-ตรวจสอบ+ARC-

MUSIS

งานบริหารงานวิจัยและนวัตกรรม
เลขที่รับ 863
วันที่ 14/12/65
เวลา

รหัสแฟ้ม.....
เก็บเอกสารถึงปี พ.ศ.....

คณะเภสัชศาสตร์
เลขที่รับ 6980
วันที่ 9 ธ.ค. 2565
เวลา 9:45 น.

งานบริหารและส่งเสริมการวิจัย
กองบริหารงานวิจัย มหาวิทยาลัยมหิดล
โทร. 02-849-6252 โทรสาร. 02-849-6247

ที่ อว 78.016/ว 6980
วันที่ 8 ธันวาคม 2565
เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการ จากแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project Grant รอบ Cycle I/2023 หัวข้อ "Engineering Next-Generation Human Nervous System Microphysiological Systems (R01 Clinical Trials Not Allowed)" หมายเลขประกาศทุน PAR-23-046

สิ่งที่ส่งมาด้วย 1. รายละเอียดประกาศทุน PAR-23-046
2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project Grant รอบ Cycle I/2023 หัวข้อ "Engineering Next-Generation Human Nervous System Microphysiological Systems (R01 Clinical Trials Not Allowed)" หมายเลขประกาศทุน PAR-23-046 **โดยเปิดรับข้อเสนอโครงการตั้งแต่วันที่ 5 มกราคม 2566 จนถึงวันที่ 5 กุมภาพันธ์ 2566 เวลา 17.00 น. ตามเวลาประเทศไทย** ทั้งนี้ โครงการที่เสนอขอทุนให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดล เรื่องหลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงานที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 และขอให้ดำเนินการตามที่ระบุในหนังสือชักชวนแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารแนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่ง https://grants.nih.gov/grants/guide/pa-files/par-23-046.html

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย **โปรดแจ้งความประสงค์การจัดส่งข้อเสนอ ภายในวันที่ 5 มกราคม 2566 และจัดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบูรณ์ภายในวันที่ 27 มกราคม 2566 ทั้งนี้ หากส่วนงานแจ้งความประสงค์การจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 27 มกราคม 2566 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว**

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

งานบริหารงานวิจัยและนวัตกรรม
พิสูจน์
9 ธ.ค. 65

เรียน คณบดี (เพื่อโปรดทราบ)
- เพื่อโปรดทราบ NIH เปิดรับข้อเสนอทุน #PAR-23-046 โดยมีหัวข้อตามที่ปรากฏในหนังสือนี้ และรายละเอียดตามเอกสารที่แนบ
ผู้สนใจเสนอขอทุนโปรดแจ้งความประสงค์ ภายใน 5 ม.ค. 2566 และจัดส่ง proposal ผ่านงานบริหารงานวิจัยฯ คณะเภสัชฯ ภายใน 26 ม.ค. 2566 เพื่อจัดส่งมหาวิทยาลัยพิจารณาต่อไป.
- สำเนาถึงหัวหน้าทุกภาควิชา
- ต้นเรื่องงานบริหารงานวิจัยฯ

9 ธ.ค. 65

(ศาสตราจารย์ ดร. นายแพทย์ ภัทรชัย กีรติสิน)
รองอธิการบดีฝ่ายวิจัย

ทราบ
14/ธ.ค./65

13/12/65

ผู้ประสานงาน : นางสาวจิตติพร นวลละออง
โทร 02-849-6252 อีเมล chittiporn.nua@mahidol.edu

รับร่องคืนจากห้องคณบดี+รองคณบดี
วันที่ 14 ธ.ค. 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 on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

Funding Opportunity Title

Engineering Next-Generation Human Nervous System Microphysiological Systems (R01 Clinical Trials 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 PAR-20-055 (https://grants.nih.gov/grants/guide/pa-files/PAR-20-055.html)

Related Notices

NOT-OD-22-195 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-195.html) New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html) Implementation Details for the NIH Data Management and Sharing Policy

NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html) Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023

NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available

Funding Opportunity Announcement (FOA) Number

PAR-23-046

Companion Funding Opportunity

PAR-23-047 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-047.html), R21 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R21&&Search.x=0&&Search.y=0&&Search_Type=Activity) Exploratory/Developmental Grants

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.242, 93.866, 93.173, 93.867, 93.273

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) encourages research grant applications directed toward developing next-generation human cell-derived microphysiological systems (MPS) and related assays that replicate complex nervous system architectures and physiology with improved fidelity over current capabilities. Supported projects will be expected to enable future studies of complex nervous system development, function, and aging in healthy and disease states.

This FOA is intended to encourage the further development of projects with feasibility support for the line of investigation. Applicants proposing exploratory research at the early and conceptual stages of project development may instead wish to apply to the companion R21 FOA (PAR-23-047 (https://grants.nih.gov/grants/guide/pa-files/PAR-23-047.html)).

Key Dates

Posted Date

November 10, 2022

Open Date (Earliest Submission Date)

January 05, 2023

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH standard due dates (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 05, 2023 *	March 05, 2023 *	May 07, 2023 *	July 2023	October 2023	December 2023
June 05, 2023 *	July 05, 2023 *	September 07, 2023 *	November 2023	January 2024	April 2024
October 05, 2023 *	November 05, 2023 *	January 07, 2024 *	March 2024	May 2024	July 2024
February 05, 2024 *	March 05, 2024 *	May 07, 2024 *	July 2024	October 2024	December 2024
June 05, 2024 *	July 05, 2024 *	September 07, 2024 *	November 2024	January 2025	April 2025
October 05, 2024 *	November 05, 2024 *	January 07, 2025 *	March 2025	May 2025	July 2025
February 05, 2025 *	March 05, 2025 *	May 07, 2025 *	July 2025	October 2025	December 2025
June 05, 2025 *	July 05, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
October 05, 2025 *	November 05, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026

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.

Expiration Date

January 08, 2026

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 Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

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

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

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

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (/grants/guide/ApplyButtonSplash.cfm?dest=https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (/grants/guide/ApplyButtonSplash.cfm?dest=GrantsGov&oppNum=PAR-23-046) Workspace to prepare and submit your application and eRA Commons (/grants/guide/ApplyButtonSplash.cfm?dest=http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

Human cell-based assays (e.g., using induced pluripotent stem cells) hold promise for identifying molecular, cellular, and circuit defects, identifying novel targets and developing new therapeutics for patients with complex brain and other nervous system disorders. However, the methods to generate and analyze relevant cells and circuits must be made robust, replicable, and predictive for normal nervous system function as well as pathophysiology. Cells grown in monolayer culture remain a mainstay for many assays, including high-throughput screening, but a drawback of these reductionist assays is that they cannot resolve many developmental and aging trajectories, anatomical features and circuit activity representative of *in vivo* nervous system function.

As an alternative, there are increased efforts to generate assays with more physiologically-relevant organization. For example, microphysiological systems (MPS) are structured three-dimensional (3D) culture assays. One version is organoid or spheroid culture, which is a non-adherent suspension culture that relies on the self-organizing properties of stem cells in the absence of a substrate. Another type of MPS is the tissue chip, which is a multicellular structure that represents minimal units of organ function and is embedded in a non-living

microfluidic platform; this allows both efficient exposure to test compounds and efficient physiological readout. A third way to evaluate integrative cell function is by introducing human cells into another live species (known as chimeras or xenografts). While these assays currently reproduce some important features of *in vivo* prenatal development, a major unresolved technical hurdle is the application of human cell-based assays to evaluate circuit maturation, connectivity, and aging, including its relationship to specific circuits involved in disease states. Addressing this complex technical challenge requires the collaboration of experts from diverse fields, including developmental and stem cell biology, circuit and systems level neuroscience, materials science, engineering and bioethics.

Research Objectives

The purpose of this Funding Opportunity Announcement (FOA) is to stimulate basic technology-focused research to develop next-generation human cell-derived MPS and related assays with improved fidelity to complex human brain, spinal cord, and/or sensory end organ circuit physiology, which will ultimately facilitate analysis of higher order functional deficits relevant to complex nervous system diseases. This FOA is distinct from others that focus on optimization and scalability of assays for compound screening, although projects could, in principle, have utility for late stage evaluation of drug efficacy and toxicity. These models will have a multi-lineage, complex architecture representing the normal characteristics and functions of the relevant nervous system structure (e.g., sensory input systems, brain or spinal integrative systems, motor output systems) and will substantially exceed the state of the art in cellular maturation and integration, allowing reproducible measurement of human-relevant circuit-level activity under physiological conditions over a long period.

This FOA encourages innovative approaches that are first-in-class, those that propose to substantially exceed the state of the art in tissue organization and function. These can be high risk, high impact designs. Additionally, this FOA encourages approaches that aim to improve robustness and reproducibility of physiologically relevant circuit or supportive systems-level measures.

All applications should define the current state of technology as a benchmark against which the new assay system(s) will be developed and measured. Example approaches include, but are not limited to:

- Utilization of novel materials, substrates or synthesis technologies (e.g., 3D printing, bioreactors, microfluidic platforms) to promote anatomically and physiologically relevant tissue organization and/or maturation.
- Integration of defined cell types consistent with relevant nervous system anatomy (e.g., excitatory, inhibitory and modulatory neurons, astrocytes, oligodendrocytes, microglia, pericytes, endothelial cells) into functional units (assembloids) that may include multipartite synapses, vascularization-perfusion, blood-brain barrier, glymphatic system and/or cerebrospinal fluid flow.
- Novel strategies to faithfully reproduce relevant regional cellular organization (e.g., dorsoventral, rostrocaudal, laminar, columnar or nuclei structure), with both short- and long-range anatomical connectivity (e.g., local inhibitory-excitatory and/or modulatory connections, projections to distant lamina or nuclei).
- Novel strategies to promote maturation of metabolism, signaling, synaptic activity, and connectivity in the cell-based assay.
- Development of human cell-based assays with complex functional features potentially relevant to complex nervous system disorders and diseases (e.g., intrinsic and/or dynamical network properties of cell assemblies such as neural oscillatory activity, activity-dependent plasticity).
- Inclusion of conditional or intersectional strategies that allow temporally and/or spatially cell-selective monitoring or manipulation of gene expression/function or of live cell activity and function.
- Inclusion of innovative approaches to distinguish or deconvolute heterogeneous cell phenotypes in these assays (e.g., multi-parameter single cell analysis), including those that are minimally perturbing.
- Evaluation of how data obtained from the proposed assay compares with human anatomical, histological or systems-level data, or data from other physiologically relevant paradigms, to facilitate assay validation. Investigators are encouraged to explore data and tools being developed under the NIH BRAIN Initiative (https://www.braininitiative.nih.gov/), BrainSpan (http://www.brainspan.org/), PsychENCODE (https://www.synapse.org/#!Synapse:syn4921369/wiki/235539) and the PsychENCODE Human Brain Development Atlas (http://development.psychencode.org/), Human Connectome Project (http://www.humanconnectomeproject.org/about/), AMP-AD (https://www.nia.nih.gov/research/amp-ad), or related efforts which if utilized could further the authentication of human brain cell-derived assays.

Interests of Specific Institutes/Centers

The scientific interests of participating Institutes and Centers (I/Cs) are summarized below. Applicants are encouraged to contact the Scientific/Research contact of the intended I/C to ensure that the aims of the proposed project are consistent with the I/C mission.

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

NIMH is interested in all example approaches from the Research Objectives that facilitate Next-Generation MPS representing the cellular and circuit substrates of cognitive, social and affective domains of brain function. Examples from the Research Objectives can include, but are not limited to, generating correctly-specified and anatomically organized brain regions that subserve these domains of function, integration of vascularization-perfusion, blood-brain barrier or other systems-level support features into these structures; optimizing local excitatory-inhibitory-modulatory feedback circuits representing cortex or subcortical regions, longer distance cortico-cortical, cortico-striatal, thalamo-cortical and cortico-limbic connections, the emergent systems-level features (e.g., oscillations) that arise from such circuit activity and the effect of changing input on circuit behavior (e.g., transfer functions). Applications should be primarily focused on MPS technology development and basic biology, although the domains of function should be relevant to those potentially dysregulated in mental illnesses, including autism spectrum disorders, mood and anxiety disorders (e.g., bipolar disorder), attention deficit and obsessive-compulsive disorders, and/or schizophrenia. While applications can include independent variables for validating the utility of the MPS for studying a

relevant cellular/synaptic/circuit activity or domain of function (e.g., comparison of isogenic lines with and without engineered gene variants), the central focus should be on developing or improving MPS technology and not studying disease biology per se. Applications focusing on developing or utilizing cell-based assays to study mechanisms of mental illnesses can respond to PAR-20-263 (https://grants.nih.gov/grants/guide/pa-files/PAR-20-263.html) and PAR-20-264 (https://grants.nih.gov/grants/guide/pa-files/par-20-264.html).

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

NEI is interested in research proposing to develop Next Generation MPS that more closely recapitulates the cornea, lens, retina, RPE, and/or elements of the central visual pathway. Projects suitable for this announcement include, but are not limited to 1) the development of natural and/or synthetic substrates/scaffolds that promote the growth and differentiation of physiologically relevant tissue; 2) the development of microfluidic devices (eye-on-chip) derived from stem cells that model physiological functions of the visual system; 3) the development of 3D tissue platforms that model microenvironments or niches of the visual system; 4) the development of MPS with complex functional features such as circuit structure, function, and connectivity as it relates to the visual system. Demonstration of how MPS systems are improvements over animal models or other 2D in vitro systems is also desired. While it is necessary to evaluate the basic biology of the 3D tissue, the primary focus should be on the improvement of the MPS technology and to more faithfully recapitulate development and not on basic disease mechanisms, transplantation procedures, personalized gene therapy approaches, and/or therapeutic and toxicity screens.

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

NIAAA supports the generation of MPS that recapitulate nervous system tissues and brain structures throughout the lifespan. NIAAA is seeking applications for new technologies that can assess the effects of alcohol on 1) cellular physiology, 2) neural circuit formation, maintenance and plasticity, and 3) interactions of multiple cell types (neurons, glia, vasculature, and immune cells) during critical developmental stages. The institute is interested in platforms to test underlying genetic and epigenetic consequences of short and long-term alcohol exposure and the actions of drugs and potential therapeutic compounds for prevention of alcohol use disorder or other consequences of alcohol exposure. The MPS may provide a platform for the generation and testing of predictive models of molecular, cellular and/or neural circuit responses to acute and chronic alcohol exposure (use) and reveal candidates for risk of and resiliency for fetal alcohol spectrum and alcohol use disorders.

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

The National Institute on Deafness and Other Communication Disorders (NIDCD) has a continued interest and effort to support new opportunities that could provide faster, more efficient biological platforms to assess physiological function, disease models, and transplantation potential in the NIDCD mission areas of hearing, balance, taste, smell, voice, speech and language. The institute is interested in a broad variety of approaches and technology/methodology development. Some examples, but not limited to, would be technical development of microarchitecture reagents including appropriate buffers, media, polymers and synthetics to generate improved 3D platforms and microenvironments to facilitate cellular attachment, proliferation, in areas of differentiation or regeneration of taste buds, hearing/balance sensory epithelium, or vocal folds; experimental improvements of drug assessment studies, high throughput replication and comparative analyses of laryngeal, chemosensory and auditory/vestibular function (e.g., ototoxicity, noise or drug trauma, and age-related sensory loss); experimental improvements to implantable chip or scaffold-derived tissues and cells, such as for vocal fold replacement or inner ear transplantation studies; use of improved stem cell technology for the derivation of multi-cellular chip organoids replicating normal and/or disordered tissue physiology; use of gene and protein manipulation technologies to enhance the imaging and/or assessment of the created chip microsystem (e.g., cellular identities, function, and interactions, neuronal innervation, or molecule activity).

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

The National Institute on Aging (NIA) is interested in the development of next-generation MPS that more closely recapitulate the aging brain and diseases of brain aging. While applications should be primarily focused on MPS technology development, the circuits and brain regions of interest should be relevant to either those declining during brain aging or those resilient to the effects of brain aging. NIA is interested in all examples of approaches listed under the Research Objectives that would promote understanding of the aging brain and diseases of brain aging, particularly Alzheimer's disease. Examples of projects that would be appropriate for this announcement include, but are not limited to: 1) using new technologies to develop three-dimensional human cell-based assays that better recapitulate brain aging, including the integration of defined brain cell types into functional units and mechanisms to study cell-cell interactions during aging and Alzheimer's disease; 2) promoting maturation of metabolism, neuroimmune interactions, signaling, synaptic activity, and connectivity in the human cell-based assay to recapitulate the aging brain; and 3) developing human cell-based assays with complex functional features relevant to nervous system disorders of aging, including cell-selective manipulation of gene expression or cell function to model normal and disordered brain aging, such as occurs in Alzheimer's disease. Although applications can include disease-relevant perturbations for model validation and testing assay utility, the focus should be on developing or improving MPS technology. Applications proposing to use existing cell-based assays to study aging-related and Alzheimer's disease mechanisms should respond to NOT-AG-21-052 (https://grants.nih.gov/grants/guide/notice-files/NOT-AG-21-052.html) via PAR-22-093 (https://grants.nih.gov/grants/guide/pa-files/PAR-22-093.html) (R01) or PAR-22-094 (https://grants.nih.gov/grants/guide/pa-files/PAR-22-094.html) (R21).

Non-Responsive Topics

Applications addressing the following topics are not responsive to this FOA:

- A central focus on scaling assays or adapting for use in compound screening.
- Strategies directed toward cell therapy or regenerative medicine.
- Developing organoid or other MPS assays from exclusively non-human tissues.
- Assays that aim to recapitulate 3-germ-layer gastrula-like structures (e.g., gastruloids).

- Assays based on pre-gastrulation human-nonhuman chimeric manipulation, or those potentially involving human contributions to the germline.
- Utilization of existing technologies that do not significantly advance the state of the art to address disease-relevant questions.

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
Renewal
Resubmission
Revision

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

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

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

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/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 Governments

- 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.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their 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 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/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, 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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_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 Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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.

Page Limitations

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

Instructions for Application Submission

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

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

Note that the application should include expert collaborators appropriate for the particular needs of the assay being optimized, e.g., developmental or aging neurobiology, stem cell biology, circuit and systems level neuroscience, materials science, engineering and/or bioethics.

R&R or Modular Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Research Strategy: The primary focus of applications responding to this announcement is developing technologies involving human cell-based engineering of MPS or related assays, directed as described in the Research Objectives toward faithfully representing salient features of *in vivo* brain, spinal, and/or sensory end organ circuit physiology, that may include systems-level features that support circuit function (e.g., myelination, vascularization-perfusion, blood-brain barrier, glymphatic system, cerebrospinal fluid flow). As a result, applications should focus on technical improvements to and capabilities of these cell-based assays relative to current state of the art. While genetic or environmental perturbations relevant to disease states can be incorporated into the research design as a means of validating the specific utility of the assay, these are neither required nor expected.

The research strategy should:

- Exploit novel tools or technologies, including those from other disciplines, to improve the sophistication, robustness or reproducibility of nervous system assay. Alternatively, it should bring a unique conceptualization of analytic approaches being applied to the assay.
- Address an intransigent barrier to (or propose to substantially exceed the state of the art in) cellular maturation and integration within the assay. Alternatively, the plan should aim to improve robustness and reproducibility of physiologically relevant circuit or supportive systems-level measures.
- Address the goal of improving assay's fidelity to salient features of *in vivo* neural circuit structure and function and/or systems-level features that support circuit function.
- Define the current state of the human cell-based assay technology as a benchmark against which the new assay(s) will be developed and measured.

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

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

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.
- Additionally, applicants should describe how protocols for generating and validating the assay, with sufficient detail to facilitate replication, will be disseminated to the research community. Applicants are expected to register resources supported by this FOA in the Neuroscience Information Framework (https://scicrunch.org/ (https://scicrunch.org/)) and use Research Resource Identifiers (RRID) assigned by (http://scicrunch.com/resources (http://scicrunch.com/resources)) in any publication supported by this FOA.

To advance the goal of advancing research through widespread data sharing among researchers, investigators funded under this FOA are expected to share those data via the National Institute of Mental Health Data Archive (https://nda.nih.gov/) (NDA; see NOT-MH-19-033 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-033.html)). Established by the NIH, NDA is a secure informatics platform for scientific collaboration and data sharing that enables the effective communication of detailed research data, tools, and supporting documentation. NDA links data across research projects through its Global Unique Identifier (GUID) and Data Dictionary technology. Investigators funded under this FOA are expected to use these technologies to submit data to the NDA.

To accomplish this objective, it will be important to formulate a) an enrollment strategy that will obtain the information necessary to generate a GUID for each participant and b) a budget strategy that will cover the costs of data submission. The NDA website provides two tools to help investigators develop appropriate strategies: 1) the NDA Data Submission Cost Model (https://nda.nih.gov/contribute_cost_estimation.html) which offers a customizable Excel worksheet that includes tasks and hours for the Program Director/Principal Investigator and Data Manager to budget for data sharing; and 2) plain language text to be considered in your informed consent available from the NDA's Data Contribution page (https://nda.nih.gov/contribute/contribute-data.html). Investigators are expected to certify the quality of all data generated by grants funded under this FOA prior to submission to NDA and review their data for accuracy after submission. Submission of descriptive/raw data is expected semi-annually (every January 15 and July 15); submission of all other data is expected at the time of publication or prior to the end of the grant, whichever occurs first (see NDA Sharing Regimen (https://nda.nih.gov/contribute/sharing-regimen.html) for more information). Investigators are expected to share results, positive and negative, specific to the cohorts and outcome measures studied. The NDA Dating Sharing Plan is available for review on the NDA website (https://s3.amazonaws.com/nda.nih.gov/Documents/NDA+Data+Sharing+Terms+and+Conditions+01.01.20.pdf). NDA staff will work with investigators to help them submit data types not yet defined in the NDA Data Dictionary (https://nda.nih.gov/data_dictionary.html).

Appendix:

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

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

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

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

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.

Use of Common Data Elements in NIH-funded Research

Many NIH ICs encourages the use of common data elements (CDEs) in basic, clinical, and applied research, patient registries, and other human subject research to facilitate broader and more effective use of data and advance research across studies. CDEs are data elements that have been identified and defined for use in multiple data sets across different studies. Use of CDEs can facilitate data sharing and standardization to improve data quality and enable data integration from multiple studies and sources, including electronic health records. NIH ICs have identified CDEs for many clinical domains (e.g., neurological disease), types of studies (e.g. genome-wide association studies (GWAS)), types of outcomes (e.g., patient-reported outcomes), and patient registries (e.g., the Global Rare Diseases Patient Registry and Data Repository). NIH has established a "Common Data Element (CDE) Resource Portal" (http://cde.nih.gov/ (https://www.nlm.nih.gov/cde/index.html)) to assist investigators in identifying NIH-supported CDEs when developing protocols, case report forms, and other instruments for data collection. The Portal provides guidance about and access to NIH-supported CDE initiatives and other tools and resources for the appropriate use of CDEs and data standards in NIH-funded research. Investigators are encouraged to consult the Portal and describe in their applications any use they will make of NIH-supported CDEs in their projects.

NIMH has released expectations for collecting common data elements when an application involves human research participants. Details can be found at NOT-MH-20-067 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-20-067.html) and the NIMH webpage on Data Sharing for Applicants and Awardees (https://www.nimh.nih.gov/funding/managing-your-grant/nimh-data-sharing-for-applicants-and-awardees).

For projects that are considered clinical research, include patient measures that adhere to NIMH's expectation on the collection of common data elements efforts per NOT-MH-20-067 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-20-067.html). If the expected common data elements will not be collected, provide a rationale that justifies the decision to not include those common data elements.

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

For assistance with your electronic application or for more information on the electronic submission process, visit 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 field of 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 NIMH, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299)

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.

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will not be evaluated at time of review.

For this particular announcement, note the following:

As the FOA encourages innovative approaches to major methodological challenges, the level of risk is generally expected to be higher than for conventional R01 applications. The primary focus of applications responding to this announcement is developing technologies involving human cell-based engineering of MPS or related assays, directed as described in the Research Objectives toward faithfully representing salient features of *in vivo* brain, spinal, and/or sensory end organ circuit physiology, that may include systems-level features that support circuit function (e.g., myelination, vascularization-perfusion, blood-brain barrier, glymphatic system, cerebrospinal fluid flow). As a result, reviewers should primarily assess merit based on the technical improvements to and capabilities of these cell-based assays relative to current state of the art. While genetic or environmental perturbations relevant to disease states can be incorporated into the research design as a means of validating the specific utility of assays, these are neither required nor expected.

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 does the application rationalize the project as addressing an intransigent technical barrier, a need to substantially exceed the state of the art, or a need to improve robustness and reproducibility of the assay for physiologically relevant circuit or supportive systems-level measures?

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:

How well does the project engage expert collaborators appropriate for the particular needs of the assay being optimized, e.g., developmental neurobiology, stem cell biology, circuit and systems level neuroscience, materials science, engineering and/or ethics?

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 project exploit novel tools or technologies, including those from other disciplines, to improve the sophistication, robustness or reproducibility of the central nervous system assay, and/or bring a unique conceptualization of analytic approaches being applied to the assay?

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:

How well does the research strategy define and use the current state of technology as a benchmark against which the new assay(s) will be developed and measured?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

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

Study Timeline Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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

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

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will not be evaluated at time of review.

Reviewers will comment on whether the Resource Sharing Plan(s) (i.e., Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, 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.

Applications will be assigned on the basis of the Interests of Specific Institutes/Centers stated in this FOA as well as established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

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

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

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.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) 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 https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and 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 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)andhttps://www.lep.gov (https://www.lep.gov/).
- 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 http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (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 https://grants.nih.gov/grants/policy/harassment.htm (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 https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and 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 https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

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. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. 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 www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over the threshold. See the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act__ffata_.htm) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, 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 and 2 CFR Part 200 – Award Term and Condition 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: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (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: 301-637-3015

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)

David M. Panchision, Ph.D.
National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/))
Telephone: 301-443-5288
Email: panchisiond@mail.nih.gov (mailto:panchisiond@mail.nih.gov)

Lisa Neuhold
National Eye Institute (NEI)
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E-mail: lneuhold@mail.nih.gov (mailto:lneuhold@mail.nih.gov)

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National Institute on Deafness and Other Communication Disorders (NIDCD)
Phone: (301) 402-3458
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Elizabeth Powell, Ph.D.
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
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E-mail: elizabeth.powell3@nih.gov (mailto:elizabeth.powell3@nih.gov)

Amanda DiBattista, Ph.D.
National Institute on Aging (NIA (https://www.nia.nih.gov/))
Telephone: 301-496-9350
Email: amanda.dibattista@nih.gov (mailto:amanda.dibattista@nih.gov)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Heather Weiss
National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/))
Telephone: 301-443-4415
heather.weiss@nih.govEmail:

Karen Robinsonsmith
National Eye Institute (NEI)
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Robin Laney
National Institute on Aging (NIA)
Phone: 301-496-1472
E-mail: laneyr@mail.nih.gov (mailto:laneyr@mail.nih.gov)

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

- Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?11-11-22)
- NIH Funding Opportunities and Notices (/grants/guide/index.html)

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

(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)

1. ผู้สมัครจะต้องแจ้งความประสงค์และนำส่งข้อมูลเข้ามายังกองบริหารงานวิจัย ภายในกำหนดเวลาแจ้งความประสงค์การจัดส่งข้อเสนอในหนังสือประชาสัมพันธ์ โดยนำส่งข้อมูลทางอีเมล chittiporn.nua@mahidol.edu เพื่อขอเปิดบัญชี eRA commons และขอสร้างข้อเสนอโครงการในระบบออนไลน์ ASSIST ของแหล่งทุน NIH โดยแจ้งข้อมูลดังนี้

   Name: Surname:

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

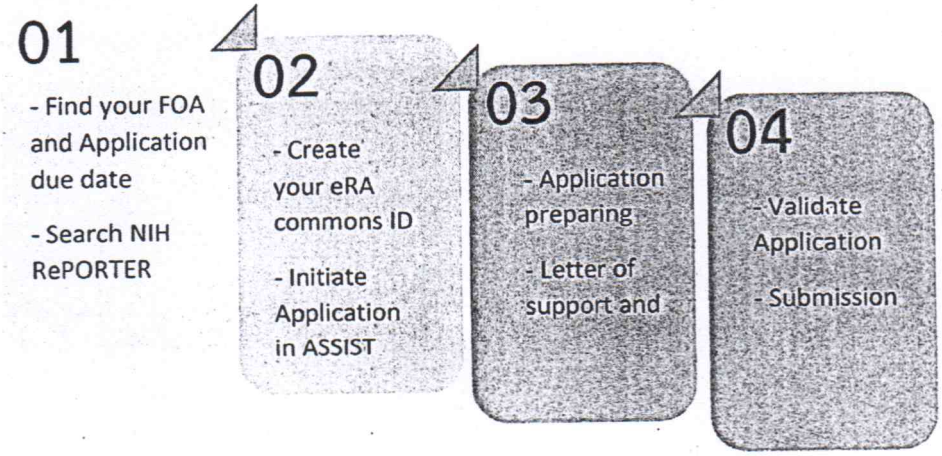
   Funding Opportunity Announcement (FOA) Number:

   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 ให้ผู้สมัครขอรับทุน ผู้ขอรับทุนจัดทำข้อเสนอโครงการและเอกสารที่เกี่ยวข้องตามข้อกำหนดของแหล่งทุนร่วมกับมหาวิทยาลัย
4. ผู้สมัครขอรับทุนนำส่งเอกสารข้อเสนอโครงการฉบับสมบูรณ์ผ่านหัวหน้าส่วนงานเพื่อขออนุมัติจัดส่งข้อเสนอโครงการผ่านระบบออนไลน์ ASSIST ตามกำหนดรับข้อเสนอของมหาวิทยาลัย** กองบริหารงานวิจัยตรวจสอบข้อเสนอโครงการ เสนออนุมัตินำส่งข้อเสนอโครงการและจัดส่งข้อเสนอโครงการในนามของมหาวิทยาลัยไปยังแหล่งทุน

   (**หากผู้สมัครขอรับทุนนำส่งข้อเสนอโครงการให้กองบริหารงานวิจัยตรวจสอบล่าช้ากว่ากำหนดของมหาวิทยาลัย มหาวิทยาลัยขอสงวนสิทธิ์ในการรับข้อเสนอโครงการเพื่อนำส่งแหล่งทุนในรอบนั้นๆ)



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