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กองบริหารงานวิจัย มหาวิทยาลัยมหิดล

โทร. 02-849-6252 โทรสาร. 02-849-6247

ที่ อว 78.016/16/16/16

วันที่ ชี ชันวาคม 2565

เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการ จากแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project Grant หัวข้อ "BRAIN Initiative Cell Atlas Network (BICAN): Specialized Collaboratory on Human, Non-human Primate, and Mouse Brain Cell Atlases (R01 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-MH-22-292

- 1. รายละเอียดประกาศทุน RFA-MH-22-292
- 2. ขั้นตอนการสมัครขอรับทุน

คณบดี / ผู้อำนวยการ เรียน

ด้วยแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project Grant "BRAIN Initiative Cell Atlas Network (BICAN): Specialized Collaboratory on Human, Non-human Primate, and Mouse Brain Cell Atlases (RO1 Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-MH-22-292 โดยเปิดรับข้อเสนอโครงการ ตั้งแต่วันที่ 1 มกราคม 2566 จนถึงวันที่ 1 กุมภาพันธ์ 2566 เวลา 17.00 **น. ตามเวลาประเทศไทย** ทั้งนี้ โครงการที่เสนอขอทนให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดล เรื่อง หลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่จัดเก็บจากโครงการวิจัยที่ได้รับ เงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการตามที่ระบุในหนังสือชักซ้อมแนว ปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจ สามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่งทุนที่ https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-22-292.html

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อ โปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย <u>โปรดแจ้งความประสงค์การจัดส่งข้อเสนอ <mark>ภายในวันที่ 29 ธันวาคม 2565 แ</mark>ละจัดส่งข้อเสนอโครงการวิจัยผ่าน</u> ส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบรณ์ภายในวันที่ <u>25 มกราคม 2566</u> ทั้งนี้ หากส่วนงานแจ้งความประสงค์การจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 25 มกราคม 2566 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

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โทร 02-849-6252 อีเมล chittiporn.nua@mahidol.edu

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รับเรื่องคืนจากห้องคณบดี+รองคณบดี 14 D.M. 2565

# Department of Health and Human Services

## Part 1. Overview Information

## Participating Organization(s)

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



## Components of Participating Organizations

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

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

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

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

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

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

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

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

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

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

## **Funding Opportunity Title**

BRAIN Initiative Cell Atlas Network (BICAN): Specialized Collaboratory on Human, Nonhuman Primate, and Mouse Brain Cell Atlases (R01 Clinical Trial Not Allowed)

#### **Activity Code**

R01 (//grants.nih.gov/grants/funding/ac search results.htm?text curr=r01&Search.x=0&Search.y=0&Search Type=Activity) Research Project Grant

### Announcement Type

Reissue of RFA-MH-21-236 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-236.html)

#### **Related Notices**

NOT-OD-22-190 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

## Funding Opportunity Announcement (FOA) Number

RFA-MH-22-292

## Companion Funding Opportunity

RFA-MH-22-290 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-22-290.html), UM1

(https://grants.nih.gov/grants/funding/ac\_search\_results.htm?text\_curr=UM1&&Search.x=0&&Search.y=0&&Search

Research Project with Complex Structure Cooperative Agreement

RFA-MH-22-291 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-22-291.html), U24

(https://grants.nih.gov/grants/funding/ac\_search\_results.htm?text\_curr=U24&&Search.x=0&&Search\_y=0&&Search\_Type=Activity)

Resource-Related Research Project (Cooperative Agreements)

## **Number of Applications**

See Section III. 3. Additional Information on Eligibility.

#### Assistance Listing Number(s)

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

#### **Funding Opportunity Purpose**

This Funding Opportunity Announcement (FOA) intends to support a group of Specialized Collaboratories that will adopt scalable technology platforms and streamlined sampling strategies and assay cascade to create comprehensive and highly granular brain cell atlases in human, non-human primates, mouse, and other species in coordination and collaboration with other BRAIN Initiative Cell Atlas Network (BICAN) projects. In particular, the Specialized Collaboratories are expected to complement the Comprehensive Centers in BICAN with distinct capabilities, competencies, and research aims. The overarching goal of the BICAN is to build reference brain cell atlases that will be widely used throughout the research community, providing a molecular and anatomical foundational framework for the study of brain function and disorders.

## **Key Dates**

#### **Posted Date**

October 03, 2022

#### Open Date (Earliest Submission Date)

January 01, 2023

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

30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 01, 2023	Not Applicable	Not Applicable	July 2023	October 2023	December 2023
February 01, 2024	February 01, 2024	Not Applicable	July 2024	October 2024	December 2024

All applications are due by 5:00 PM local time of applicant organization.

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.

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

#### **Expiration Date**

February 02, 2024

#### Due Dates for E.O. 12372

Not Applicable

#### Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=82400), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11164)).

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 <u>Section IV</u>. 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.



- 2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and <a href="mailto:eRA Commons">eRA Commons</a>
  <a href="mailto:(/grants/guide/ApplyButtonSplash.cfm?dest=https://public.era.nin.gov/commons/">eRA Commons</a>
  (/grants/guide/ApplyButtonSplash.cfm?dest=https://public.era.nin.gov/commons/) to track your application. Check with your institutional officials regarding availability.
- 3. Use <u>Grants.gov (/grants/guide/ApplyButtonSplash.cfm?dest=GrantsGov&oppNum=RFA-MH-22-292)</u> Workspace to prepare and submit your application and <u>eRA Commons (/grants/guide/ApplyButtonSplash.cfm?dest=http://public.era.nih.gov/commons/)</u> to track your application.

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## Part 2. Full Text of Announcement

# Section I. Funding Opportunity Description

#### Background

Since 2014, the <u>Brain Research through Advancing Innovative Neurotechnologies</u> (BRAIN) <u>Initiative (https://braininitiative.nih.gov/)</u> has aimed to accelerate the development and application of innovative neurotechnologies, enabling researchers to produce a new dynamic picture of the brain that reveals how individual cells and complex neural circuits interact in both time and space. It is expected that these advances will ultimately lead to new ways to treat and prevent brain disorders.

As one of several federal agencies involved in the BRAIN Initiative, NIH's contributions to the BRAIN initiative were initially guided by "BRAIN 2025; A Scientific Vision (http://braininitiative.nih.gov/pdf/BRAIN2025\_508C.pdf)," a strategic plan that detailed seven high-priority research areas (https://braininitiative.nih.gov/strategic-planning/brain-priority-areas). This plan was updated and enhanced in 2019 by: "The BRAIN Initiative 2.0; From Cells to Circuits, Toward Cures (https://braininitiative.nih.gov/sites/default/files/images/brain\_2.0\_6-6-19-final\_revised10302019\_508c.pdf)." and "The BRAIN Initiative and Neuroethics: Enabling and Enhancing Neuroscience Advances for Society (https://braininitiative.nih.gov/sites/default/files/images/bns\_roadmap\_11\_october\_2019\_sent\_to\_acd\_for\_oct\_2019\_revised\_10282019\_508c.pdf)." This and other BRAIN Initiative Funding Opportunity Announcements (FOAs) are based on this vision and issued with input from Advisory Councils of the 10 NIH Institutes and Centers supporting the BRAIN Initiative (https://braininitiative.nih.gov/about/brain-partners), as assisted by the NIH BRAIN Multi-Council Working Group (https://braininitiative.nih.gov/about/multi-council-working-group).

The NIH BRAIN Initiative recognizes that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogeneous teams. There are many benefits that flow from a diverse scientific workforce, including fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved populations participate in and benefit from research, and enhancing public trust.

To support the best science, the NIH BRAIN Initiative encourages inclusivity in research. Examples of structures that promote diverse perspectives include but are not limited to:

- Transdisciplinary research projects and collaborations among neuroscientists and researchers from fields such as computational biology, physics, engineering, mathematics, computer and data sciences, as well as bioethics.
- Engagement from different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
- Individual applications and partnerships that enhance geographic and regional heterogeneity.
- Investigators and teams composed of researchers at different career stages.
- Participation of individuals from diverse backgrounds, including groups historically underrepresented in the biomedical, behavioral, and
  clinical research workforce (see NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)), such as
  underrepresented racial and ethnic groups, those with disabilities, those from disadvantaged backgrounds, and women.
- Project-based opportunities to enhance the research environment to benefit early- and mid-career investigators.

RFA-MH-22-292: BRAIN Initiative Cell Atlas Network (BICAN): Specialized Collaboratory on Human, Non-human Primate, an...

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

The BRAIN Initiative requires a high level of coordination and sharing between investigators. It is expected that BRAIN Initiative awardees will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings and in other activities such as the annual PI meeting. The data sharing expectations for BRAIN Initiative awards can be found at <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-010.html">NOT-MH-19-010.html</a>).

This FOA is related to the recommendations by the Advisory Committees to the NIH Director as described in "Priority Area 1: Discovering Diversity" and "Priority Area 2: Maps at Multiple Scales" in "BRAIN 2025 Report (https://braininitiative.nih.gov/strategic-planning/brain-2025-report)," and the transformative project, "The Human Brain Cell Atlas," in "The BRAIN Initiative 2.0: From Cells to Circuits. Toward Cures (https://braininitiative.nih.gov/sites/default/files/images/brain 2.0 6-6-19-final revised10302019 508c.pdf)."

The BRAIN Initiative cell census and atlas efforts are expected to produce a new foundational framework for analyzing brain structure and function in health and disease, with the possibility of extending the quantitative analysis to many other species to elucidate the conservation and divergence of molecular and cellular mechanisms underlying the brain function and disorders.

#### The BRAIN Initiative Cell Atlas Network (BICAN) and Goals

12/6/22, 3:00 PM

The BRAIN 2025 (https://braininitiative.nih.gov/strategic-planning/brain-2025-report) Report envisioned a systematic census of neuronal and glial cell types in multiple mammalian species. The NIH BRAIN Initiative has implemented this vision by successfully completing a 3-year pilot phase (2014-2017), followed by launching a 5-year phase 2 (2017-2022) BRAIN Initiative Cell Census Network (BICCN) with an emphasis on the mouse brain. The BICCN has applied a set of advanced single-cell approaches to characterizing molecular signatures, anatomical phenotypes, and functional properties of brain cell types, and rapidly disseminated the cell census data to the public. The BICCN is on track to complete a comprehensive cell census spanning the entire adult mouse brain, as well as to set the stage for large-scale cell atlas research in human and non-human primate (NHP) brains. Advances in single-cell transcriptomic and epigenomic profiling, anatomical mapping at cellular resolution, and other approaches have proven to be powerful and scalable. At this time, the BRAIN Initiative Cell Census program is looking to establish the BICAN to broaden and deepen the systematic cell census and atlas efforts with a new emphasis on human brain. This FOA and the companion announcements intend to establish a network of projects that will work cooperatively to:

- Generate comprehensive and high-resolution brain cell atlases that encompass molecular, anatomical, and functional annotations of brain
  cell types (neurons, glia, and other non-neuronal cells) across the lifespan in human and other species, thereby providing a framework to
  enable both basic neuroscience and brain disorders-focused research;
- Develop and use leading-edge scalable technologies and multi-modal assays to enhance the capability and capacity of large-scale brain cell census research;
- Coordinate and collaborate across and beyond the BRAIN Initiative toward establishing a broadly accessible data ecosystem for brain cell types and circuits.

The expected outcomes of the BICAN include:

- Fundamental knowledge on diverse cell types and their three-dimensional organizational principles in the brain across the lifespan and evolutionary trajectories;
- Comprehensive molecular taxonomies of brain cell types in human, non-human primates, and mouse;
- Open-access digital brain cell reference atlases of human, non-human primates, and mouse;
- Validated high throughput and low-cost approaches to characterizing brain cell diversity in human, non-human primate, and other species.

The BICAN will be made up of interactive projects with complementary roles from the following funding opportunities:

- Comprehensive Centers on Human and Non-human Primate Brain Cell Atlases (UM1; RFA-MH-21-235
   <a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-235.html">https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-235.html</a>)): The UM1 centers will have the primary responsibility for generating comprehensive and high-resolution brain cell atlas data.
- Specialized Collaboratories on Human, Non-human Primate, and Mouse Brain Cell Atlases (U01; <u>RFA-MH-21-236</u>:
   (<a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-236.html">https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-236.html</a>) <u>R01</u>; <u>RFA-MH-22-292</u>): The U01 and R01 Collaboratories will complement and enhance the UM1 Centers with distinct capabilities, competencies, and research aims in creating comprehensive and high-resolution brain cell atlases.
- Coordinating Unit for Biostatistics, Informatics, and Engagement (CUBIE) (U24; <u>RFA-MH-21-237 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-237.html)</u>): The U24 CUBIE will coordinate BICAN operation and establish common data analysis pipelines and knowledgebase of brain cell types.
- BRAIN Initiative Data Archives (R24; RFA-MH-20-600 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-20-600.html)): The R24 Data Archives will serve as BICAN data repositories and provide public access to all data and analyses generated by the BICAN.
- Sequencing Centers (RFP; NIH-NIMH-75N95022R00031 (https://sam.gov/opp/249eb6e9905b456485ffd430178917ca/view)): The
  sequencing centers will perform large-scale DNA and RNA sequencing of the libraries generated by BICAN and submit sequencing data
  to a BRAIN Initiative designated data archive.
- Scalable Technologies and Tools Projects (R01): The R01 projects will provide leading-edge scalable technologies and tools to enhance the productivity of the BICAN.

The BICAN will operate as a collaborative network to promote collaboration and coordination within and beyond the network. All projects in the BICAN will work together to achieve the common goals. In addition, the BICAN will coordinate and collaborate with external research consortia, programs, and entities (e.g., Human Cell Atlas (https://www.humancellatlas.org/), Human BioMolecular Atlas Program (https://humancellatlas.org/), Human Tumor Atlas Network (https://humantumoratlas.org/), LungMAP (https://lungmap.net/), GUDMAP

(https://www.gudmap.org/), KPMP (https://www.kpmp.org/), RBK (https://www.rebuildingakidney.org/)), which have joined interests in sharing technology know-how and developing common data and knowledge frameworks for the characterization of cell diversity in health and disease.

#### Research Objectives

This FOA seeks to support a group of Specialized Collaboratories that will complement the Comprehensive Centers with distinct capabilities, competencies, and research aims in creating brain cell atlases. The Collaboratories are expected to have a specialized focus on creating brain cell atlases in select brain regions and cell types in human, non-human primates, and mouse, or using specialized and innovative technology and assay platforms to characterize brain cell type features. Applicants are expected to propose according to their best knowledge and capabilities a set of research aims using unique assay and analysis platforms or offering distinct expertise, technologies, tools, and other approaches that may be less comprehensive in breadth than Centers but will provide greater depth of coverage and analysis for specific brain regions, brain cell types, species, and developmental stages. Successful Collaboratories will clearly distinguish themselves from existing and prior projects in their goals, tissues, assays, and personnel to maximize the capabilities of the BICAN.

Collaboratories are expected to optimize and streamline individual steps and processes of the data generation pipelines. Specifically, Collaboratories are expected to work closely together with Centers to:

- Optimize tissue processing, dissection and microdissection; coordinate sampling strategies to achieve both broad coverage of all brain cell types and deep characterization of rare cell types in order to generate anatomically annotated high granular brain cell atlases;
- · Adopt and improve scalable technology platforms and iterative assay cascade to achieve high production and cost efficiency;
- Generate large-scale molecular and anatomical data in a systematic and cost-effective manner aiming to meet Complete, Accurate, and Permanent (CAP) criteria;
- Process and rapidly share verified raw data, perform data analysis, visualization, and mapping to common coordinate systems;
- Work closely with other BICAN projects to coordinate and harmonize the data generation and analysis workflows, and establish data standards for joint analysis and publications;
- Use the brain cell atlas data to provide new insights into brain cellular organizational rules underlying brain circuits and function, individual variabilities, and changes across the lifespan.

In addition, Collaboratories are encouraged to:

 Coordinate with researchers who study brain disorders and structure/function and develop advanced technologies and tools (e.g., cell type-specific armamentarium, large-scale functional recordings, theories and models supported by the BRAIN Initiative; Human Connectome Project) to link and map molecular and anatomical atlases with brain disorders and function.

#### **Research Activities**

Examples of responsive research activities include but are not limited to the following parts:

#### 1. Data Generation

#### i. Molecular Signatures

Collaboratories are expected to produce high-resolution molecular signatures data to characterize cell heterogeneity in select species and brain regions, focusing on one or more age groups across the lifespan. The research objectives may include but are not limited to:

- · Streamlining sampling strategies for a highly granular characterization of brain cell diversity, including rare cell types at adequate depth;
- Generating single-cell transcriptome data that include coding and non-coding RNAs, and RNA isoforms;
- · Generating single-cell epigenome data that include chromatin accessibility, chromatin conformation, DNA methylation;
- · Generating spatially- and anatomically-defined single-cell omics (transcriptomics, epigenomics, proteomics, metabolomics, etc.) data;
- Generating multi-modal and multi-omics data at both single-cell and bulk levels as appropriate to allow quantification and mapping of gene expression, gene regulatory elements, and QTLs (quantitative trait loci) to individual cell types;
- Determining tissue composition and the ratio of various cell types (e.g., neurons, glial cells, vascular cells, immune cells, progenitor cells)
  and their variations across individuals and/or the lifespan.

#### ii. Anatomical Phenotypes

Collaboratories are expected to produce spatial and anatomical cell atlas data to characterize cell diversity in the brain, focusing on one or more age groups. The research objectives may include but are not limited to:

- · Generating immunohistochemistry and immunocytochemistry data by developing and using validated protein affinity reagents;
- Generating histological data using Nissl, H&E (hematoxylin and eosin), and other staining and labeling approaches, established dyes, molecular probes, and tissue processing methods;
- Generating multimodal and multiscale imaging data to quantify and map individual variability;
- Characterizing cell spatial location and morphology (e.g., cell size, shape, neurite arborization);
- Characterizing cellular microenvironment, tissue composition, myelin density, spatial location and ratio of various cell types, and cellular components (e.g., neurons, glial cells, vascular cells, immune cells, progenitor cells, synapses, spines, stroma);
- · Characterizing long- and short-distance neuronal arborizations and synaptic contacts;
- Determining intra-, inter- and extra-cellular organizational features and their variations across individuals and/or the lifespan.

## iii. Functional Characterization and Brain Cell Atlas Use Cases

Collaboratories may perform focused and integrative brain cell functional studies linking molecular and anatomical cell types to circuits and function, and/or propose use case research to facilitate the adoption of the reference cell atlases in functional and brain disorders' research:

 Generating multi-modal electrophysiological, functional imaging, molecular, and anatomical data combining with cell type-specific access and manipulation approaches; Collaborating with NIH Institutes and Centers (ICs) and cross-IC brain research programs (such as IC disease research centers, <u>Áccelerating Medicines Partnership (AMPs) (https://www.nih.gov/research-training/accelerating-medicines-partnership-amp#:~:text=Launched%20in%202014%2C%20the%20Accelerating.transform%20the%20current%20model%20for), PsychENCODE (<a href="https://psychencodestg.wpengine.com/">https://psychencodestg.wpengine.com/</a>), NIMH Convergent Neuroscience, <a href="https://psychen.codestg.wpengine.com/">HEAL (https://psychen.codestg.wpengine.com/</a>), NIMH Convergent Neuroscience, <a href="https://psychen.codestg.wpengine.com/">HEAL (https://psychen.codestg.wpengine.com/</a>), NIMH Convergent Neuroscience, <a href="https://psychen.codestg.wpengine.com/">HEAL (https://psychen.codestg.wpengine.com/</a>), Developmental GTEx (https://www.genome.gov/Funded-Programs-Projects/Developmental-Genotype-Tissue-Expression">https://psychencodestg.wpengine.com/</a>), Developmental GTEx (https://www.genome.gov/Funded-Programs-Projects/Developmental-Genotype-Tissue-Expression</a>)) to identify and map Genetic risk variants and QTLs (quantitative traits locus) to cell types and circuits.</u>

#### 2. Data Analysis and Management

Central to the goals of the BICAN is the construction of searchable high-resolution 2D and 3D reference brain atlases containing molecular, cellular, anatomical, functional, and brain lifespan data. The research objectives may include but are not limited to:

- Developing computational tools and performing biostatistical research that will facilitate the construction of brain cell atlases through the
  modeling and visualization of multi-modal datasets from imaging and omics assays;
- Providing central data storage, data management, and information security services to all researchers within the project, and timely submission of data to the BRAIN Data Archives for public release;
- Working together with other projects of BICAN, CUBIE, and the Data Archives to establish data and metadata standards, ontology, and Common Coordinate Systems that will map and link multi-scale, multi-modal, and multi-species cell atlas data.

The brain cell census and atlas data will be an important and unique resource for use by the broader research community, and thus applicants are expected to address the following issues related to large-scale data production and analysis and the BICAN operation as a whole.

Common Coordinate Systems. The BRAIN Initiative embraces the existing efforts of the research community to collaboratively build atlases with broadly accessible common coordinate systems to integrate and disseminate the brain cell atlas and census data in order to enable cross-modality, cross-scale, and cross-species data integration, as well as to facilitate the analysis of individual variability and the transfer of information and knowledge between basic and clinical or structural and functional studies. Applicants may describe how imaging-based cell atlas data will be registered to common coordinate systems, which include *in situ* hybridization, immunohistochemistry, cell morphology, neuronal connectivity mapping, and functional cell imaging. In case non-imaging based approaches are used, applicants may propose how to spatially assign the data to the brain regions as accurately as possible.

Data Quality and Reproducibility. Two of the cornerstones of science advancement are rigor in designing and performing scientific research and the <u>ability to reproduce (//grants.nih.gov/reproducibility/index.htm)</u> biomedical research findings. Data reproducibility is especially important in view of the inherent biological variation and expected technical noise. The BICAN will strive to quantify and benchmark variabilities throughout the data generation and analysis pipelines, and establish and disseminate data and metadata standards. Applicants are expected to develop and establish stringent data quality control and quality assurance processes for sample and data processing and assay and statistical approaches, to ensure that the data generated will be broadly referenced and used by the research community.

Assay Sampling Plan. Applicants are expected to provide a detailed Assay Sampling Plan describing the sampling strategy and workflow and to address the level of granularity and resolution that will be achieved in anatomically distinct brain regions. The Assay Sampling Plan is expected to list the assays to be performed and the numbers of samples (e.g., brain structures/regions, cells, species, sex, age groups/developmental stages, ancestry, etc.) to be analyzed, and describe the iterative assay design. At the beginning of the project, awardees will be expected to share the Assay Sampling Plan with other BICAN projects to coordinate, harmonize and develop an overall BICAN brain Assay Sampling Plan.

Data Open Access and Rapid Sharing. The broad use of reference brain cell census and atlas data will be facilitated by data open access and rapid sharing of data and preprints. Rapid sharing of verified raw data and data analysis has played a critical role for the BICCN in enhancing research rigor and data reproducibility, cross validating assay technologies, and facilitating joint analysis and joint publications. BICAN projects are expected to abide by the agreed data and resource sharing policy and public release timeline to ensure unhindered data and resource exchange and sharing.

Data Production and Cost Efficiency. The numbers of brains, regions, and cells in study may be constrained by experimental materials and supplies costs. Collaboratories are expected to attain a high level of production at an affordable cost by adopting scalable technology platforms and streamlined workflows. Collaboratories are expected to establish adequate process control with quantitative quality metrics at key points in the production workflow, and have plans to improve production workflow and cost efficiency. Costs associated with single-cell genomics are currently driven by those of commercial library construction kits and DNA sequencing. Applicants are expected to provide a detailed brain Assay Sampling Plan and itemized data production goals consistent with the requested funds. Given the pace of technology innovation, the sequencing and commercial reagents costs are expected to decrease with time (see <a href="https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost">https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost</a>)). Collaboratories are expected to address cost adaptability and flexibility of data production pipelines during the project years, and adjust data production milestones accordingly as a result of the reduction of the sequencing, commercial reagents, and other costs.

#### Milestones

The success of the Collaboratory will be facilitated by the adoption of clear, quantitative milestones with realistic and efficient timelines. Applications to this FOA must include annual milestones with metrics that will document progress towards the achievement of the specific aims. Applications that fail to include annual milestones will be considered incomplete and will be withdrawn before review. At the beginning of the project, joint overall data production and analysis milestones will be coordinated and established across BICAN projects. During the project period, the awardees will be expected to refer to these milestones in progress reports. The funding institute will use the milestones and other measures of productivity and success to evaluate the progress, impact, and value of the program, and modify the milestones accordingly.

#### Plan for Enhancing Diverse Perspectives (PEDP)

This FOA requires a Plan for Enhancing Diverse Perspectives (PEDP) as part of the application (see further below). Applicants are strongly encouraged to read the FOA instructions carefully and view the available <u>PEDP guidance material (https://braininitiative.nih.gov/about/plan-</u>

enhancing-diverse-perspectives-pedp). Applications must include a Plan for Enhancing Diverse Perspectives (PEDP) submitted as Other Project Information as an attachment (see Section IV). The PEDP will be assessed as part of the scientific and technical peer review evaluation, as well as considered among programmatic matters with respect to funding decisions.

### Applications Not Responsive to this FOA

Proposed research that is not responsive to this FOA and will not be reviewed includes the following:

- Studies of dissociated cultured cells, and/or stem cell-derived lines and organoids;
- · Early-stage technology development. Note: Applications for the early-stage technology development may be submitted in response to other separate BRAIN FOAs ( RFA-MH-21-175 (https://grants.nih.gov/grants/guide/ffa-files/RFA-MH-21-175.html), RFA-MH-21-180 (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-180.html), and their reissuances) that support development and validation of novel tools to analyze cell-specific and circuit-specific processes in the brain.

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

## Section II. Award Information

#### **Funding Instrument**

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

#### **Application Types Allowed**

New

Resubmission

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. Only those application types listed here are allowed for this FOA.

#### 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

Issuing IC and partner components intend to commit an estimated total of \$6M per fiscal year to fund 4-8 Specialized Collaboratories.

#### **Award Budget**

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

#### **Award Project Period**

The maximum project period is 3 years.

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

## Section III. Eligibility Information

#### 1. Eligible Applicants

#### **Eligible Organizations**

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

#### For-Profit Organizations

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

#### Local 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)

### Federal Government including the NIH Intramural Program

- · Eligible Agencies of the Federal Government
- · U.S. Territory or Possession

#### Other

- · Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- · Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

## Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) are eligible to apply.

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

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

#### **Required Registrations**

#### **Applicant Organizations**

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

- System for Award Management (SAM)— (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=82390) Applicants must complete and
  maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial
  registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations
  which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url redirect.htm?id=11176) Foreign
    organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
  - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all
    registrations, as well as on the grant application.
- <u>eRA Commons (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=11.123)</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82300) Applicants must have an active 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 diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for

12/6/22, 3:00 PM RFA-MH-22-292: BRAIN Initiative Cell Atlas Network (BICAN): Specialized Collaboratory on Human, Non-human Primate, an...

NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

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

#### 2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url\_redirect.htm? ig=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, per 2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section 2/2.3.7 policies affecting applications.htm#Submissi). 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 2.3.9.4 Similar. Essentially Identical, or Identical Applications
   <a href="https://grants.nih.gov/grants/policy/nihgps/HTML5/section-2/2.3.9">https://grants.nih.gov/grants/policy/nihgps/HTML5/section-2/2.3.9</a> application receipt information and deadlines.htm#Similar.))

## Section IV. Application and Submission Information

## 1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in <a href="Part 1">Part 1</a> of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

## 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the <u>SF424 (R&R) Application Guide</u> (<a href="https://grants.nih.gov/grants/guide/url\_redirect.htm?id=82400">https://grants.nih.gov/grants/guide/url\_redirect.htm?id=82400</a>) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

#### Letter of Intent

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

By the date listed in <u>Part 1. Overview Information</u>, prospective applicants are asked to submit a letter of intent that includes the following information:

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

The letter of intent should be sent to:

Email: nimhpeerreview@mail.nih.gov (mailto:nimhpeerreview@mail.nih.gov)

#### **Page Limitations**

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

#### Instructions for Application Submission

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

#### SF424(R&R) Cover

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

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

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

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## SF424(R&R) Other Project Information

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

#### Other Attachments:

#### Plan for Enhancing Diverse Perspectives (PEDP)

In an "Other Attachment" entitled "Plan for Enhancing Diverse Perspectives," all applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity. The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application and can incorporate elements with relevance to any review criteria (significance, investigator(s), innovation, approach, and environment) as appropriate. Where possible, applicant(s) should align their description with these required elements within the research strategy section. The PEDP will vary depending on the scientific aims, expertise required, the environment and performance site(s), as well as how the project aims are structured. The PEDP may be no more than 1-page in length and should include a timeline and milestones for relevant components that will be considered as part of the review. Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:

- Discussion of engagement with different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
- · Description of any planned partnerships that may enhance geographic and regional diversity.
- Plan to enhance recruiting of women and individuals from groups historically under-represented in the biomedical, behavioral, and clinical research workforce.
- Proposed monitoring activities to identify and measure PEDP progress benchmarks.
- Plan to utilize the project infrastructure (i.e., research and structure) to support career-enhancing research opportunities for diverse junior, early- and mid-career researchers.
- Description of any training and/or mentoring opportunities available to encourage participation of students, postdoctoral researchers and co-investigators from diverse backgrounds.
- Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
- Publication plan that enumerates planned manuscripts and proposed lead authorship.
- Outreach and planned engagement activities to enhance recruitment of individuals from diverse groups as research participants including those from under-represented backgrounds.

For further information on the Plan for Enhancing Diverse Perspectives (PEDP), please see <a href="https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp">https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp</a>).

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

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

#### R&R or Modular Budget

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

Applications are expected to describe major data production cost items (e.g., assay reagents, sequencing) at the beginning of the project and then describe anticipated cost reductions during the project period with a cost model incorporating a standardized cost structure including a useful unit (e.g., per experiment or per cell characterized) and identifying large-cost items that dominate the cost model.

#### Brain Cell Census Assay Reagents Costs:

The use of Brain Cell Assay Reagents in research is generally procured from an external source utilizing a purchase order by the applicant institution with the analysis undertaken by the applicant institution either utilizing the staff of the requested project or by a specialized service center. The appropriate budgeting and costing for the procurement and use of these Brain Cell Assay Reagents is addressed below:

For purposes of budgeting and accounting for high volume purchases of Brain Cell Assay Reagents in excess of \$50,000 per year, the standard treatment of these resources as supplies in determining the F&A base of an award will be non-applicable. Instead, the requested and reimbursed costs for Brain Cell Assay Reagents will utilize as a surrogate the concept of subcontracts (consortium/contractual cost). Therefore for each budget year, the first \$50,000 of Brain Cell Assay Reagents will be treated as "supplies", and any Brain Cell Assay Reagents in excess of \$50,000 (for high volume requirements) will use as a surrogate the budgeting and reimbursement concept utilized for subcontracts (consortium/contractual cost), providing consistent budgeting, accounting and reimbursement of these costs.

#### **DNA Sequencing Costs:**

For award applications that propose to use DNA sequencing service for omics data production, sequencing costs should be included in the budget request. If a sequencing contract is established during the project period, sequencing costs may be consolidated, shared, or eliminated depending on the needs of the BICAN projects.

#### **BICAN Semi-annual In-person Meeting Costs:**

Applications should budget for ccsts to participate in semi-annual in-person BICAN meetings.

## PEDP implementation costs:

Applicants may include allowable costs associated with PEDP implementation (as outlined in the Grants Policy Statement section 7: <a href="https://grants.nih.gov/grants/policy/nihgps/html5/section-7/7.1\_general.htm">https://grants.nih.gov/grants/policy/nihgps/html5/section-7/7.1\_general.htm</a>).

#### **R&R Subaward Budget**

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

#### PHS 398 Cover Page Supplement

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

## PHS 398 Research Plan

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

#### Specific Aims

Describe the scientific and data and resource production goals of the proposed research program, and state in priority order the aims of the Collaboratory to generate brain cell census and atlas (molecular, anatomical, and/or functional) data toward the overall goal of a high resolution brain cell atlas.

#### Research Strategy:

In addition to the information requested in the application guide, the applicants should also address the following parts including: 1. Data Generation, 2. Data Analysis and Management, and 3. Milestones.

- 1. The Data Generation part includes the research activities under the following three research segments: (i) Molecular Signatures, (ii) Anatomical Phenotypes, and (iii) Functional Characterization and Brain Cell Atlas Use Cases. Applications are expected to:
  - Describe the data and resource to be generated and research theme(s);
  - Provide a detailed Assay Sampling Plan that will be shared across the BICAN if funded, listing the assays to be performed, the numbers
    of samples (e.g., brain structures/regions, cell types, species, sex, age groups/developmental stages, ancestry) to be analyzed, and the
    iterative assay design;
  - Describe currently existing cell census and atlas datasets and the state-of-the art approaches used;
  - State the general issues, gaps, and challenges in the relevant cell census/atlas research;
  - Define "breadth and depth" for the proposed project, describing cell sampling strategy and supporting data, and how to create highly granular and high-resolution brain cell atlases for each data type being investigated;
  - Explain how the proposed research segments will contribute uniquely to the overall research aims of the project and the overarching BICAN goals:
  - Propose experimental design to ensure the data generated are rich in content and spatially annotated in a common brain coordinate framework for the dissemination and use by the broad research community;
  - Describe scalable methods with preliminary data and case studies to support their feasibility of generate high-quality data in cost-effective manner;
  - · Provide current estimates of data quality and plans for how data quality will be evaluated during the course of the project;
  - Describe how to optimize experimental procedures to reduce technical noise and enhance data quality;
  - Describe production workflow including throughput as well as rate-limiting steps, and provide plans for assessing and improving the
    pipeline;
  - Describe quality control/quality assurance measures and decision making process;
  - Describe innovative aspects including the generation of novel datasets and tools.
- 2. The Data Analysis and Management part is expected to:
  - Describe database infrastructure, information management and monitoring, management of multimodality data, statistical analysis and
    inference of biological mechanisms, data integration and registration to a common brain coordinate system, and computational modeling if
    appropriate;
  - Propose and justify data/metadata formats and standards to be used while demonstrating flexibility for adopting different ones once the BICAN is formed:
  - Propose data analysis methods and procedures including analysis algorithms and data hierarchy;
  - Provide statistical rationale about data quality and informatics analysis about data novelty;
  - List and define the data/metadata that have been established by the BICCN projects to ensure seamless and efficient continuous
    operation; and
  - For shared data, propose when it will be made available and how others will be able to find, access, and reuse it. Note that BICAN
    projects will be required to share data in accordance with agreed-upon BICAN sharing policy and standards consistent with achieving the
    goals of the program.
- 3. Milestones. For each approach, clear, quantitative outcomes should be set and described. Annual milestones should reflect the current ability to produce data from the beginning of the project, and include plans for critically evaluating and revising these milestones on a regular basis. Year 1 milestones will include planning and defining the Assay Sampling Plan and workflow harmonization across BICAN, which should be communicated in these milestones. The milestones should be regarded as criteria for evaluating the progress and direction of the project and should not be just a restatement of the specific aims. Applications are required to describe in the Research Strategy section the annual milestones providing specific and quantitative items, which include but are not limited to:
  - Target number of attempted experiments (define "experiment" as it relates to the proposed method(s), including informatics);
  - Target number of verified experiments (a practical definition for "verification" is when a dataset has been demonstrated to be of sufficient
    quality to merit follow-up experiments and for public release);
  - Target number of cells, brain regions, samples, and/or experimental conditions tested;
  - Target number of probes and/or antibodies generated and validated (if applicable);
  - Product (data or tool) quality as measured by characterization experiments and use of relevant data or tool standards;

Production efficiency and cost effectiveness as measured by throughput and cost per experiment, including informatics.

Letters of Support: Include letters of support/agreement for any collaborative/cooperative arrangements, subcontracts, or consultants.

The applications are expected to include written statements from the officials responsible for intellectual property issues at all of the applicant institutions (including subcontractors) to the effect that the institution supports and agrees to abide by the resource sharing plans put forth in the application if applicable. Such letters would be clear expressions of commitment. A separate letter should be sent by each participating organization, including each subcontractor. Please note that institutional sign-off on the grant application signifies that all relevant components of the institution, including the relevant office handling intellectual property matters have reviewed and approved the document.

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

The following modifications also apply:

· All applications, regardless of the amount of direct costs requested for any one year, must address a Data Sharing Plan. The data sharing expectations for BRAIN Initiative awards can be found at NOT-MH-19-010 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-010.html).

A central goal of this FOA is to build up a comprehensive brain cell atlas data resource that will be widely used throughout the research community for further advancing research. It will take the combined resources of researchers in the public and private sectors many years to catalog and characterize the biology of brain cells, neuronal connectivity of interest, to understand brain function, and then to use that information to further the study of neurobiology and to improve public health. The open sharing of the brain census data, research tools, and resources will not only lead more rapidly to their broad use by the research community, but also encourage scientific rigor in data production and analysis, with resulting benefits to public health. In order to reap the maximum value from this program, all molecular, anatomical, and physiological data, experimental protocols, tools generated are expected to be made publicly available. Applications must include a detailed plan for sharing data and resources and include the following key elements:

- · Project management of data and resource sharing;
- A summary of what specific data and resources will be shared;
- Schedule/timeline for sharing the data and resources;
- · Archives and repositories that will house the data and other resources;
- · A description of data standards to use and/or to develop.

Data and Data Analysis Sharing. Applicants must provide a specific proposal for data sharing in the application, and address the issues related to the public release of data and data analyses (see the rationale for Findability, Accessibility, Interoperability, and Reusability (FAIR) Data Principles (https://www.go-fair.org/fair-principles/)). NIH BRAIN Initiative Cell Census program is also committed to the timely release of open source software and data analyses including models, tools, analytic workflows, and user manuals. Applicants are expected to propose open dissemination of computational methods, software, and tools for unrestricted redistribution and modification. After the initial peer review, the BRAIN Initiative program staff will be responsible for any additional administrative review of the sharing plan and may negotiate modifications of the sharing plan with the prospective awardee prior to award. The final negotiated version of the sharing plan will become a term and condition of the award of the cooperative agreement. After all of the awards have been made, the BICAN Steering Committee, of which all awardees will be members, will develop a final, common data and resource release plan as appropriate for the project that will address the interests of the data producers and analysts, as well as the users of the BICAN brain cell census/atlas datasets. Applicants should indicate their willingness to participate in the development of such a final plan and to accept it. The NIH expects that verified raw data will be submitted "in real time" or other agreed-upon timeframe depending on the data types and verification requirements to BRAIN Initiative data archives or other long-term publicly accessible archives such as GEO or others as appropriate. Agreement to abide by the data and data analysis sharing policy is a requirement for anyone to join the BICAN.

Resource Sharing. Resources generated by the BICAN projects should be made rapidly available to the research community, which include assay protocols, technology platforms, tools, reagents, user manuals, and preprints. Rapid dissemination of these resources would accelerate scientific exploration and avoid duplicative resource development effort. The applicant should provide specific plans for resource sharing and distribution via repositories such as protocols.io, Addgene, GitHub, bioRxiv, or other open repositories in the application. After the initial peer review, the BRAIN Initiative program staff will be responsible for any additional administrative review of the plan for sharing resources and may negotiate modifications of the resource sharing plan with the prospective awardee prior to award. The final negotiated version of the resource sharing plan will become a term and condition of the award of the cooperative agreement.

### Appendix:

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

## PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

**Delayed Onset Study** 

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

## PHS Assignment Request Form

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

## Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm? id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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

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

### 4. Submission Dates and Times

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

Organizations must submit applications to <u>Grants.gov (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11128)</u> (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the <u>eRA Commons (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=11123)</u>, 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/policy/nihgps/html5/section 10/10.10.1 executive orders.htm)

### 6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the <a href="https://examts.nih.gov/grants/guide/url-redirect.htm?id=11120">NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url-redirect.htm?id=11120)</a>.

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

## 7. Other Submission Requirements and Information

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

Applicants must complete all required registrations before the application due date. <u>Section III. Eligibility Information</u> contains information about registration.

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

#### Important reminders:

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

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

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

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

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Applications must include annual milestones. Applications that fail to include annual milestones will be considered incomplete and will be withdrawn. Applications must include a PEDP submitted as Other Project Information as an attachment. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn before review.

## 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 <a href="mailto:the-policy">the policy</a>. (//grants.nih.gov/grants/guide/url redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

## Section V. Application Review Information

#### 1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

Since this FOA specifically seeks applications to systematically generate brain cell census and atlas data and possibly related tools, the NIH expects that some applications may propose mature and well-established approaches to produce robust high quality datasets for broad use by the research community.

#### **Overall Impact**

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

#### Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

#### Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA:

How well do the proposed aims and scientific questions align with the overarching goals and the expected outcomes of the BICAN? To what extent do the efforts described in the Plan for Enhancing Diverse Perspectives further the significance of the project?

### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

Specific to this FOA:

Are the PD/PI and other key personnel devoting sufficient time/effort to achieve the goals? To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required for the project?

#### Innovation

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

Specific to this FOA:

How well does the application describe evidence that demonstrates the novelty of cell atlas and census data to be generated? To what extent will the novel data lead to transformative, paradigm-shifting advances of the field? To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation?

#### Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Specific to this FOA:

- For projects involving the use of human brain tissue, how well does the application describe and discuss Human Brain Specimen Acquisition, Processing, and Characterization? Is the proposed plan likely to result in high quality brain specimens suitable for the proposed analyses?
- How well does the application describe and discuss the data quality and reproducibility, and data breadth and depth? Does the Assay Sampling Plan provide adequate details? Are potential pitfalls clearly discussed and minimized accordingly?
- How well does the application provide a rationale and supporting data on the adequacy of the cell sampling strategy? Will
  experimental designs result in high-resolution cell atlas and cell census data?
- How well does the application present preliminary data to support feasibility of the proposed scalable methods and adequate throughput? Are rate-limiting steps identified and appropriately addressed?
- How well does the application demonstrate an effective workflow? Does the adequately application describe workflow assessments and proposed improvements?
- Does the application demonstrate the capability to generate data at scale? Does the application provide sufficient evidence of how
  production goals are set and can be attained?
- How well does the application describe data management, modeling, analysis, visualization, and integration? Is the plan for data
  registration to a brain atlas and/or common brain coordinate system adequate? Does the application adequatelypropose and justify
  standards and formats of the data/metadata, data analysis methods? Are there appropriate data infrastructure(s) and pipeline(s) to
  support data sharing?
- How well does the Data Sharing Plan provide a summary of the shared data, a description of the data standards, a plan for the data archiving, and a timeline for data submission to the archive and sharing data with the research community?
- How well does the Resource Sharing Plan provide a summary of the shared resources, a plan for the resource dissemination via open repositories, and a timeline for sharing the resources with the research community?
- Are the timeline and milestones associated with the Plan for Enhancing Diverse Perspectives well-developed and feasible?

#### 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?

To what extent will features of the environment described in the Plan for Enhancing Diverse Perspectives (e.g., collaborative arrangements, geographic diversity, institutional support) contribute to the success of the project?

#### **Additional Review Criteria**

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

#### Milestones

Are the milestones and timelines sufficiently clear, quantitative, and actionable? Do the milestones provide proper criteria for evaluating the progress and direction of the proposed research? How thorough and appropriate are the plans for critically evaluating and revising milestones on a regular basis? How feasible are the timelines proposed for achieving the milestones?

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

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their

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participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

## Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the <a href="Guidelines for the Review of Inclusion in Clinical Research (I//grants.nih.gov/grants/guide/url\_redirect.htm?id=11174).">Guidelines for the Review of Inclusion in Clinical Research (I//grants.nih.gov/grants/guide/url\_redirect.htm?id=11174).</a>

#### **Vertebrate Animals**

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

#### **Biohazards**

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

#### Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project

#### Renewals

Not Applicable

#### Revisions

Not Applicable

## **Additional Review Considerations**

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

#### **Applications from Foreign Organizations**

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

## Select Agent Research

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

#### Resource Sharing Plans

Not Applicable

## 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 NIMH, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#\_1. Criteria).

Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

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.

Aqueals (https://grants.nih.gov/grants/policy/nihgps/html5/section 2/2.4.2 appeals of initial scientific review.htm) 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.
- Programmatic balance. The purpose is to develop a network with complementary capabilities towards generating a comprehensive brain cell atlas. Therefore, decisions about awards will consider the mix of capabilities offered by the proposed centers and collaboratories.
- Relevance of the proposed project to program priorities including the PEDP.

#### 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 <u>eRA Commons (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=11123)</u>. 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 <u>NIH Grants Policy Statement</u> (<u>//grants.nih.gov/grants/guide/url\_redirect.htm?id=11120</u>).

## Section VI. Award Administration Information

#### 1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section 2/2.5.1 just-in-time procedures.htm).

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 recipient's business official.

Recipients 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 <u>Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part\_ii\_subpart\_b.htm)</u> website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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

#### 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, Recipients, and Activities (//grants.nih.gov/grants/guide/url redirect.htm? id=11159), including of note, but not limited to:

- Federalwide Research Terms and Conditions
  (https://grants.nih.gov/grants/policy/nihgps/HTML5/section 3/3.1 federalwide standard terms and conditions for research grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.2.1 acknowledgement of federal funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <a href="https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html">https://www.hhs.gov/civil-rights/for-providers/providers/provider-obligations/index.html</a> (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

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.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting
  the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals
  see <a href="https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html">https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html</a>
  (<a href="https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html">https://www.lep.gov/(index.html)</a>) and <a href="https://www.lep.gov/(https://www.lep.gov/)</a>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see <a href="http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html">http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html</a>).
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see
   <a href="https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html">https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html</a> (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <a href="https://grants.nih.gov/grants/policy/harassment.htm">https://grants.nih.gov/grants/policy/harassment.htm</a> (https://grants.nih.gov/grants/policy/harassment.htm).
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see <a href="https://www.hhs.gov/conscience/conscience-protections/index.html">https://www.hhs.gov/conscience/conscience-protections/index.html</a> (https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <a href="https://www.hhs.gov/ocr/about-us/contact-us/index.html">https://www.hhs.gov/ocr/about-us/contact-us/index.html</a> or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

# Cooperative Agreement Terms and Conditions of Award Not Applicable

#### 3. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section\_8/8.4.1\_reporting.htm)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section 8/8.6 closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

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

(https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1.8 federal funding accountability and transparency act flata .htm) for additional information on this reporting requirement.

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

## Section VII. Agency Contacts

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

#### **Application Submission Contacts**

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

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

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

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

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

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National Institute of Mental Health (NIMH)

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Email: yyao@mail.nih.gov (mailto:yyao@mail.nih.gov)

#### Peer Review Contact(s)

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National Institute of Mental Health (NIMH)

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

Heather Weiss

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

Telephone: 301-443-4415

Email: heather.weiss@nih.gov (mailto:heather.weiss@nih.gov)

## Section VIII. Other Information

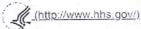
Recently issued trans-NIH <u>policy notices (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11163)</u> may affect your application submission. A full list of policy notices published by NIH is provided in the <u>NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11164)</u>. All awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11120)</u>.

#### **Authority and Regulations**

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?10-07-22)
NIH Funding Opportunities and Notices (/grants/guide/index.html)





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

USA.gov (http://www.usa.gov/)

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

## ขั้นตอนการสมัครขอรับทุน National Institute of Health (NIH)

Name:

Surname:

Email (XXXX@mahidol.ac.th หรือ XXXX@mahidol.edu):

Funding Opportunity Announcement (FOA) Number:

Application title:

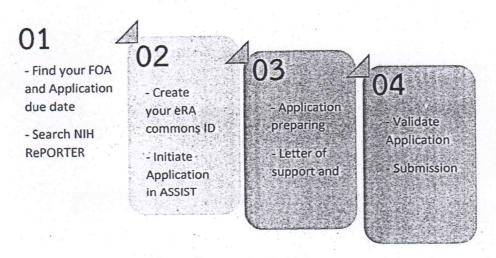
Application due date:

2. ผู้สมัครขอรับทุนศึกษาประกาศทุน (Funding opportunity announcements หรือ FOA) อย่างละเอียด ตรวจสอบกำหนดการส่งข้อเสนอของมหาวิทยาลัย และสืบค้นข้อมูลที่เกี่ยวข้องกับงานวิจัยของตนเองผ่าน NIH RePORTER https://reporter.nih.gov

3. มหาวิทยาลัยสร้างบัญชี eRA commons และสร้างข้อเสนอโครงการในระบบ ASSIST ให้ผู้สมัครขอรับ ทุน ผู้ขอรับทุนจัดทำข้อเสนอโครงการและเอกสารที่เกี่ยวข้องตามข้อกำหนดของแหล่งทุนร่วมกับ มหาวิทยาลัย

4. ผู้สมัครขอรับทุนนำส่งเอกสารข้อเสนอโครงการฉบับสมบูรณ์ผ่านหัวหน้าส่วนงาน พื่อขออนุมัติจัดส่ง ข้อเสนอโครงการผ่านระบบออนไลน์ ASSIST ตามกำหนดรับข้อเสนอของมหาวิทยาลัย\*\* กองบริหาร งานวิจัยตรวจสอบข้อเสนอโครงการ เสนออนุมัตินำส่งข้อเสนอโครงการและจัดส่งข้อเสนอโครงการในนาม ของมหาวิทยาลัยไปยังแหล่งทุน

(\*\*หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าซ้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)



สอบถามข้อมูลเพิ่มเติม คุณจิตติพร 02-8496252 <u>chittiporn.nua@mahidol.edu</u> หน่วยสนับสนุนการขอทุนวิจัยจากแหล่งทุนต่างประเทศ Mahidol University: Supporting Unit for International Research Funding (MU: SURF)