

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

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

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

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

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

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

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

National Institute on Drug Abuse ([NIDA \(http://www.nida.nih.gov\)](http://www.nida.nih.gov/))

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

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

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

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

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

Funding Opportunity Title

BRAIN Initiative: Team-Research BRAIN Circuit Programs - TeamBCP (U19 Clinical Trial Not Allowed)

Activity Code

[U19 \(//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u19&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_pre](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u19&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_pre)
Research Program – Cooperative Agreements

Announcement Type

Reissue of [RFA-NS-17-018 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-17-018.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-17-018.html)

Related Notices	None
Funding Opportunity Announcement (FOA) Number	RFA-NS-19-003
Companion Funding Opportunity	RFA-NS-19-002 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html) U19 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u19&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_pre) Research Program – Cooperative Agreements
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.853, 93.867, 93.866, 93.273, 93.286, 93.865, 93.173, 93.279, 93.242, 93.213, 93.313
Funding Opportunity Purpose	<p>This RFA will support integrated, interdisciplinary research teams from prior BRAIN technology and/or integrated approaches teams, and/or new projects from the research community that focus on examining circuit functions related to behavior, using advanced and innovative technologies. The goal will be to support programs with a team science approach that can realize meaningful outcomes within 5-plus years. Awards will be made for 5 years, with a possibility of one renewal. Projects will incorporate overarching principles of circuit function in the context of specific neural systems underlying sensation, perception, emotion, motivation, cognition, decision-making, motor control, communication, or homeostasis. Applications should incorporate theory-/model-driven experimental design and should offer predictive models as deliverables. Applications should seek to understand circuits of the central nervous system by systematically controlling stimuli and/or behavior while actively recording and/or manipulating relevant dynamic patterns of neural activity and by measuring the resulting behaviors and/or perceptions. Applications are expected to employ approaches guided by specified theoretical constructs, and are encouraged to employ quantitative, mechanistic models where appropriate. Applications will be required to manage their data and analysis methods in a prototype framework that will be developed and used in the proposed U19 project and exchanged with other BRAIN U19 awardees for further refinement and development. Model systems, including the possibility of multiple species ranging from invertebrates to humans, can be employed and should be appropriately justified. Programs should employ multi-component teams of research expertise – including neurobiologists, statisticians, physicists, mathematicians, engineers, computer scientists, and data scientists, as appropriate - that seek to cross boundaries of interdisciplinary collaboration.</p>

Applicants proposing to include human subjects with invasive neural recording must apply to the companion FOA, [RFA-NS-19-002 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html).

Key Dates

Posted Date	August 29, 2018
Open Date (Earliest Submission Date)	September 30, 2018
Letter of Intent Due Date(s)	September 30, 2018; September 30, 2019; and September 30, 2020
Application Due Date(s)	October 30, 2018, October 30, 2019 and October 30, 2020, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	February 2018, February 2019 and February 2020
Advisory Council Review	May 2018, May 2019 and May 2020
Earliest Start Date	June 1, 2018, June 1, 2019 and June 1, 2020
Expiration Date	October 31, 2020
Due Dates for E.O. 12372	Not Applicable

**** ELECTRONIC APPLICATION SUBMISSION REQUIRED****

NIH's new Application Submission System & Interface for Submission Tracking (ASSIST) is available for the electronic preparation and submission of multi-project applications through Grants.gov to NIH. Applications to this FOA must be submitted electronically using ASSIST or an institutional system-to-system solution; paper applications will not be accepted.

Required Application Instructions

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

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

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

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

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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 an 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/%20>). This RFA is 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>)).

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/%20>)) support those research efforts through investigator-initiated applications as well as through specific FOAs. Potential applicants to this RFA 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> 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. 2, 3, 4, 5 and 7 of the Final Report (<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 "Maps at Multiple Scales", "The Brain in Action", "Demonstrating Causality", "Identifying Fundamental Principles" and "From BRAIN Initiative to the Brain" (Section III Implementation: Goals, Deliverables, Timelines and Costs, Parts 2 3, 4, 5 and 7) of the Final Report.

NIH BRAIN Integrated Approaches Funding Opportunities

This RFA is one of a family of "Integrated Approaches" NIH BRAIN FOAs that range from small or exploratory, targeted brain circuits projects with specific research outcomes (R34, R01) to large, team-research projects with exploratory aims (U01) or with extensive and elaborated goals and a 5-plus year horizon of discovery (U19). There is also a special RFA for doing investigative neuroscience in invasive research opportunities in humans (U01). In each case, the FOAs are guided by **BRAIN 2025 A Scientific Vision**: "The Application of Integrated Technologies to Study Fundamental Questions in Neuroscience: Numerous long-standing problems in brain science will benefit dramatically from the integrated experimental approach made possible by the BRAIN Initiative."

Potential applicants are encouraged to visit the NIH BRAIN Initiative website for information and guidance <https://www.braininitiative.nih.gov/funding/initiatives.htm> (<https://www.braininitiative.nih.gov/funding/initiatives.htm>).

FOAs in this family of initiatives emphasize the use of cutting-edge methods of activation and recording to understand the behavior of circuits at cellular and sub-second levels of spatial and temporal resolution using human or non-human animal subjects. This family of initiatives also seek advances in theory and/or analytics and

have a requirement of a data standards and management plan, as well as a data dissemination plan to facilitate use of the results by the research community.

Team-Research Brain Circuits Programs

Awards within this RFA will support research programs with 2-5 Research Projects focused on a high impact topic and cutting-edge technologies in large-scale recording and manipulation of circuits in vivo in the context of measurable behaviors. These research teams should offer resources and governance that bridge across institutional 'silos.' For example, research teams might comprise components across institutions or across colleges within a university. Projects should investigate neural function related to defined, ethologically relevant behaviors, well-defined neural systems, and/or biological mechanisms at an anatomic resolution of cells and circuits, and at a sub-second temporal resolution. We expect that awarded projects will become part of a consortium among BRAIN Initiative awardees in developing technologies, methods, expertise, and data and tools for sharing and reuse within the research community. There will be annual reviews by an External Advisory Board per award, with expanded programmatic site visits during years 2 and 4.

The proposed studies must relate to at least one of the seven major topic areas of the BRAIN 2025 report:

1. Discovering diversity: Identify and provide experimental access to the different cell types to determine their roles in the context of circuit function.
2. Maps at multiple scales: Generate structural and functional circuit diagrams that can span resolution from synapses to the whole brain.
3. The brain in action: Produce a dynamic picture of the functioning brain by developing and applying improved methods for large-scale monitoring of neural activity.
4. Demonstrating causality: Link brain activity to behavior with precise interventional tools that change neural circuit dynamics.
5. Identifying fundamental principles: Produce conceptual foundations about circuit dynamics and functional connectivity for understanding the biological basis of mental processes through development of new theoretical and data analysis tools.
6. Advancing human neuroscience: Develop innovative technologies to understand brain circuits and ensembles of circuits that inform understanding of the human brain and mechanisms for treating its disorders.
7. From BRAIN Initiative to the brain: Integrate new technological and conceptual approaches produced in Goals #1-6 to discover how dynamic patterns of neural activity are transformed into cognition, emotion, perception, and action in health and disease.

Specific Research Requirements

This RFA solicits applications from diverse interdisciplinary research teams that integrate theoretical models with innovative neurotechnologies for recording and manipulating neural circuits across multiple brain regions and scales. Studies of complex behaviors, including behavioral assays of freely-moving animals and objective measures of cognitive/perceptual processes, are encouraged. Applications may be submitted by teams with prior BRAIN technology and/or integrated approaches awards, and/or by new teams. The goal will be to support programs with a systematic, team-science approach that can realize meaningful outcomes within 5 and more years. Awards from this RFA will be made for no more than 5 years, with a possibility of one renewal.

Projects must include the following features:

- Teams: Investigators should seek to cross boundaries of interdisciplinary collaboration by bridging fields and linking theory and data analysis to experimental design. Teams must leverage appropriate multi-disciplinary expertise to develop new principles and methods for data acquisition, analysis, and interpretation. Budgets will be commensurate with multi-component teams of research expertise – including neurobiologists, statisticians, physicists, mathematicians, engineers, computer scientists, and data scientists as appropriate - that seek to cross boundaries of interdisciplinary collaboration.
- Content: The project should address overarching principles of circuit function in the context of specific neural systems underlying sensation, perception, emotion, motivation, cognition, decision-making, motor control, communication, or homeostasis. It should seek to understand circuits of the central nervous system by systematically controlling stimuli and/or behavior while actively recording and/or manipulating relevant dynamic patterns of neural activity and by measuring the resulting behaviors and/or perceptions.
- Experimental Design: The project should employ exceptionally innovative approaches to theory and analysis. It should incorporate theory-/model-driven experimental design and offer predictive models as deliverables. It should employ approaches guided by specified theoretical constructs that incorporate theories about causal mechanisms of circuit functions, and are encouraged to employ quantitative, mechanistic models where appropriate.
- Innovative algorithmic approaches: Applicants are encouraged to include dynamic tracking of activity from continuous data and real-time signal processing, and to develop methods for interactive data exploration and visualization, and to accomplish innovative dimensionality reduction in high-dimensional data sets.
- Analytical methods and experimental approaches: Applicants are encouraged to link neural processes across multiple scales of structure and time (including the requirement of cellular recording resolution) (e.g., ion channels, to cell compartments/structures, to spike rates/timing, to LFPs/oscillations, to circuits/networks/ensembles, to brain states)
- Technology: The project should employ and/or develop new and emerging capabilities for large scale recording and manipulation of neural activity of specific circuits or systems, ideally across multiple brain regions.
 - A cellular resolution of recording circuit activity, at sub-second temporal resolution, is required in order to address mechanistic understanding of circuit functions.
 - Scale of recording should be sufficient to account for the dynamic activity of the circuit or distributed ensemble of neurons under study, or to validate a specific, model-predicted outcome. This will be evaluated using species-appropriate considerations.
 - The resolution of mechanistic manipulation of circuits is relaxed from that of single cells to that of cell type/location specificity (e.g., compatible with focal TMS, micro-stimulation, micro-injection, optogenetics/DREADDs, targeted viral vectors).

Some representative, but not exhaustive, examples of technology included in these projects are:

- Reporters of chemical and biochemical signals of brain activity
- Reporters of subthreshold and subcellular voltage signals
- Multi-area population recording at cellular resolution
- Development of recording and manipulating methods that minimize tissue damage due to invasiveness
- Ability to identify and record from the same neurons over long periods of time
- Ability to anatomically identify recorded cells, including their phenotype and functional context
- Compatibility with quantitative measures of complex behavior

Model system: The application should employ justified and appropriate model systems of study, including the possibility of multiple, “ideal” species. It should be made clear how the selected model species offer the best conditions for revealing general principles about the circuit basis of the specific behavior or neural system of interest.

Resource Components: In addition to multiple Research Projects, applications are allowed to propose well-justified Resource Cores that may include professional research staff that will serve the shared technical needs of the Research Projects. Resource Cores will serve technical needs of two or more Research Projects, and support opportunities for sharing technology and technology expertise with external investigators, where appropriate. A dedicated Data Science Resource Core is a requirement.

Data Science Resource: A Data Science Resource Core is a requirement for applications to this RFA. The proposed science in each awarded U19 (the brain circuit of focus) should drive the Data Science Plan (i.e., the research strategy for the Data Science Resource). Therefore, the plan should be customized to fit the science and the specific data science needs of the proposed collection of U19 research components. The Data Science Plan should be offered as a part of the Data Science Resource Core according to the Data Science Qualifications listed in the instructions in that section below.

This RFA will not accept applications that include human studies with invasive neural recording. Programs including such human studies should be submitted to the companion funding announcement allowing for mechanistic clinical trials ([RFA-NS-19-002 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html)).

Applications must apply NIH standards of experimental and publication rigor (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html> (<https://grants.nih.gov/grants/guide/notice-files/not-od-16-011.html>)), should strive to promote ethnic, racial, gender and career stage diversity of the research teams, and must comply with NIH policy on reporting disaggregated sex-based data and other consideration of sex as a biological variable as elaborated in [NOT-OD-15-102 \(https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html), [NOT-OD-15-103 \(https://grants.nih.gov/grants/guide/notice-files/not-od-15-103.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-15-103.html) and [NOT-OD-16-031 \(https://grants.nih.gov/grants/guide/notice-files/not-od-16-031.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-16-031.html).

Research Objectives

Applications should seek to demonstrate how new and unprecedented experimental capabilities can be used to transform general understanding of neural information processing within the context of specific systems or circuits. The list below includes representative, but not exhaustive, examples of topics that could be considered responsive to this RFA.

- Innovative approaches to understand network coding of sensory information, at multiple stages of processing, in response to diverse naturalistic inputs and perceptual contexts.
- Innovative approaches and new paradigms for identifying and understanding nociception and pain in the context of circuit mechanisms of the central nervous system.
- New paradigms to assess motor coding during complex behaviors or freely-moving subjects.
- Novel approaches to understand neural circuitry associated with diverse social behaviors.
- Large-scale, dynamic changes in functional circuit connectivity underlying the brain's ability to store information and to learn new behaviors.
- Distributed circuits that contribute to the coordination of motivational states and reward behavior.
- New approaches to capture and assess information processing across brain regions during memory consolidation, memory retrieval, spatial/relational processing, attention, or planning.
- Large-scale approaches to assess distributed representations and the information processing underlying advanced mental processes such as decision making, numerical cognition, reasoning, and metacognition.
- Empirical and analytical approaches to understand how behavioral states are emergent properties of the interaction of neurons, circuits, and networks.
- Research to advance principles of circuit function and neural systems in the central nervous system that

regulate homeostasis, including biorhythms, and the balance of temperature, respiratory, energy and metabolic functions.

- Research for mechanistic understanding of circuits that spans stages of development.

Applications for the study of specific disease mechanisms, or specific disease therapeutics and treatments will be considered nonresponsive to this BRAIN Initiative RFA. While fundamental basic research often generates insights relevant to disorders of the nervous system, this RFA is not intended to stimulate research that is explicitly disease-related. Studies for the investigation of specific diseases and disorders should be directed to the appropriate NIH Institutes.

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

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

Section II. Award Information

Funding Instrument	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.
Application Types Allowed	New The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)
Funds Available and Anticipated Number of Awards	NIH BRAIN and partner components intend to commit an estimated total of \$22M in fiscal years 2019, 2020, 2021 to fund up to 5 new awards, each year for this RFA and the companion RFA-NS-19-002 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html) .
Award Budget	Application budgets are not limited but need to reflect the actual needs of the proposed project.
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is 5 years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government - 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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11118](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118)), **are** allowed.

Required Registrations

Applicant Organizations

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

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](http://fedgov.dnb.com/webform) (<http://fedgov.dnb.com/webform>) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](https://www.sam.gov/portal/public/SAM/) (<https://www.sam.gov/portal/public/SAM/>) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11176](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176)) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82300](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300)) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11126](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126))

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

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

Section IV. Application and Submission Information

1. Requesting an Application Package

A button to access the online ASSIST system is available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

Most applicants will use NIH's ASSIST system to prepare and submit applications through Grants.gov to NIH. Applications prepared and submitted using applicant systems capable of submitting electronic multi-project applications to Grants.gov will also be accepted.

2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) Instructions in the [SF424 \(R&R\) Application Guide](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([//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 and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. 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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137) ([//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 Gnad, PhD

Telephone: 301-496-9964

Email: BRAINCircuits@nih.gov (mailto:BRAINCircuits@nih.gov)

Page Limitations

Available Component Types	Research Strategy/Program Plan Page Limits
Overall	12
Admin Core	6
Data Science Core	6
Core (use for Resource Core)	6
Project (use for Research Project)	6

Additional page limits described in the SF424 Application Guide and the [Table of Page Limits](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) ([//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 the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: required
- Administrative Core: required; maximum of 1
- Data Science Core: required; maximum of 1
- Resource Core: optional; maximum of 3
- Research Project: required; minimum of 2; maximum of 5

Overall Component

When preparing your application in ASSIST, use Component Type 'Overall'.

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

SF424 (R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall

component.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Facilities & Other Resources:

As part of the overall environment for research programs, the BRAIN 2025 report advises that “*advances can then best move forward through partnership with other [academic,] clinical and industrial aspects of the research enterprise, which should shoulder some of the cost.*”

In this section, describe the institutional, commercial, and industrial investments and resources that constitute the environment for this research program. New cost-sharing commitments are not required. Some examples of institutional environment could include recruitment and salary support of new faculty or professional staff positions to support the resource components, start-up packages, space renovations for team investigators, new facilities within the component projects, dedicated equipment for research and resource components, dedicated budget lines or facilities for a team consortium, dedicated use of commercial products and technologies, equipment and technology contributions from commercial collaborators, etc. Institutional environment can include evidence of pre-application institutional investments promoting and leveraging the NIH BRAIN Initiative interests from its 2014 date of inception, critical start up resources early in the award, or evidence of institutional annual support in the budget.

Administrative Core should clearly indicate the facilities, resources, services and professional skills that the Core will provide. Moreover, information must be provided about how the collective operation of the Core will be affected in a coherent manner.

Project/Performance Site Location(s) (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research & Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/Pis (if applicable to this FOA) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Specific Aims:

Provide a concise description of the overall program goals for an impactful and extended scope of work with a 5-plus year horizon. Outline how the approaches and goals of the multiple Research Projects will address the initial up to 5 years of investigative research.

Research Strategy:

The Research Strategy should include a description of the scientific problems being addressed, the integration of the research and resource components, and why these components are essential for accomplishing the goals. The overall research strategy should be targeted to a broad audience and be concise. This section should lay out a compelling argument for why a team-research approach is needed to approach the aims, and how the synergy between projects and cores will interact and inform each other in ways not possible as separate research project grants, and at an economy of scale.

The overall research plan should include:

1. Goals, relevant background, significance, and a description of the impact of the science proposed in relation to the state-of-the-art of the field. This section should also include an explanation of how the work proposed is innovative.
2. An explanation of how the goals of the program will address fundamental questions in systems neuroscience.
3. A section should address how a team-research plan will allow a multidisciplinary approach necessary to accomplish the goals presented. The necessary expertise of each component should be justified, along with how the value of each component would contribute to the whole. This section should describe the working scientific and logistical design, as well as the resource support components necessary to implement the research.
4. The overall research strategy should include evidence for feasibility and can include general and background preliminary findings from the multiple research and resource components. This section should also present very clear evidence that the research team has been/will be able to work together effectively to accomplish the research proposed in the projects. Applicants should offer well-reasoned justifications for new and innovative approaches, including discussion of feasibility.
5. A descriptive and graphic timeline must be included in the Research Strategy section for the Overall Center. This section should also include specific proof-of-concept test(s) along with any alternative strategies should any component efforts fail to perform as expected.

Letters of Support:

Statements of individual and Institutional Commitment, as appropriate to the overall application, should be included in this section.

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

1. A Resource Sharing Plan for the entire program should be included in the Overall Component. Separate Resource Sharing Plans for other components are not necessary.

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Overall)

When involving NIH-defined human subjects research, clinical research, and/or clinical trials 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 (Note that this RFA will not accept applications that include human studies with invasive neural recording. Programs including such human studies should be submitted to the companion funding announcement allowing for mechanistic clinical trials ([RFA-NS-19-002 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-19-002.html)):

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

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 (Overall)

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

Research Project

When preparing your application, use Component Type ‘Project.’

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

SF424 (R&R) Cover (Research Project)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Project)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Project)

Human Subjects: Answer only the ‘Are Human Subjects Involved?’ and ‘Is the Project Exempt from Federal regulations?’ questions.

Vertebrate Animals: Answer only the ‘Are Vertebrate Animals Used?’ question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Other Attachments: If the application includes investigative human studies (not Clinical Trial), applicants are required to include the following items: Human Studies Team Management Plan, 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.

Human Studies Team Management Plan: The team management plan must not exceed one page. NIH strongly encourages applicants to form 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, and to execute the research strategy. 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 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 Human Studies Team Management Plan should establish a Human Studies 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 Human Studies Scientific Steering Group, who together would have intellectual and leadership responsibilities, would likely be members of the Internal Advisory Committee. 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, and must include the following information:

- Compliance with HIPAA and informed consent must be explicitly described.
- A list of participant eligibility criteria
- Applications should specify 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).
- 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>)

- Discussion of the challenges expected in implementing the study and how these might be overcome

Project /Performance Site Location(s) (Research Project)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Project)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Research Project)

Budget forms appropriate for the specific component will be included in the application package.

The Project Lead must commit at least a total minimum effort of 1.8 person-months per year to the project.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Project)

Specific Aims:

This section should provide a concise description of the aims for the research project.

Research Strategy:

Significance: Describe overall goals and the impact of the science proposed in relation to the state of the field. This section should also explain the contribution of the research project to the overall goals of the U19 program and how the component will interact with and benefit from other components.

Innovation: Describe the unique and innovative contributions that will be made by this project. Explain how these contributions will be made possible by team synergy beyond the otherwise independent research projects.

Approach: Describe and offer evidence for the feasibility of the proposed experiments, the advantages of any new methodologies, the potential pitfalls and alternative approaches for the project and how these might impact overall progress

Carefully relate and justify any proposed human studies to the circuit-level of mechanistic understanding required for these awards. Human research aspects must inform the overall program requirement of understanding specified behaviors or neural systems in terms of functional circuits, for example, as comparative projects that overlap or extend the cellular and sub-second spatio-temporal requirements of the overall research program to the coarser scales of multi-unit spikes and LFPs/oscillations of circuits, to functionally interconnected networks and ensembles, to brain states and percepts.

Letters of Support:

Statements of individual and institutional Commitment, as appropriate to the Research Project, should be included in this section.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification: Not Applicable for each component. Resource Sharing Plan should be submitted only in the Overall section only. See instructions in Overall section.

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Research Project)

When involving NIH-defined human subjects research, clinical research, and/or clinical trials 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 a **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.

Administrative Core

When preparing your application in ASSIST, use Component Type ‘Admin Core.’

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

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

- Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the ‘Are Human Subjects Involved?’ and ‘Is the Project Exempt from Federal regulations?’ questions.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment

indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: Provide a concise description of the goals of the Administrative Core.

Research Strategy: The Administrative Core is expected to have appropriate and effective administrative and organizational capabilities to support multidisciplinary research, outreach, to foster synergy, and to support planning and evaluation activities.

Describe how each Project or Resource Core (as applicable) will draw upon the Administrative Core and how it in turn will respond to Project or Resource Core needs. The description of the Administrative Core should clearly indicate the, services and professional skills that the Core will provide. Moreover, information must be provided about how the collective operation of the Core will be affected in a coherent manner.

Additional information required in the Administrative Core Research Strategy:

A Team Director and an Internal Advisory Committee composed of membership from each contributing component should be described, along with a governance plan that will organize and direct efforts across components. When multiple institutional sites are involved, a detailed description of the cooperative administrative arrangements should be included. (Documentation of these arrangements should be included in the Letters of Support section.) This section should include acknowledgement of establishing a to-be-named External Advisory Board to be convened annually to assess progress and accomplishments, and to advise the team governance. It is very important that potential advisory board members not be contacted before submission in order to minimize conflicts during the application review process and so that all individuals with appropriate scientific expertise remain eligible for consideration by review staff for the peer review panel.

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.

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving NIH-defined human subjects research, clinical research, and/or clinical trials 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 a **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.

Resource Cores

When preparing your application in ASSIST, use Component Type ‘Core.’

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

SF424 (R&R) Cover (Resource Cores)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Resource Cores)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Resource Cores)

Human Subjects: Answer only the ‘Are Human Subjects Involved?’ and ‘Is the Project Exempt from Federal regulations?’ questions.

Vertebrate Animals: Answer only the ‘Are Vertebrate Animals Used?’ question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Resource Cores)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Resource Cores)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Resource Cores)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Resource Cores)

Specific Aims: Provide a concise description of the goals of the Resource Core.

Research Strategy: Explain how the Resource Core will contribute to individual Research Projects.

A Resource Core can be a laboratory, a facility, a service, or other shared resource that supports at least two Research Project components. Descriptions for each Resource Core should include a brief overview and a description of the services and resources to be provided to other components. This section should address how the Resource Core will contribute to the overall goals of the program as well as which research projects will be supported by the Resource Core and the manner in which that support will be rendered. The description of each Resource Core should clearly indicate the facilities, resources, services, and professional skills that the facility will provide. Issues to be addressed can include: quality control, special expertise, cost effectiveness, and increased efficiency.

Where appropriate, describe how Resource Cores will be a point of contact for dissemination of technology, expertise, materials, and potential collaborations with other research individuals, teams and communities.

Significance: Describe overall goals of the science proposed in relation to the state of the field. This section should also explain the contribution of the core to the overall goals of the program and how the component will interact with and benefit from other components.

Innovation: Describe the unique and innovative contributions that will be made by this component. Explain how these contributions will be made possible by team synergy beyond the otherwise independent research projects.

Approach: Describe and offer evidence for the feasibility of the proposed experiments, the advantages of any new methodologies, the potential pitfalls and alternative approaches for the project and how these might

impact overall progress.

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Resource Cores)

When involving NIH-defined human subjects research, clinical research, and/or clinical trials 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, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

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.

Data Science Core

When preparing your application in ASSIST, use Component Type ‘Data Science Core’

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

SF424 (R&R) Cover (Data Science Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Data Science Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Data Science Core)

Human Subjects: Answer only the ‘Are Human Subjects Involved?’ and ‘Is the Project Exempt from Federal regulations?’ questions.

Vertebrate Animals: Answer only the ‘Are Vertebrate Animals Used?’ question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Data Science Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Data Science Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Data Science Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

Budgets should include sufficient resources to administer, prepare and disseminate data, and to coordinate data-related activities identified by the consortia.

PHS 398 Research Plan (Data Science Core)

Specific Aims: This section should provide a concise description of the aims for the Data Science Resource Core.

Research Strategy:

Significance: Describe overall goals of the science proposed in relation to the state of the field. This section should also explain the contribution of the data science resource core to the overall goals of the program and how the component will interact with and benefit from other components.

Innovation: Describe the unique and innovative contributions that will be made by this component. Explain how these contributions will be made possible by team synergy beyond the otherwise independent research projects.

Approach: Describe and offer evidence for the feasibility of the proposed experiments, the advantages of any new methodologies, the potential pitfalls and alternative approaches for the project and how these might impact overall progress.

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

As this is a Data Science Core which is expected to disseminate and share data, a Data Science Plan, with a timeline, is a requirement for applications to this FOA, consistent with achieving the goals of the program. A dedicated Data Sharing Plan must be included in this Data Science Resource Component, including a budget justified to support software engineering support and infrastructure as needed. A Data Sharing Plan should not be included in the Resource Sharing Plan. The science in the proposed U19 (the brain circuit of focus) should drive the Data Science Plan, where the plan's goal is to develop: 1) a service to the proposed U19 research components; and 2) a prototype data science framework for facilitating the workflow for data aggregation and analysis between the proposed Research Components. The latter is considered a pilot effort in which high risk-high impact methodologies are employed to optimize the framework for the U19 and produce generalizable approaches for the other BRAIN BCP efforts. The plan should be customized to fit the science and the specific data science needs of the Research Components. The prototype framework will be shared with the other U19 awardees for further testing and refinement. The Data Science Plan may include efforts to:

- Identify best practices, standards, tools, workflows, and computational infrastructures already in use by the research community
- Adopt existing resources for use by the research components of the proposed U19 project
- Define common data formats or create tools to harmonize disparate data formats within the U19 project
- Facilitate the comparison of data across species, as appropriate
- Provide robust and flexible data management and retrieval tools to function within the U19 project
- Provide guidance for addressing data provenance
- Integrate, when appropriate, predictive computational models and analytical tools for driving experiments
- Incorporate methods of uncertainty quantification to assess the robustness of model predictions and analytical methods
- Formulate methods to ensure reproducibility and reusability of models and analytical tools developed in the U19 (e.g. modular models, useable interfaces, etc.)
- Integrate, when appropriate, formal statistical inference frameworks for causal analyses of the range of data obtained in this project
- Help determine the magnitude and type of "missing" data that need to be acquired to improve the causal analyses
- Provide sufficient documentation, end-user training, and technical support for reuse and refinement of the prototype data science framework with other U19 awardees
- Participate in a BRAIN Initiative U19 consortium to strategize on harmonizing the Data Science Plan and its implementation with other U19 awardees as appropriate for the science

The plan must comply with the Data Science Qualifications listed below:

- 1) The data, algorithms, and workflows proposed in the Data Science Plan should consider the FAIR Guiding Principles for scientific data management and stewardship (Wilkinson, M. D. et al. 2016).
- 2) The Data Science Plan should maximally leverage existing shared data, algorithms, workflows and computational infrastructure resources and capabilities at the institutional, regional, and national levels - in neuroscience and other scientific domains that can be adapted for the purposes of this U19. The use of these existing resources should be noted in the plan.
- 3) The data used, collected, and subsequently managed in this project should be well-defined, utilizing reference data where possible. Investigators are encouraged to work toward consensus standards within the appropriate experimental subfield for representation of data in commonly used domains.
- 4) The analytical methods, models, and tools to visualize and analyze the data should be optimized for the

science, consistently annotated, and described for each project's own re-use and use by future users. Software services and tools, such as user interfaces and API's, are encouraged.

5) The framework for integrating the data and analysis methods across the proposed Research Components should include workflows to expeditiously collect, manage, integrate, archive, and analyze the data. This framework should be developed as a prototype to be shared with other U19 awardees to be further refined and developed with input from within this consortium of investigators and the NIH, as described in the cooperative agreement terms and conditions (Section VI.2).

Data scientists and dedicated, software engineering support may be incorporated into the data science plan. Applicants are welcome to consider editing this example data sharing plan, https://grants.nih.gov/grants/sharing_example_data_sharing_plan.doc to include the sharing of all the tool deliverables from this FOA (e.g. theories, models, methods, software, etc.). Awards made under this FOA must share data using appropriate standards in an appropriate repository. For example, the NIH BRAIN Initiative will be supporting candidate activities and repositories through 3 BRAIN Informatics FOAs ([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 and disseminate data, as appropriate and consistent with achieving the goals of the program.

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Data Science Core)

When involving NIH-defined human subjects research, clinical research, and/or clinical trials 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, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

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.

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

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and

Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

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

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

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#). (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](#) (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](#) (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.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf (https://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf).

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](#) (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](#)

(<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) and component Project Leads 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.

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 (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](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.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](#). 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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](#), 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 FOA, note the following:

The entire research program will receive one Impact Score based on critical considerations of the Overall Program and the collective assessment of Research Projects and Resource Cores. To guide the final scoring, reviewers will make interim assessment scores of the Overall Program and each Research Project (scores 1-9), along with evaluation of each Resource Core (exceptional, adequate, or inadequate). The final Impact Score will reflect assessment of aggregate impact and synergies of the overall program that will balance the collective strengths and weaknesses of the overall goals and the individual components, and not necessarily the arithmetic average of the interim assessment scores.

The BRAIN Initiative invites fundamental basic applications that meet the goals outlined under Research Strategy and have high levels of innovation, which assumes some degree of risk. Reviewers should evaluate whether a sound rationale has been provided as to how and why the research is tractable and likely to generate an exceptionally high impact if successful. Although reviewers will consider feasibility, they will be instructed to not penalize unavoidable risks that are intrinsic to new and innovative approaches. While fundamental basic research often generates insights relevant to disorders of the nervous system, this FOA is not intended to stimulate research that is explicitly disease-related.

The collective U19 team effort will be evaluated as an integrated research effort. The relationship and contributions of the Research Projects and Resource Cores to the overall objectives will be discussed and evaluated. Is there synergy between the components that could not be achieved through individual NIH award mechanisms? Are there clear advantages of conducting the proposed research as a collective program rather than through separate efforts?

Individual Components will be assessed for relevant strengths and weaknesses in the context of the whole Program. Final Impact Score need not reflect a cumulative enumeration of minor weaknesses but should reflect a balance of both the quality of the individual components, and the collective synergies and impacts of all the components.

Overall Impact - Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the program 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 program proposed).

Scored Review Criteria - Overall

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 program that by its nature is not innovative may be essential to advance a field.

Significance

Does the program 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 program 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?

1. Does the program seek to identify fundamental principles or produce conceptual foundations about circuit

dynamics and functional connectivity?

2. Does the program offer potentially transformative and paradigm-shifting advances in understanding brain circuitry underlying complex behaviors?

3. Are the projects and cores synergistic, such that they will interact and inform each other in ways not possible as separate research project grants, and at an economy of scale?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the program? 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?

Is the team diverse and interdisciplinary, such that it is comprised of appropriate content experts recognizable as leaders in their field? Are the team management plans clear and appropriate?

Team Director: Has the proposed Team Director demonstrated leadership in the area of science proposed with a strong record of scientific achievements? Has the proposed Team Director demonstrated his/her ability to organize, direct, and administer a complex research program?

Is there evidence that the research team has been/will be able to work together effectively to accomplish the research proposed in the projects?

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 program offer novelty and innovation appropriate for/commensurate with the goals of the BRAIN Initiative? Innovative approaches to cross-cutting questions in neuroscience are expected.

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the program? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the program 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?

Is there appropriate synergy of the research projects to the overall program objectives?

Have the applicants addressed appropriate research designs to maximize the reliability and replicability of

their findings?

Does the program involve the use of cutting-edge methods of activation and recording to understand behavior or a neural system in terms of a mechanistic understanding of specific circuits at cellular and sub-second levels of spatial and temporal resolution?

Is the scale of recording sufficient to account for the dynamic activity of the circuit or distributed ensemble of neurons under study, or to validate a specific, model-predicted outcome? This should be evaluated using species-appropriate considerations.

Does the program justify how the selected model species offer the best conditions for revealing general principles about the circuit basis of the specific behavior or neural system of interest?

Does this program aim to link theory and data analysis to experimental design, and will it produce predictive models (quantitative or conceptual) as deliverables?

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?

Scored Review Criteria - Research Projects

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 justify how its experimental capabilities and/or quantitative and/or theoretical frameworks will support the overall goal? Is the project necessary for success of the program? Would the program suffer if the project were flawed?

Does the project make an important contribution to the U19 program as a whole?

Is this project well integrated with the scientific objectives of the U19 program?

Is the project original and innovative?

Are the conceptual design, methods, and analyses adequately developed, well integrated, and well-reasoned?

Investigator(s)

Are the Project Lead(s), collaborators, and other researchers well suited to the program? 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?

Are the proposed research Project Lead(s) at the forefront of the area of science proposed, with a successful record of bringing novel and potentially high-risk projects to fruition as the principal investigator? Do the individuals bring complementary and integrated expertise to the overall program?

Innovation

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

Approach

Are the strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the program? 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 effectively managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Have the applicants addressed appropriate research designs to maximize the reliability and replicability of their findings?

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?

Review Criteria - Cores

In contrast to the review of Projects, reviewers will not provide individual criterion scores for Cores and will assign overall ratings of exceptional, adequate or inadequate. The review criteria for the individual Cores are provided below.

Administrative Core

Does the Administrative Core have appropriate and effective administrative and organizational capabilities to support multidisciplinary research, outreach, to foster synergy, and to support planning and evaluation activities? Does the Administrative Core clearly indicate how the collective operation of the whole program will be managed in a coherent manner? Has the Team Director demonstrated leadership in the area of science proposed with a strong record of scientific achievements? Has the Team Director demonstrated his/her ability to organize, direct, and administer a complex, distributed research program? Is the Internal Advisory Committee composed of membership from each contributing component, along with a governance plan that will organize and direct efforts across components? Is the Internal Advisory Committee well positioned to foster synergy, ensure appropriate prioritization of research, apply strategic course corrections and identify problems and appropriate solutions, oversee effective sharing of resources, and convey a high likelihood of effective, productive management of the program as a whole? Is there an organizational structure that will facilitate coordination and integration of progress? Is a process described that will resolve disagreements within the collective program?

Does the application include acknowledgement of establishing a to-be-named External Advisory Board to be

convened annually to assess progress and accomplishments, and to advise the team governance?

Data Science Core

Does the Data Science Core provide a reliable service to the proposed U19 research components? Does the Data Science Core provide a reasonable plan to optimally design a prototype data science framework for facilitating the workflow for data aggregation and analysis between the proposed Research Components? To what extent is the proposed data science framework development process incorporating risk to test new methodologies to produce generalizable approaches for the other BRAIN BCP efforts?

Does the application offer a Data Science Core that will identify best practices, standards, tools, workflows, and computational infrastructures already in use by the research community? Does the application provide robust and flexible data management and retrieval tools to function within the U19 project? Does the core integrate, where appropriate, predictive computational models and analytical tools for driving experiments? Does the plan incorporate appropriate data science staff and software engineering support? Have the investigators appropriately included plans to reuse existing best practices, standards, software tools, and computational infrastructures to manage their data, algorithms, and workflows? To what extent have the investigators proposed to develop new data standards, software tools for reusability, and computational infrastructures? Is this effort appropriate and well-justified for providing a prototype data science framework for this U19 project?

Resource Cores

Does each Resource Core offer supporting services to two or more Research Projects, and operate independent of any and all research operations intrinsic to the Research Projects? Does each Resource Core address a critical need or technical barrier to progress in the Research Project components? Does the application describe how each Resource Core will respond to Research Project needs and other Program needs like dissemination of resources, products and expertise to the greater research community? Does the proposed Core Lead offer appropriate expertise and sufficient independence from the Research Project components to distribute efforts and resources equitably? Does the application offer a detailed description of the cooperative administrative arrangements when multiple institutional sites are involved? Are the institutional support, equipment and other physical resources available adequate for the Core proposed?

Additional Review Criteria - Overall

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11174](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174)).

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable.

Renewals

Not Applicable.

Revisions

Not Applicable.

Additional Review Considerations - Overall

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11151](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151)); 2) [Sharing Model Organisms](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11152](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152)); and 3) [Genomic Data Sharing Plan](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)) .

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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11154](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154)), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) ([//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 on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

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

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

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

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

2. Administrative and National Policy Requirements

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

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

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <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>)

[lvl=2&lvlid=53](#)).

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

Cooperative Agreement Terms and Conditions of Award

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 Part 75, 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:

- Determine and coordinate the research approaches and procedures, conduct experiments, and analyze and interpret research data generated under this award.
- Endeavor to meet the timeline stated in their application.
- Participate with an External Advisory Board including appointed research experts outside the research team and NIH staff.
- Communicate across U19 projects to facilitate collaborative efforts. Efforts may include activities determined by a Data Science Consortium. Share resources and data as appropriate and in a consistent manner to be monitored by a Data Science Consortium.
- PDs/PIs will ensure that results are published in a timely manner.
- Submit data for quality assessment and/or validation in any manner specified by the External Advisory Board or the NIH Program Director.
- Submit periodic progress reports as agreed by the External Advisory Board.
- Accept and implement any other common guidelines and procedures approved by the External Advisory Board.
- Attend annual External Advisory Board meetings. It is likely that meetings will be by telephone or using internet assisted meeting software. In award years 2 and 4, there will be an in-person meeting on site.
- 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 and will be named in the award notice.
- An External Advisory Board 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 awardees as well as about progress being made by others in the field.
- An extramural NIH program staff member will be assigned as a Project Officer for this award.
- The same person may serve as the Project Officer(s) for multiple BRAIN Initiative awards.
- The Project Officer(s) will interact scientifically with the PDs/PIs of the cooperative agreement and other named key personnel as a partner in the research.
- The Program Director and the Project Officer(s) will have ex officio membership in the External Advisory Board.
- One purpose of the External Advisory Board is to evaluate the project in terms of the goals outlined in the BRAIN 2025 Report.
- It is expected that most of the decisions on the activities of the External Advisory Board will be reached by consensus. If a vote is needed, each appointed external advisor will each have a vote.
- The Project Officer interacts scientifically with the External Advisory Board and 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.
- The Program Director and the Project Officer(s) may attend External Advisory Board meetings as a non-voting participant. In all cases, the role of NIH staff will be to assist and facilitate, but not to direct activities.

Areas of Joint Responsibility include:

- Formation of a Data Science Consortium to strategize on harmonizing the U19 Data Science Plans.
- Execution of individual U19 Data Science Plans: The PDs/PIs of each U19 project, the NIH Program Director and other NIH program staff will work closely to develop and implement of the prototype framework for integrating data and analysis methods used for understanding the brain circuits of focus in the awarded project.
- During the award period, each U19 prototype framework will be shared with the other U19 investigators to further refine and develop, as determined by the Data Science Consortium.

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 External Advisory Board 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. - See more at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-15-005.html#sthash.VD3On9ep.dpuf>

3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report](#)

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

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

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

Scientific/Research Contact(s)

James Gnadt, PhD
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-496-9964
Email: BRAINCircuits@nih.gov (<mailto:BRAINCircuits@nih.gov>)

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)

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

Section VIII. Other Information

Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) (https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) (https://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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

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

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



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