Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

National Eye Institute (NEI (http://www.nei.nih.gov))
National Institute on Aging (NIA (http://www.nia.nih.gov))
National Institute on Alcohol Abuse and Alcoholism (NIAAA (http://www.niaaa.nih.gov))
National Institute of Biomedical Imaging and Bioengineering (NIBIB (http://www.nibib.nih.gov))
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (http://www.nichd.nih.gov))
National Institute on Deafness and Other Communication Disorders (NIDCD (http://www.nidcd.nih.gov))
National Institute on Drug Abuse (NIDA (http://www.nida.nih.gov))
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov))
National Center for Complementary and Integrative Health (NCCIH (http://www.nccam.nih.gov))

Funding Opportunity Title

BRAIN Initiative: New Technologies and Novel Approaches for Large-Scale Recording and Modulation in the Nervous System (R01 Clinical Trial Not Allowed)

Activity Code

R01 (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-NS-17-003 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-17-003.html)

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).
- **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).
- **January 22, 2019** - Notice of Data Sharing Policy for the BRAIN Initiative. See Notice NOT-MH-19-010 (/grants/guide/notice-files/NOT-MH-19-010.html).
- **November 26, 2018** - NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Research Grant Applications. See Notice NOT-OD-18-228 (/grants/guide/notice-

files/NOT-OD-18-228.html)).

- August 10, 2018 (//grants.nih.gov/grants/guide/notice-files/NOT-NS-18-087.html) - Notice of Change of Receipt Date for RFA-NS-18-020. See Notice NOT-NS-18-087 (//grants.nih.gov/grants/guide/notice-files/NOT-NS-18-087.html).

Funding Opportunity Announcement (FOA) Number

RFA-NS-18-020

Companion Funding Opportunity

RFA-NS-18-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-18-019.html), U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity)
Research Project – Cooperative Agreements

Number of Applications

See Section III. 3. Additional Information on Eligibility.

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

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

Funding Opportunity Purpose

Understanding the dynamic activity of neural circuits is central to the NIH BRAIN Initiative. This FOA seeks applications for proof-of-concept testing and development of new technologies and novel approaches for largescale recording and manipulation of neural activity to enable transformative understanding of dynamic signaling in the nervous system. In particular, we seek exceptionally creative approaches to address major challenges associated with recording and manipulating neural activity, at or near cellular resolution, at multiple spatial and/or temporal scales, in any region and throughout the entire depth of the brain. It is expected that the proposed research may be high-risk, but if successful could profoundly change the course of neuroscience research.

Proposed technologies should be compatible with experiments in behaving animals, and should include advancements that enable or reduce major barriers to hypothesis-driven experiments. Technologies may engage diverse types of signaling beyond neuronal electrical activity for large-scale analysis, and may utilize any modality such as optical, electrical, magnetic, acoustic or genetic recording/manipulation. Applications that seek to integrate multiple approaches are encouraged. Where appropriate, applications are expected to integrate appropriate domains of expertise, including biological, chemical and physical sciences, engineering, computational modeling and statistical analysis.

Key Dates

Posted Date

March 14, 2018

Open Date (Earliest Submission Date)

April 15, 2018

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Date(s)

New Dates May 15, 2018, November 27, 2018, May 1, 2019, October 29, 2019, May 1, 2020, and October 29, 2020, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.

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

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

August 2018, January 2019, August 2019, January 2020, August 2020, and January 2021

Advisory Council Review

January 2019, May 2019, January 2020, May 2020, January 2021, and May 2021

Earliest Start Date

February 2019, June 2019, February 2020, June 2020, February 2021, June 2021

Expiration Date

October 30, 2020

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of

Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (http://public.era.nih.gov/commons/) 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-NS-18-020) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The BRAIN Initiative

The **B**rain **R**esearch through **A**dvancing **I**nnovative **N**eurotechnologies (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 (https://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 FOA and other recently issued FOAs 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).

In addition to the National 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/)) 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.

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 (https://www.nsf.gov/statistics/women/)). Such individuals include those from underrepresented racial and ethnic groups, those with disabilities, and those from disadvantaged backgrounds.

The BRAIN Initiative will require a high level of coordination and sharing between investigators. 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.

Objectives

This FOA is related to the recommendations in section III of the BRAIN 2025 Report, with the goal to 'produce a dynamic picture of the functioning brain by developing and applying improved methods for large-scale monitoring of neural activity'. Towards this end, the report calls for accelerated development of new and improved electrodes for large-scale recording, new and improved electrical and chemical optical sensors of neural activity, and new and improved instruments for optical monitoring of neural activity. These new technologies and approaches will provide unprecedented opportunities for exploring how the nervous system encodes, processes, utilizes, stores, and retrieves vast quantities of information. A better understanding of this dynamic neural activity will enable researchers to seek new ways to diagnose, treat, and prevent brain disorders. Moreover, this FOA is intended to support the core principles of technology validation and dissemination highlighted in the BRAIN 2025 Report.

This FOA seeks applications to conduct proof-of-concept development and testing of new technologies and novel approaches for large-scale recording and manipulation of neural activity, to enable transformative understanding of dynamic signaling in the nervous system.

An additional BRAIN FOA (RFA-NS-18-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-18-019.html)) solicits applications for iterative refinement and validation of existing and emerging technologies for large-scale recording and manipulation of neural activity.

Applications are expected to address any or all of the following three general goals for the FOA:

1. Develop New Large-Scale Network Recording Capabilities

Recording dynamic neural activity from complete neural networks, over long periods, in any area of the brain is a challenging but essential goal. Advances in the exploration and development of new technologies for neural cell recording, including methods based on electrodes, microelectronics/microchips, imaging, molecular genetics, and nanoscience are encouraged. It is expected that progress will initially be tractable in non-human animals (invertebrate or vertebrate), but extrapolation to human circuits is an ultimate goal.

2. Develop Tools for Circuit Manipulation

The ability to activate and inhibit specific populations of neurons is key to understanding functional circuits, which will advance the scope of our knowledge from observation of neural phenomena to a mechanistic understanding of neural causation. A new generation of tools for optogenetics, pharmacogenetics, biochemical, electromagnetic and/or acoustic modulation needs to be developed for

use in animals, and eventually in humans, to enable the immense potential of circuit manipulation.

3. Link Neural Activity to Behavior

The goal of this FOA is to produce technologies with potential to elucidate nervous system function, in health and disease, in the context of complex behaviors. Proposed technologies should be compatible with experiments in behaving animals and should be validated under in vivo experimental conditions. In addition, novel approaches for enabling large-scale neural recording or manipulation during complex behaviors are encouraged along with the computational and statistical tools necessary to link neural activity to behavior. In combination with concurrent measurement and manipulation of neuronal activity, applications may propose methods to enhance the ability to quantify and interpret animal behavior, at high temporal and spatial resolution, reliably and objectively, over long periods of time and under a broad set of conditions.

Applications submitted in response to this FOA should address the following considerations:

- This FOA is for new technologies and/or novel approaches for which proof-of-concept testing is required. In particular, we seek exceptionally creative approaches to address major challenges associated with recording and manipulating neural activity, at or near cellular resolution, at multiple spatial and/or temporal scales, in any region and throughout the entire depth of the brain.
- It is expected that the proposed research may be high-risk, but if successful could profoundly change the course of neuroscience research.
- The proposed technologies should enable hypothesis-driven experiments that are currently infeasible, or reduce barriers to experiments that currently are costly, difficult, or take too long to perform.
- Proposed technologies should be compatible with experiments in behaving animals, and should increase the spatial and/or temporal scale of current methods, while minimizing the loss of cellular/sub-cellular and temporal resolution.
- Technologies may engage diverse types of signaling beyond neuronal electrical activity for large-scale analysis, including, for example, non-neuronal or modulatory signaling that contributes to circuit function.
- Applications may utilize experimental recording and manipulating techniques of any modality such as optical, electrical, magnetic, acoustic or genetic recording/manipulation.
- Applications that seek to integrate multiple technical and experimental approaches are encouraged.
- Applicants should note that crossing boundaries in interdisciplinary collaborations is a major goal of the BRAIN Initiative. Accordingly, applicants are strongly encouraged to consider, where appropriate, multi-PD/PI applications that integrate various domains of expertise, including biological, chemical and physical sciences, engineering, computational modeling and statistical analysis.

The following types of approaches are encouraged. Each bullet includes representative, but not exhaustive, examples.

Probes for Large-Scale Sensing and/or Manipulation of Neural Activity In Vivo

- Probes for resolving changes in membrane potential, with high spatial and temporal resolution, from large numbers of neurons in behaving animals
- Probes for sampling or manipulating activity over a range of spatial and temporal scales in the same experiment, or for large-scale sampling/manipulation of cellular activity with simultaneous whole-brain activity measurements
- Probes for recording/manipulating diverse cell types simultaneously, with distinguishable readouts and interventions (e.g., probes responsive to different ranges of the energy spectrum)
- Probes for neural plasticity events, at the cellular or synaptic level (including genetic and epigenetic events), which underlie network adaptation and learning
- Probes for cellular or network modulatory states (e.g., as assessed by intracellular signaling

cascades, or modulatory transmitter levels), which are major determinants of cellular and network responses to incoming information.

- Probes for signaling at specific sets of nerve terminals, or by specific neurotransmitters with synaptic resolution, especially techniques/approaches that distinguish transmitters or classes of synapses from one another

Imaging Instrumentation for Recording and/or Manipulating Neural Activity with Cellular Resolution In Vivo

- Optical imaging instrumentation with major increases in large-scale sampling capabilities, including frame rates sufficient to capture millisecond-scale signaling events, across full volumes of neural tissue rather than single focal planes
- New imaging modalities for less-invasive or non-invasive cellular-resolution imaging at tissue depths that are currently unavailable, such as structured imaging or adaptive strategies using spatial light modulation and/or wavefront sensing, photoacoustic wavefront shaping, backscattering and deconvolution strategies, or signal relay approaches
- Methods for simultaneous imaging of cellular resolution neural activity from multiple brain regions, or for large-scale sampling/manipulation of cellular activity with simultaneous whole-brain activity measurements

Development of Electrodes for Large-Scale Recording and/or Circuit Manipulation In Vivo

- Transforming technologies for simultaneous high-density recording and manipulation of neural activity from multiple brain regions (cortical, sub-cortical, deep-brain) in freely behaving animals
- Adaptable multi-functional platforms to enable new combinations of capabilities sufficient for large-scale recordings in vivo (e.g., combinations of electrical recordings, optical modulation, chemical sensing, and/or fluid delivery)
- Innovative new electrode concepts, delivery methods or biocompatible materials to dramatically reduce the invasiveness of acute or chronic electrode recordings
- Innovative methods to solve the impediments to effective day-to-day stability of single-unit recordings
- New in vivo electrical capabilities, such as chronic multi-unit intracellular recording, or high-density three-dimensional arrays across multiple spatial planes
- Strategies for integrating in vivo electrical recordings with other recording technologies, such as optical imaging and stimulation or high-field MRI

Techniques and Approaches for Recording/Manipulating Neural Activity during Behaviors

- New or improved miniaturized devices for head-mounted recording of neural activity at cellular-resolution in freely behaving animals
- Innovative approaches for head-fixed recording or manipulation of neural activity at cellular-resolution, for ethologically robust behavioral analysis
- Innovative methods to transform neural signals into effector systems of behavior
- In combination with concurrent development of large-scale technology for recording/manipulation, computational and statistical tools to analyze and model neural circuit activity underlying behavior and/or to affect systems of behavior

Applicants are strongly encouraged to consult the Scientific/Research Contact listed below to discuss the alignment of their proposed work with the goals of this FOA, and the BRAIN Initiative Program.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R)
Application Guide provide details on these application types.

Clinical Trial?

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)

Funds Available and Anticipated Number of Awards

The NIH anticipates providing $10M per year to fund an estimated 15 to 20 awards.

Award Budget

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

Award Project Period

Awards are for three years of support.

NIH grants policies as described in the *NIH Grants Policy Statement* (//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 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/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) 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) - 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/) (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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – 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/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)).

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 Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications (//grants.nih.gov/grants/guide

/url_redirect.htm?id=41137).

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:

Edmund (Ned) Talley, PhD
National Institute of Neurological Disorders and Stroke (NINDS)
Email: BRAIN-FOAs@nih.gov (mailto:BRAIN-FOAs@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) 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. The budget should include funds necessary for travel for up to two key personnel to participate in a BRAIN investigator meeting, lasting not more than two days and including up to two overnight stays, for each year of the project.

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: This FOA is for new technologies and/or novel approaches, including proof-of-concept testing. Because projects are expected to be early-stage and potentially high-risk, preliminary data on feasibility are not required. However, a sound rationale should be provided as to why the approach proposed is the most appropriate and likely to generate an exceptionally high impact if successful, and emphasis should be placed in details of the approach, particularly feasibility-testing.

Although proposed technologies should enable or reduce major barriers to hypothesis-driven experiments, applications should focus on the technology rather than experimental or biological aims. Projects may engage in iterative development in the context of specific experiments, but these experiments should be formulated to validate the technology and demonstrate its capabilities, rather than advancing the state of biological knowledge. Applicants are expected to explain the specific biological assay(s) to be utilized for validation.

All applications should include the following:

Current State-of-the-Art: Investigators should specifically define the current state of technology as a benchmark against which their proposed new technology or improvements will be measured.

Given that projects are likely to be early-stage and high-risk in nature, this should include the specific proof-of-concept test(s) that will indicate whether/how a proposed tool actually "works", along with alternative strategies should that effort fail to perform as expected. Tests should include a comparison against existing benchmark technologies; if a tool is truly first-in-class, comparisons may be done against a nearest neighbor technology. Investigators should briefly note how results will be used to inform future phases of tool development, such as testing in other model systems or in human brain.

Milestones and Timeline: A timeline and milestones should be included that propose indicators of progress at critical junctures. These should be tailored to the unique scope of each project and written concretely enough to evaluate what exactly will have been achieved (e.g., crucial steps in tool making) during the course of the project.

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, with the following modification:

A central goal of the companion FOA, RFA-NS-18-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-18-019.html) is to further advance research by generating transformative tools and technologies that will be widely used throughout the research community. However, the focus of this FOA is to generate proof-of-concept for a new technology, and consequently a plan for dissemination of proposed resources may be premature. If applicable, applications should include a detailed plan for dissemination and sustainability of proposed resources.

Dissemination plans should include the following key elements:

- Project management of resource sharing or dissemination;
- Description of the specific resources to be shared;
- Milestones with schedule for availability and for breadth of dissemination;
- Persons who will have access to the resources (written as broadly as possible to the extent consistent with applicable laws, regulations, rules, and policies);
- Plan for post award disposition of resources. It is expected that preference will be given towards eventual commercial manufacture, although plans with an end-goal of future dissemination capitalizing on existing NIH or alternate funding agency funding mechanisms will be considered.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when

applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

PHS Assignment Request Form

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

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the _NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11137)_, and procedures for foreign institutions.

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

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

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide /url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//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).

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//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). 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). 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) 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.

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 (//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

NEW **Important Update:** See NOT-OD-18-228 (/grants/guide/notice-files/NOT-OD-18-228.html) for updated review language for due dates on or after January 25, 2019.

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), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

This FOA is for new technologies and/or novel approaches, including proof-of-concept testing. Because projects are expected to be early-stage and potentially high-risk, preliminary data on feasibility are not required. However, a sound rationale should be provided as to why the approach proposed is the most appropriate and likely to generate an exceptionally high impact if successful.

The research approach will be evaluated for logic and novelty. Although reviewers will consider feasibility, they will be instructed to not penalize unavoidable risks that are intrinsic to new and innovative approaches.

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 there a strong scientific premise for the project? 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?

Does the proposed technology represent a major improvement over current state-of-the-art? Will it serve to enable hypothesis-driven experiments that are currently infeasible, or reduce major barriers to experiments that currently are costly, difficult, or take too long to perform?

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 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?

Are the experiments formulated to validate the technology and demonstrate its capabilities, rather than advancing the state of biological knowledge? Are there proposed development milestones that are adequate, measurable and feasible?

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 children, 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 six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of

materials. For additional information 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)](//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information 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)](//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)](//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 (//grants.nih.gov /grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants /guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//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 NINDS, in accordance with NIH peer review policy and procedures (//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 (//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 the National Advisory Neurological Disorders and Stroke 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 (//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).

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).

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.

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.

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. 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 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 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 https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov /ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov

/omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (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.

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) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//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* (//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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (//grants.nih.gov/grants/guide/url_redirect.htm?id=82301) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Scientific/Research Contact(s)

Edmund (Ned) Talley, PhD
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-1917
Email: BRAIN-FOAs@nih.gov (mailto:BRAIN-FOAs@nih.gov)

Sahana Kukke, Ph.D.
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-1447
Email: sahana.kukke@nih.gov (mailto:sahana.kukke@nih.gov)

Peer Review Contact(s)

Chief, Scientific Review Branch
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-9223
Email: nindsreview.nih.gov@mail.nih.gov (mailto:nindsreview.nih.gov@mail.nih.gov)

Financial/Grants Management Contact(s)

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

Section VIII. Other Information

Recently issued trans-NIH policy notices (//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_ (//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 (//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.

◀ **1**

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

(http://www.hhs.gov/) Department of Health
and Human Services (HHS)

(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).