

## Part 1. Overview Information

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|--|---|
| <b>Participating Organization(s)</b>             | National Institutes of Health ( <a href="http://www.nih.gov">NIH (http://www.nih.gov)</a> )   |
| <b>Components of Participating Organizations</b> | <p>National Institute of Neurological Disorders and Stroke (<a href="http://www.ninds.nih.gov/">NINDS (http://www.ninds.nih.gov/)</a>)</p> <p>National Eye Institute (<a href="http://www.nei.nih.gov/">NEI (http://www.nei.nih.gov/)</a> )</p> <p>National Institute on Aging (<a href="http://www.nia.nih.gov/">NIA (http://www.nia.nih.gov/)</a> )</p> <p>National Institute on Alcohol Abuse and Alcoholism (<a href="http://www.niaaa.nih.gov/">NIAAA (http://www.niaaa.nih.gov/)</a>)</p> <p>National Institute of Biomedical Imaging and Bioengineering (<a href="http://www.nibib.nih.gov/">NIBIB (http://www.nibib.nih.gov/)</a> )</p> <p><i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (<a href="http://www.nichd.nih.gov/">NICHD (http://www.nichd.nih.gov/)</a>)</p> <p>National Institute on Deafness and Other Communication Disorders (<a href="http://www.nidcd.nih.gov/">NIDCD (http://www.nidcd.nih.gov/)</a>)</p> <p>National Institute on Drug Abuse (<a href="http://www.nida.nih.gov/">NIDA (http://www.nida.nih.gov/)</a> )</p> <p>National Institute of Mental Health (<a href="http://www.nimh.nih.gov/">NIMH (http://www.nimh.nih.gov/)</a> )</p> <p>National Center for Complementary and Integrative Health (<a href="http://www.nccam.nih.gov/">NCCIH (http://www.nccam.nih.gov/)</a> )</p> <p>Office of Behavioral and Social Sciences Research (<a href="http://obsr.od.nih.gov/">OBSSR (http://obsr.od.nih.gov/)</a> )</p> <p>Office of Research on Women's Health (<a href="http://orwh.od.nih.gov/">ORWH (http://orwh.od.nih.gov/)</a> )</p> |
| <b>Funding Opportunity Title</b>                 | <p><b>BRAIN Initiative: Research Opportunities Using Invasive Neural Recording and Stimulating Technologies in the Human Brain (U01 Clinical Trial Required)</b></p>  |
| <b>Activity Code</b>                             | <p><a href="http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity">U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&amp;Search.x=0&amp;Search.y=0&amp;Search_Type=Activity)</a><br/>           Research Project – Cooperative Agreements</p>  |
| <b>Announcement Type</b>                         | <p>Reissue of <a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-18-010.html">RFA-NS-18-010 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-18-010.html)</a></p>   |

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| <b>Related Notices</b>   | None   |
| <b>Funding Opportunity Announcement (FOA) Number</b>           | <b>RFA-NS-19-001</b>   |
| <b>Companion Funding Opportunity</b>                           | None   |
| <b>Number of Applications</b>                                  | See <a href="#">Section III. 3. Additional Information on Eligibility</a> .  |
| <b>Catalog of Federal Domestic Assistance (CFDA) Number(s)</b> | 93.853; 93.867; 93.866; 93.273; 93.286; 93.865; 93.173; 93.279; 93.242; 93.213, 93.313   |
| <b>Funding Opportunity Purpose</b>                             | <p>Invasive surgical procedures provide the unique ability to record and stimulate neurons within precisely localized brain structures in humans. Human studies using invasive technology are often constrained by a limited number of patients and resources available to implement complex experimental protocols and are rarely aggregated in a manner that addresses research questions with appropriate statistical power. Therefore, this RFA seeks applications to assemble diverse, integrated, multi-disciplinary teams that cross boundaries of interdisciplinary collaboration to overcome these fundamental barriers and to investigate high-impact questions in human neuroscience. Projects should maximize opportunities to conduct innovative in vivo neuroscience research made available by direct access to brain recording and stimulating from invasive surgical procedures. Projects should employ approaches guided by specified theoretical constructs and quantitative, mechanistic models where appropriate.</p> <p>Awardees will join a consortium work group, coordinated by the NIH, to identify consensus standards of practice, including neuroethical considerations, to collect and provide data for ancillary studies, and to aggregate and standardize data for dissemination among the wider scientific community.</p> |
| <b>Key Dates</b>   |  |
| <b>Posted Date</b>   | August 28, 2018  |
| <b>Open Date (Earliest Submission Date)</b>                    | October 14, 2018   |
| <b>Letter of Intent Due Date(s)</b>                            | October 14, 2018; September 18, 2019; May 19, 2020; September 19, 2020   |
| <b>Application Due Date(s)</b>                                 | November 14, 2018; October 18, 2019; June 19, 2020; October 19, 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.  |

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| <b>AIDS Application Due Date(s)</b> | Not applicable ( <a href="http://grants.nih.gov/grants/guide/url_redirect.htm?id=11112">http://grants.nih.gov/grants/guide/url_redirect.htm?id=11112</a> ). |
| <b>Scientific Merit Review</b>      | Jan/Feb 2019; Jan/Feb 2020; Sept/Oct 2020; Jan/Feb 2021   |
| <b>Advisory Council Review</b>      | May, 2019; May 2020; Jan 2021; May 2021   |
| <b>Earliest Start Date</b>          | June, 2019; June 2020; Feb 2021; June 2021  |
| <b>Expiration Date</b>              | October 20, 2020  |
| <b>Due Dates for E.O. 12372</b>     | Not Applicable  |

### Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/\)](http://grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

#### Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

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

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(http://public.era.nih.gov/commons/\)](#) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-NS-19-001\)](#) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](#) to track your application.

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## Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

#### The BRAIN Initiative

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a Presidential initiative 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," which details seven high-priority research areas and calls for a sustained federal commitment of \$4.5 billion over 12 years. This report can be found at <http://braininitiative.nih.gov/> (<http://braininitiative.nih.gov/>). This FOA and other FOAs issued in Fiscal Year 2015 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 (<http://braininitiative.nih.gov/MCWG-Roster.pdf> (<http://braininitiative.nih.gov/MCWG-Roster.pdf>)), which held its first two meetings in 2014 and 2015 (see <http://videocast.nih.gov/summary.asp?file=18555&bhcp=1> (<http://videocast.nih.gov/summary.asp?file=18555&bhcp=1>) and <http://videocast.nih.gov/Summary.asp?File=18880&bhcp=1> (<http://videocast.nih.gov/Summary.asp?File=18880&bhcp=1>)).

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.

This RFA encourages applications from diverse teams of investigators, including team members 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). Such individuals include those from underrepresented racial and ethnic groups, those with disabilities, and those from disadvantaged backgrounds.

To achieve the goals of the program, the BRAIN Initiative will require a high level of coordination and sharing between investigators. By involvement as 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 RFA is related to the Recommendations in Section 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 RFA solicits applications that will address the recommendations on "ADVANCING HUMAN NEUROSCIENCE" (Section III Implementation: Goals, Deliverables, Timelines and Costs, Part 6) of the Final Report.

#### Background

The BRAIN Initiative seeks to understand the circuits and patterns of neural activity that give rise to mental experience and behavior, which will provide a foundation for understanding and treating diverse neurological, psychiatric, and behavioral disorders. Dynamic activity of ensembles of neurons in specially organized networks gives rise to the internal states we experience as sensations, perceptions, emotions, thoughts, and memories and to observable motor behavior. The activity of these networks is the substrate of cognitive processes such as attention, intention, reasoning and decision making; of emotional states of happiness, sadness, and fear; of sensation such as touch, pain, hearing, olfaction, taste, and vision; and to motor behaviors such as balance, motor control. Dysfunction of these large systems of neurons due to disease, injury, or developmental anomaly is the basis of neural and mental disorders. Furthermore, investigative studies of neural circuits in human subjects offer unique opportunities for mechanistic understanding of complex capabilities especially advanced in humans.

While research using non-invasive imaging and stimulation methods is typically considered 'non-significant risk' by Institutional Review Boards and does not require an Investigational Device Exemption (IDE) from the FDA, opportunities for research involving invasive, higher-resolution stimulating/recording devices for human neuroscience research often have limited time windows. These opportunities are mostly restricted to patients undergoing neurosurgical procedures or implantation for less than 30 days with devices such as ECoG/EEG grids and indwelling penetrating arrays. There are few stimulating/recording devices that are FDA market-approved for implantation for greater than 30 days. These inherent challenges associated with research using invasive devices in the human nervous system therefore require a greater degree of planning and interdisciplinary collaboration.

### **RFA Research Objectives**

Investigations within the human brain offer revolutionary, but challenging, opportunities for experimental investigation of how the human brain senses, thinks, perceives, remembers, plans, registers emotions, activates movements, and makes decisions. Invasive surgical procedures provide the unique ability to record and stimulate neurons within precisely localized brain structures in humans. However, human studies using invasive technology are often constrained by a limited number of patients and resources available to implement complex experimental protocols and are rarely aggregated in a manner that addresses research questions with appropriate statistical power. Therefore, this RFA seeks applications to assemble diverse, integrated, multi-disciplinary teams that cross boundaries of interdisciplinary collaboration to overcome these fundamental barriers and to investigate high-impact questions in human neuroscience. Projects should propose prospective testing and validation of explicit or model-driven hypotheses. Studies that offer deployment or development for high temporal resolution of behavioral quantification integrated with invasive recording of brain activity is encouraged, especially those that would transition to use in naturalistic environments outside of strict laboratory settings.

Projects should engage diverse, multidisciplinary teams consisting of clinicians, scientists, device engineers, data/computational scientists, regulatory specialists, and/or ethics specialists. Teams may be assembled within a single institution, but because of the likelihood of a limited number of patients at any single research center, integration of research teams across sites is strongly encouraged.

Awardees are expected to actively participate in a consortium work group, coordinated by the NIH, to identify consensus standards of practice, including neuroethical considerations, to collect and provide data for ancillary studies, and to aggregate and standardize data for dissemination among the wider scientific community. In the interest of iterative models of discovery, support for complementary animal studies are allowed if they validate or inform these empirical studies of human physiology. Applicants are expected to employ approaches guided by specified theoretical constructs, and are encouraged to employ quantitative, mechanistic models where appropriate.

We anticipate that implantable devices for most of these applications will rely on existing technology sufficiently advanced for an IRB Non-Significant Risk designation, or an FDA IDE without needing significant additional pre-clinical testing on the device. We also anticipate that newly IDE-approved devices may become available over the course of these awards. NIH BRAIN is supporting new device development and regulatory approval through other NIH BRAIN initiatives, including the availability of template Memoranda of Agreements (MOUs), Confidential Disclosure Agreements (CDAs) and Collaborative Research Agreements (CRAs) with various private and commercial device providers that may facilitate awardees to adopt novel technologies to fit their needs (see <http://braininitiative.nih.gov/> (<http://braininitiative.nih.gov/>) for up to date information

and NIH Scientific/Research contacts). Where appropriate, applicants are encouraged to anticipate potential and alternative plans for adopting newly available technologies. Furthermore, use of the cooperative agreement mechanism will allow awardees to negotiate the incorporation of new technologies by working through NIH Program staff in collaboration with technology providers.

### Activities Supported

The list below includes representative, but not exhaustive, examples of activities that could be considered responsive to this RFA . Applications may:

- propose statistically-powered hypothesis testing.
- integrate non-invasive technologies to image and/or perturb the nervous system for use in conjunction with the invasive implants in order to cross spatial and temporal scales.
- combine multi-modal techniques.
- offer a combination of quantitative psychophysics and behavioral assays in combination with brain recording or stimulating that tests mechanistic hypotheses.
- utilize approved, chronic implants, (e.g., DBS implants; FDA-approved indwelling electrodes) to address mechanistic hypotheses about brain function, plasticity, etc.

### Topics supported

The list below includes representative, but not exhaustive, examples of topics that could be considered responsive to this RFA.

- Human research studies as mechanistic investigations. A mechanistic investigation is designed to understand a biological or behavioral process, or the mechanism of action of an intervention.
- Investigative studies for understanding the neurobiology of cognitive functions specially advanced in humans.
- Approaches to understanding network coding of sensory information.
- Paradigms to assess motor coding during complex behaviors.
- Approaches to understand neural circuitry associated with diverse social behaviors.
- Changes in circuit functions underlying the brain's ability to store information and to learn new behaviors (plasticity).
- New approaches to capture and assess information processing across brain regions during memory consolidation, memory retrieval, spatial/relational processing, attention, or planning.
- Assessment of distributed representations and information processing underlying advanced mental processes such as language, decision making, numerical cognition, reasoning, consciousness, and metacognition.
- Investigation of distributed circuits that contribute to the coordination of motivational states and reward behavior.
- Empirical and analytical approaches to understand how behavioral states are emergent properties of the interaction of neurons, circuits, and networks.

### The following are non-responsive for this program:

- Human research studies that include clinical trials designed to answer specific questions about safety, tolerability, efficacy, and/or effectiveness of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions (e.g., phase 1, phase II, phase III, or pivotal clinical trials).
- Studies designed primarily to develop or improve disease/disorder therapeutics or devices.
- Studies for which the primary goal is to achieve regulatory approval of neurotechnology (see <http://braininitiative.nih.gov/> (<http://braininitiative.nih.gov/>) for other BRAIN FOAs supporting this activity, and the NIH bioengineering grant program <http://www.ninds.nih.gov/research/bioengineering/index.htm> (<http://www.ninds.nih.gov/research/bioengineering/index.htm>)) or the peripheral nervous system (see NIH SPARC <http://commonfund.nih.gov/sparc/index> (<http://commonfund.nih.gov/sparc/index>)).
- Imaging approaches not coupled with intra-cranial recording or stimulating.
- Implementing rehabilitation therapies.
- Definitive clinical trials of therapeutic devices, such as a traditional feasibility study and/or pivotal trial (see <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf2>

(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulati%20onandGuidance/GuidanceDocuments/UCM279103.pdf>)

for the definition of an early feasibility study, feasibility study and pivotal trial).

- Projects focused on augmentation of neural function in healthy individuals.

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

## Section II. Award Information

|   |   |
|---|---|
| <b>Funding Instrument</b>                               | Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA. |
| <b>Application Types Allowed</b>                        | New<br>The <a href="https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116">OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116)</a> and the SF424 (R&R) Application Guide provide details on these application types.   |
| <b>Clinical Trial?</b>                                  | Required: Only accepting applications that propose clinical trial(s)<br><a href="https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370">Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)</a>   |
| <b>Funds Available and Anticipated Number of Awards</b> | Issuing IC and partner <a href="#">components</a> intend to commit an estimated total of \$8M to fund 5 awards per receipt date.  |
| <b>Award Budget</b>                                     | Application budgets are not limited but need to reflect the actual needs of the proposed project.   |
| <b>Award Project Period</b>                             | The scope of the proposed project should determine the project period. The maximum project period is 5 years.   |

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

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

Higher Education Institutions

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

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

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)

- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

#### Nonprofits Other Than Institutions of Higher Education

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

#### For-Profit Organizations

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

#### Governments

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

### Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply

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

Foreign components, as [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

### Required Registrations

#### Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (formerly CCR) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government

Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

- [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126\)NIH Grants Policy Statement. \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

## **3. Additional Information on Eligibility**

### **Number of Applications**

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))

**Additional Eligibility Information:** Applications submitted in response to this solicitation may not duplicate or be substantially similar to other applications concurrently under consideration by other programs or study sections including the inter-agency programs such as Collaborative Research in Computational Neuroscience (CRCNS), EARly-concept Grants for Exploratory Research (EAGER) or Next Generation Networks For Neuroscience (NeuroNex). Duplicate or substantially similar applications will be returned without review.

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

## 1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

## 2. Content and Form of Application Submission

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

James Gnadt, PhD  
Telephone: 301-496-9964  
6001 Executive Blvd  
North Bethesda, MD 20892  
Email: [BRAINResOppHu@ninds.nih.gov](mailto:BRAINResOppHu@ninds.nih.gov) (<mailto:BRAINResOppHu@ninds.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](http://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.

#### Other Attachments:

Applicants are required to include the following items: Team Management Plan and Clinical Protocol Synopsis. These items must be uploaded as separate attachments in pdf format with filenames that correspond to the individual items (Team Management Plan, and Clinical Protocol Synopsis). Applications lacking these required items will be deemed incomplete and will not be reviewed.

**Team Management Plan:** The team management plan must not exceed one page; applications that exceed this limit will be

withdrawn. NIH strongly encourages applicants to form diverse, multidisciplinary teams that consist of clinicians, scientists, device engineers, mathematicians, statisticians, data scientists, regulatory specialists and/or ethics specialists, as appropriate. This multidisciplinary team should be able to address the details of the plans and experiments, to execute the research strategy, and to dedicate resources and personnel to participate in and contribute to consortia activities, which include coordinating data science and analysis within and across BRAIN teams, integrating data into the BRAIN data archives, and identifying consensus standards of practice. An organizational structure that clearly defines the team structure and relationships among the various components must be described in the team management plan and illustrated in an organizational chart. This plan should also describe the governance and organizational structure of the leadership team, without repeating information from the Multiple PD/PI Plan if submitted, and the research project, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts. For publications, policies to address the ordering and recognition of authors, and decisions about what material to publish, consistent with the interests of commercial partners (where applicable), should be presented.

The team management plan should establish a Scientific Steering Group that consists of representatives from each of the partnering organizations and meets regularly to discuss project status, problems, and directions. Those individuals identified in the team management plan, who together would have the intellectual and leadership responsibilities, would likely be members of the Scientific Steering Group. Plans for enhancing the abilities and opportunities for investigators to work across disciplinary boundaries should also be included.

**Clinical Protocol Synopsis:** The clinical protocol synopsis must not exceed six pages; applications that exceed this limit will be withdrawn. The clinical protocol synopsis must include the following information:

- Compliance with HIPAA and informed consent must be explicitly described.
- A list of participant eligibility criteria
- How recruitment and retention plans will accommodate access to the appropriate brain areas of recording, including a discussion of the availability of participants for the proposed study and the ability of enrollment sites to recruit and retain the proposed number of participants, including women and minority participants.
- Participant recruitment and retention plans, including a discussion of the availability of participants for the proposed study and the ability of enrollment sites to recruit and retain the proposed number of participants meeting the eligibility criteria, including women and minority participants. Data supporting recruitment and retention estimates must be provided.
- A description of all assessments including clinical, laboratory, physiological, behavioral, patient-centered, or other outcomes addressing the primary and secondary research questions.
- Discussion of the potential biases in the study and how they will be addressed
- Statistical Methods: Discussion of sample size and power calculations where hypothesis testing is explicit, study outcome measures, plans for interim and final analyses, methods of bias control, and methods for handling missing data. Examples of the critical elements of a well-designed clinical study are summarized on the NINDS website. [http://www.ninds.nih.gov/funding/transparency\\_in\\_reporting\\_guidance.pdf](http://www.ninds.nih.gov/funding/transparency_in_reporting_guidance.pdf) ([http://www.ninds.nih.gov/funding/transparency\\_in\\_reporting\\_guidance.pdf](http://www.ninds.nih.gov/funding/transparency_in_reporting_guidance.pdf)).
- Data Management and Quality Control: Details of efficient data management and methods for monitoring quality, methods for monitoring the quality and consistency of intervention administration, and methods for ensuring participant confidentiality. Applicants are expected to incorporate data elements from the NINDS Common Data Elements (CDE) Project in their data collection forms (see <http://www.commondataelements.ninds.nih.gov> (<http://www.commondataelements.ninds.nih.gov>))
- Discussion of the challenges expected in implementing the studies and how these might be overcome

### **SF424(R&R) Senior/Key Person Profile**

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

Applications to this RFA should assemble diverse, integrated, multi-disciplinary teams of clinicians, scientists, device engineers, mathematicians, statisticians, data scientists, regulatory specialists and/or ethics specialists, as appropriate, to propose innovative research plans within the context of the unique research opportunities offered by these clinical procedures. These teams may be assembled within a single university or medical center, or may comprise integrated teams across multiple

institutions to aggregate these limited opportunities to address high-impact neuroscience questions.

### **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:** Harmonization of recruitment and methods (including collection, curation, and analysis) across multiple sites should be well planned and described as appropriate and consistent with achieving the goals of the program. The aims of this application must investigate fundamental questions in human neuroscience. While fundamental basic research often generates insights relevant to disorders of the nervous system, this RFA is not intended to generate research that is explicitly disease-therapeutic.

All applications are required to include the following points, which must be incorporated within the page limits of the Research Strategy:

- Statement of the neurobiological, neurological or mental health questions to be addressed, including the theoretical and conceptual framework that drives the research design and questions, and discussion of the analytical methods for interpreting the results.
- Description of how studies in the brain tissues potentially affected by the disease or disorder can adequately address the research questions and mechanisms posed, including comparison to complementary studies in animals if appropriate and feasible.
- Description of recording/manipulation methods that will be employed or developed to approach the questions as a functional system, and how the invasive intervention and/or the implantation of foreign (device) materials may confound the interpretation of results.
- If complementary animal studies are proposed, then anticipated, non-human, experimental components must be adequately described and justified.
- Where the adoption of newly developing technology pending FDA-approved is anticipated, reasonable description as an alternative methodology (to the extent that details are available), along with potential advantages and pitfalls, is required.
- Description of a timeline for completion of tractable research goals, strategic goals, and key stages of progress for the project, especially in terms of participant accrual.
- Applicants must address the technical, procedural, and ethical aspects specific to invasive studies in human patients, and the strategic plans for addressing functional studies of a specified neural system in the context of patients with neural dysfunctions and invasive device interventions.
- Description of resources and personnel dedicated to active participation in a consortium work group, coordinated by the NIH, to identify consensus standards of practice, including neuroethical considerations, to collect and provide data for ancillary studies, and to aggregate and standardize data for dissemination among the wider scientific community.

**Neuroethical considerations:** Applications must include this section that describes and discusses in detail the process of informed consenting of research subjects who can expect no direct benefit from engaging in the investigative research proposed, considerations of FDA-defined conditions of non-significant risk/significant risk beyond established standards of clinical care, ethical and practical considerations of invasive device maintenance and ultimate removal, and other ethical issues specific to invasive human neuroscience research.

**Protection of Human Subjects:** Assurance of the protection of human participants and the biohazard safety of employees (if applicable) must be provided for the overall study and for each clinical site. The applicant must discuss any issues which might lead to concern for the welfare of participants. Additionally, the human subjects section of the application must address data security measures and confidentiality.

Please note that The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46 ([NOT-OD-16-094 \(https://grants.nih.gov/grants/guide/notice-files/not-od-16-094.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-16-094.html)).

**Long-Term Plan for Patients:** Applicants must describe a plan for the care of patients at the end of the study and after the study period, if appropriate. These plans may vary from project to project, but examples might include 1) explant of indwelling devices once the approved study period is complete, 2) surgical removal of batteries and ‘capping’ the exposed metals from leads/IS-1 connectors, 3) manufacturer-supported device maintenance for patients responding to therapy, 4) manufacturer support for filing of compassionate use exemptions for device maintenance, etc.

**Data and Safety Monitoring Plan:** For minimal- to no-additional risk studies, it generally will be acceptable for the data and safety monitoring to be conducted by an investigator-appointed Study Monitoring Committee (SMC), an Independent Medical Monitor (IMM), or, for single-site studies involving low risk, the Program Director/Principal Investigator and his/her IRB. However, NIH may decide to establish an independent Data and Safety Monitoring Board (DSMB) depending on the score and risk of the study. Applicants should refer to NIH’s policy on data and safety monitoring (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html> (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>)) as well as the NINDS Guidelines for Data and Safety Monitoring ([http://www.ninds.nih.gov/research/clinical\\_research/policies/data\\_safety\\_monitoring.htm](http://www.ninds.nih.gov/research/clinical_research/policies/data_safety_monitoring.htm) ([http://www.ninds.nih.gov/research/clinical\\_research/policies/data\\_safety\\_monitoring.htm](http://www.ninds.nih.gov/research/clinical_research/policies/data_safety_monitoring.htm))).

**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, including description of plans for accommodating research-community input and requests for collecting and disseminating data that will be valuable to the wider research community beyond the primary outcomes. IRB-compliant plans for sharing de-identified data for maximizing and expanding dissemination of data collected from this valuable resource should be included in the research plan, including statements of cooperation to join a future collaborative consortium of awardees to maximize the data sharing (including collection, curation, analysis and sharing) for this unique population of human subjects.

Applicants are welcome to consider editing this example data sharing plan, [https://grants.nih.gov/grants/sharing\\_example\\_data\\_sharing\\_plan.doc](https://grants.nih.gov/grants/sharing_example_data_sharing_plan.doc) ([https://grants.nih.gov/grants/sharing\\_example\\_data\\_sharing\\_plan.doc](https://grants.nih.gov/grants/sharing_example_data_sharing_plan.doc)) to include the sharing of all the tool deliverables from this RFA (e.g. theories, models, methods, software, etc.).

Awards made under this RFA are expected to share data using appropriate standards in an appropriate repository, as appropriate and consistent with achieving the goals of the program. For example, the NIH BRAIN Initiative will be supporting candidate activities and repositories through 3 BRAIN Informatics RFAs ([RFA-MH-17-255 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-255.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-255.html)), [RFA-MH-17-256 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-256.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-256.html), and [RFA-MH-17-257 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-257.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-17-257.html)). Project-specific details will be established at the time of award. Budgets should include sufficient resources to prepare, analyze, and disseminate data and to coordinate data-related activities identified by the consortia.

## 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.

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

### **6. Funding Restrictions**

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

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

### **7. Other Submission Requirements and Information**

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains

information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11144\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Guidelines for Applicants Experiencing System Issues \(//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

#### **Important reminders:**

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

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

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

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review 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.

### **Prior Consultation with Scientific/Research Staff**

Consultation with relevant Scientific/Research staff is strongly encouraged, not later than the Letter of Intent due date. This is not the same as the Letter of Intent, and should be included as a separate communication to the Scientific/Research Contacts, see Section VII. If requested by the applicants, staff can advise whether the proposed project meets the goals of this RFA and the mission of the BRAIN Initiative, and discuss responsiveness questions. Staff will not evaluate the technical and scientific merit of the proposed project; technical and scientific merit will be determined during peer review using the review criteria indicated in this RFA. During the consultation phase, if the proposed project does not meet the programmatic needs of this RFA, applicants will be strongly encouraged to consider other Funding Opportunities.

### **Post Submission Materials**

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

## Section V. Application Review Information

### 1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11149](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149)), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

#### For this particular announcement, note the following:

The application must investigate fundamental questions in human neuroscience. While fundamental basic research often generates insights relevant to disorders of the nervous system, this RFA is not intended to generate research that is explicitly disease-therapeutic.

If complementary animal studies are proposed, then anticipated, non-human, experimental components must be adequately described and justified.

The BRAIN Initiative invites applications with high levels of innovation, which assumes some degree of risk. Reviewers should evaluate whether a sound rationale has been provided as to why the research approach is the most appropriate, and likely to generate an exceptionally high impact if successful. Although reviewers will consider feasibility, they should not penalize unavoidable risks that are intrinsic to new and innovative approaches. In addition to the review criteria below, reviewers will assess the technical, procedural, and ethical aspects specific to invasive studies in human patients, and the strategic plans for addressing functional studies of a specified neural system in the context of patients with neural dysfunctions and invasive device interventions.

In the interest of the possibility of adopting new and developing technologies during the award, when applicants offer anticipated or alternative, newly developed, IDE-approved devices in the research plan, reviewers should assess feasibility, risk and opportunity, along with strategic contingencies.

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 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 project investigate high-impact questions in human neuroscience as appropriate for the goals of this RFA and the BRAIN Initiative? Does the project offer the theoretical and conceptual framework that drives the research design and questions and the discussion of the analytical methods for interpreting the results?

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?

Does the project engage diverse multidisciplinary teams consisting of clinicians, scientists, device engineers, data/computational scientists, regulatory specialists, and/or ethics specialists, as appropriate?

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

## **Innovation**

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

Does the project offer novelty and innovation appropriate for/commensurate with the goals of the BRAIN Initiative?

Does the project maximize opportunities to conduct innovative in vivo neuroscience research made available by direct access to brain recording and stimulating from invasive surgical procedures?

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 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?

Where the adoption of newly developing technology pending FDA-approved is anticipated, does the project provide a reasonable description of alternative methodology (to the extent that details are available), along with potential advantages and pitfalls?

Does the application address how studies in the brain tissues potentially affected by the disease or disorder can adequately address the research questions and mechanisms posed, including comparison to complementary studies in animals if appropriate and feasible?

Does the application offer a description of recording/manipulation methods that will be employed or developed to approach the questions as a functional system, and how the invasive intervention and/or the implantation of foreign (device) materials may confound the interpretation of results?

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?

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?

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

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

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

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2)

adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

### **Additional Review Criteria**

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

#### **Study Timeline**

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

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

#### **Protections for Human Subjects**

For research that involves human subjects but does not involve one of the 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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11174).

#### **Vertebrate Animals**

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

#### **Biohazards**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

## Resubmissions

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.

### Plans for Patient Recruitment/Retention

Does the application document the following?

- Availability of the requisite eligible subject pool in proposed clinical center(s);
- Plans for recruitment outreach and, as appropriate, follow-up procedures to ensure collection of data at stated intervals; and
- Are retention plans and practices adequate?

### Neuroethical considerations

Does the application adequately address neuroethical considerations about informed consenting of research subjects who can expect no direct benefit from engaging in the investigative research proposed, considerations of FDA-defined conditions of non-significant risk/significant risk beyond established standards of clinical care, ethical and practical considerations of invasive device maintenance and explantation, and other ethical issues specific to invasive human neuroscience research?

Is a plan described for the care of patients at the end of the study and after the study period?

### Applications from Foreign Organizations

Not applicable.

### Select Agent Research

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

### Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11153\)](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 NINDS, in accordance with [NIH peer review policy and procedures \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html\)](http://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

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

# Section VI. Award Administration Information

## 1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

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

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

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov

Protocol Registration and Results System Information Website (<https://register.clinicaltrials.gov>). NIH expects registration of all trials whether required under the law or not. For more information, see [http://grants.nih.gov/ClinicalTrials\\_fdaaa/](http://grants.nih.gov/ClinicalTrials_fdaaa/)

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

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

## 2. Administrative and National Policy Requirements

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

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

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

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html>. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>); and <http://www.hhs.gov/ocr/civilrights/understanding/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/index.html>).

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

### **Cooperative Agreement Terms and Conditions of Award**

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies. The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below. The PD(s)/PI(s) will have the primary responsibility for:

- PDs/PIs will determine and coordinate the research approaches and procedures, conduct experiments, and analyze and interpret research data generated under this award.
- PDs/PIs will endeavor to meet or exceed the timeline stated in their application.
- PDs/PIs will agree to participate as a voting member in Research Consortia composed of other BRAIN Initiative awardees and NIH staff.
- PDs/PIs will share resources and data, as appropriate and consistent with achieving the goals of the program.
- PDs/PIs will ensure that results are published in a timely manner.
- PDs/PIs will submit data for quality assessment and/or validation in any manner specified by the NIH Program Director.
- PDs/PIs will submit periodic progress reports.
- PDs/PIs will accept and implement any other common guidelines and procedures approved by the Program Director.
- PDs/PIs will attend BRAIN Initiative-related meetings. It is likely that there will be one in-person meeting per year and that other meetings will be by telephone or using internet assisted meeting software.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- A Program Director will be assigned to this award. The Program Director will be responsible for normal scientific and programmatic stewardship and guidance.
- A group of NIH program staff from the ICs contributing to the NIH BRAIN Initiative will form a Project Team for this award.
- The Project Team will be led by the Program Director(s) for these BRAIN Initiative awards.
- The Project Team will review annual progress reports and other documents from the awardees and will advise the Program Director about their view of the progress being made by the awardee as well as about progress being made by others in the field.
- One extramural NIH program staff member will be assigned as the Project Officer for this award. The same person may serve as the Project Officer for multiple BRAIN Initiative awards

- The Project Officer will also be a member of the Project Team.
- The Project Officer will interact scientifically with the PDs/PIs of the cooperative agreement and other named key personnel as a partner in the research.
- The Project Officer may assist in research planning, may present experimental findings from the group from published sources or from relevant contract projects, may participate in the design of experiments agreed to by the group, may participate in the analysis of results, and may help ensure that duplication is avoided.
- In all cases, the role of NIH staff will be to assist and facilitate, but not to direct activities.
- Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include: None; all responsibilities are divided between awardees and NIH staff as described above. Dispute Resolution: Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

### 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) ([//grants.nih.gov/grants/rppr/index.htm](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). ([//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) ([//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) ([//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) ([//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 on-time submission, and post-submission issues)

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

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

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

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

Telephone: 301-945-7573

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

Contact Center Telephone: 800-518-4726

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

### Scientific/Research Contact(s)

James Gnadt, PhD

National Institute of Neurological Disorders and Stroke (NINDS)

Telephone: 301-496-9964

Email: [BRAINResOppHu@ninds.nih.gov](mailto:BRAINResOppHu@ninds.nih.gov) (<mailto:BRAINResOppHu@ninds.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) (<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) (<mailto:decostert@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.

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[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?08-31-18) ([//grants/guide/WeeklyIndex.cfm?08-31-18](http://grants/guide/WeeklyIndex.cfm?08-31-18))

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

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Department of Health  
and Human Services (HHS)

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