parameters affect the functioning.
- A fourth area would be modifying devices for use in more natural settings. For example, devices that could be used outside the clinic, that allow long term stimulation, that are informed by endogenous oscillations, or are personalized to individual anatomy and physiology could all be significant improvements to existing technologies.
- A fifth area entails creating a common standard for sham and control conditions for non-invasive

neuromodulation.

- A sixth area of interest is the development of advanced and scalable non-invasive brain stimulation devices that are compatible with brain recording capability. For example, combining transcranial magnetic stimulation devices with magnetic resonance imaging (MRI) that can be easily used within 3T and/or 7T MRI scanners. The MRI compatible stimulation device(s) must be able to allow concurrent or interleaved data acquisition during MRI scans and should be scalable beyond the developer's unique lab set up.

As mentioned above, this FOA uses two paths to foster development of new neuromodulation tools and techniques: development of wholly novel brain stimulation methods that do not involve existing stimulation methods, and optimization of existing technologies. The higher risk inherent in the former is balanced overall by the parallel emphasis on improving existing methods in the second area.

The following types of studies are not responsive to this FOA and will not be reviewed:

- Studies with devices that require surgery or penetrate the brain parenchyma
- Projects without a description of how the methods would be scaled up for use in humans
- Projects that propose to explore the use of non-invasive devices for recreational uses
- Studies directed toward inducing maladaptive behaviors

Applicants may want to make use of some of the ideas that have been made available as part of the NIH BRAIN Initiative Public Private Partnership program ([http://braininitiative.nih.gov/BRAIN\\_PPP/](http://braininitiative.nih.gov/BRAIN_PPP/) ([http://braininitiative.nih.gov/BRAIN\\_PPP/](http://braininitiative.nih.gov/BRAIN_PPP/))).

### **Institute Staff Involvement**

A grant awarded under this FOA may be converted to a cooperative agreement (U01) if substantial NIH scientific programmatic staff involvement is needed. NIH ICs routinely consider the desirability of substantial continued staff involvement in a supportive mode during the period of grant performance. Additional staff involvement may include review of the study protocol, participation on the steering committee and related meetings, and oversight of a data and safety monitoring board. If it is determined that the cooperative agreement mechanism is appropriate for an ongoing grant award, NIH program staff will consult with the grantee institution to mutually effect the conversion.

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

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?**

Optional: Accepting applications that either propose or do not propose clinical trial(s)

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

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### **Funds Available and Anticipated Number of Awards**

Issuing IC and partner components intend to commit an estimated total of \$3 million to fund approximately 5 awards.

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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 4 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- including the NIH Intramural Program
- 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 \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11118\)](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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. 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. \(//grants.nih.gov/grants\)](https://grants.nih.gov/grants)



[/guide/url\\_redirect.htm?id=11126](/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

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

### 2. Content and Form of Application Submission

It is critical that applicants follow the 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 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.

#### Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

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

#### Page Limitations

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

#### Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

### **SF424(R&R) Cover**

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

### **SF424(R&R) Project/Performance Site Locations**

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

### **SF424(R&R) Other Project Information**

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

### **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:

#### **Research Strategy:**

**Current State-of-the-Art Statement:** Applicants must describe the significance of their proposed devices/techniques by comparing them to the current state-of-the-art and propose metrics to measure the success of their new tools or techniques.

Investigators must describe how their new device/technique will be a significant improvement on existing technologies, that is likely to be adopted by the research community.

Any proposed work in animals must include a description of how the methods would be scaled up for use in humans. In recognition of the fact that these methods might be in early stages of development, work with human volunteers can, but does not need to, be included.

**Protection of Human Subjects:** The NIMH has published updated policies and guidance for investigators regarding human research protection and clinical research data and safety monitoring ([NOT-MH-19-027 \(https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html)). The application should reflect the policies and guidance in this notice.

**Data Safety Monitoring Plan:** The NIMH has published updated policies and guidance for investigators regarding human research protection and clinical research data and safety monitoring ([NOT-MH-19-027 \(https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html)). The application should reflect the policies and guidance in this notice.

**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.
- The NIMH has published a guide notice in reference to data sharing in clinical research (including [NOT-MH-15-012 \(https://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-012.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-012.html)). Data sharing plans should reflect the guidance in this notice. The specific infrastructure for such data sharing will be established prior to award. One purpose of this data sharing is to establish standards related to describing noninvasive experiments for the research community. A second purpose is to prevent duplication of effort in order to move the field forward more quickly.

### **Appendix:**

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

(R&R) Application Guide.

## PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions: If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

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

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

### Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

## PHS Assignment Request Form

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

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

### Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See [Section III](#) of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11146\)](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 and responsiveness by [components of participating organizations](#), NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

In order to expedite review, applicants are requested to notify the NIMH Referral Office by email at [nimhreferral@mail.nih.gov](mailto:nimhreferral@mail.nih.gov) (<mailto:nimhreferral@mail.nih.gov>) when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

## Applications Involving the NIH Intramural Research Program

The requests by NIH intramural scientists will be limited to the incremental costs required for participation. As such, these requests will not include any salary and related fringe benefits for career, career conditional or other Federal employees (civilian or uniformed service) with permanent appointments under existing position ceilings or any costs related to administrative or facilities support (equivalent to Facilities and Administrative or F&A costs). These costs may include salary for staff to be specifically hired under a temporary appointment for the project, consultant costs, equipment, supplies, travel, and other items typically listed under Other Expenses. Applicants should indicate the number of person-months devoted to the project, even if no funds are requested for salary and fringe benefits.

If selected, appropriate funding will be provided by the NIH Intramural Program. NIH intramural scientists will participate in this program as PDs/PIs in accord with the Terms and Conditions provided in this FOA. Intellectual property will be managed in accord with established policy of the NIH in compliance with Executive Order 10096, as amended, 45 CFR Part 7; patent rights for inventions developed in NIH facilities are NIH property unless NIH waives its rights.

Should an extramural application include the collaboration with an intramural scientist, no funds for the support of the intramural scientist may be requested in the application. The intramural scientist may submit a separate request for intramural funding as described above.

## Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](#)

([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82299](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. Applications submitted to the NIH in support of the [NIH mission \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11149\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

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?

Will the proposed device/technique be a significant improvement on existing technologies?

#### 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?

Do the specific goals of the application include defining the current state of the science/technology as a benchmark against which the proposed research will be measured? Do the applicants provide an assessment of how their application will advance the field beyond the current state-of-the-art?

### **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?

Is the proposed approach likely to result in a device/technique that will be adopted by the research community?

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?

### **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? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

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



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

#### *Data Management and Statistical Analysis*

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

### **Environment**

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**

Not Applicable

### **Renewals**

Not Applicable

### **Revisions**

Not Applicable

## **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 NIMH, 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.

[Appeals](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html)) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by National Advisory of Mental Health Council. 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11156) ([//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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) ([//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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](#) 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>) (<https://register.clinicaltrials.gov/>). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see <https://grants.nih.gov/policy/clinical-trials/reporting/index.htm> (<https://grants.nih.gov/policy/clinical-trials/reporting/index.htm>)

**Institutional Review Board or Independent Ethics Committee Approval:** Grantee institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols. Data and Safety

**Monitoring Requirements:** The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at [http://grants.nih.gov/grants/policy/hs/data\\_safety.htm](http://grants.nih.gov/grants/policy/hs/data_safety.htm) and in the application instructions (SF424 (R&R) and PHS 398).

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

## 2. Administrative and National Policy Requirements

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

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 (FAPIS) requirements. FAPIS 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 <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html>). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>) <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

## 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 \(RPPR\)](#) (<https://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](#). ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_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](#) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161)).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov](http://www.fsrs.gov) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11170](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11170)) on all subawards over \$25,000. See the [NIH Grants Policy Statement](#) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11171](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171)) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory

requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

### **Application Submission Contacts**

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, 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 instructions, 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)**

David McMullen, M.D.

National Institute of Mental Health (NIMH (<https://www.nimh.nih.gov/index.shtml>))

Telephone: 301-451-0180

Email: [david.mcmullen@nih.gov](mailto:david.mcmullen@nih.gov) (<mailto:david.mcmullen@nih.gov>)

### **Peer Review Contact(s)**

Nicholas Gaiano, Ph.D.

National Institute of Mental Health (NIMH)

Telephone: 301-827-3420

Email: [nick.gaiano@nih.gov](mailto:nick.gaiano@nih.gov) (<mailto:nick.gaiano@nih.gov>)

### **Financial/Grants Management Contact(s)**

Terri Jarosik

National Institute of Mental Health (NIMH)

Telephone: 301-443-3858

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

## Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) ([//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) ([//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) ([//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.



[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?06-28-19\)](/grants/guide/WeeklyIndex.cfm?06-28-19)

[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)

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National Institutes of Health [\(/grants/oer.htm\)](/grants/oer.htm)  
Office of Extramural Research



[\(http://www.hhs.gov/\)](http://www.hhs.gov/)

Department of Health  
and Human Services (HHS)



[\(http://www.usa.gov/\)](http://www.usa.gov/)

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