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

ที่ อว 78.016/ว 6466
วันที่ 8 ธันวาคม 2565
เรื่อง ประชาสัมพันธ์การเปิดรับข้อเสนอโครงการ จากแหล่งทุน National Institutes of Health (NIH) ประเภท Research Project Grant หัวข้อ "Investigating the Effects of Addictive Substances on Brain Developmental Trajectories Using Innovative Scalable Methods for Quantification of Cell Identity, Lineage and Connectivity (R01 - Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-DA-23-036

สิ่งที่ส่งมาด้วย 1. รายละเอียดประกาศทุน RFA-DA-23-036
2. ขั้นตอนการสมัครขอรับทุน

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน National Institutes of Health (NIH)) ประเภท Research Project Grant หัวข้อ "Investigating the Effects of Addictive Substances on Brain Developmental Trajectories Using Innovative Scalable Methods for Quantification of Cell Identity, Lineage and Connectivity (R01 - Clinical Trial Not Allowed)" หมายเลขประกาศทุน RFA-DA-23-036 **โดยเปิดรับข้อเสนอโครงการ ตั้งแต่วันที่ 2 มกราคม 2566 จนถึงวันที่ 2 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/rfa-files/RFA-DA-23-036.html

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ทุนวิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย **โปรดแจ้งความประสงค์การจัดส่งข้อเสนอ ภายในวันที่ 2 มกราคม 2566 และจัดส่งข้อเสนอโครงการวิจัยผ่านส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยเพื่อตรวจสอบรายละเอียดข้อเสนอโครงการฉบับสมบูรณ์ภายในวันที่ 26 มกราคม 2566 ทั้งนี้ หากส่วนงานแจ้งความประสงค์การจัดส่งข้อเสนอโครงการวิจัยหลังจากวันที่ 26 มกราคม 2566 มหาวิทยาลัยขอสงวนสิทธิ์ในการยื่นข้อเสนอโครงการวิจัยเพื่อขอรับทุนดังกล่าว**

จึงเรียนมาเพื่อโปรดทราบและประชาสัมพันธ์ข่าวทุนวิจัยดังกล่าวต่อไปด้วย จักขอบคุณยิ่ง

งานบริหารงานวิจัยและนวัตกรรม
14 ธ.ค. 65

(ศาสตราจารย์ ดร. นายแพทย์ ภัทรชัย กีรติสิน)
รองอธิการบดีฝ่ายวิจัย

ทราบ
14/ธ.ค./65

เรียน คณบดี (ผ่านรองฯ วิจัย)
- เพื่อโปรดทราบ NIH เปิดรับข้อเสนอทุน # RFA-DA-23-036 โดยมีหัวข้อการให้ทุน หลากหลาย ตามเอกสารที่แนบ ผู้สนใจเสนอขอทุน โปรดแจ้งความประสงค์ส่งเสนอขอทุนภายใน 2 ธ.ค. 65. หลังจากนั้น Proposal ฉบับสมบูรณ์ พร้อมเอกสารอื่นๆ ตามเงื่อนไข ภายใน 25 ธ.ค. 66 เพื่อคณะส่งให้มหาวิทยาลัยตรวจสอบรายละเอียดต่อไป
- สำเนาเรียน เพื่อ ทุกท่านทราบ

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

- ต้นเรื่อง ส่งมหาวิทยาลัย ภายในวันที่ 9 ธ.ค. 65 14 ธ.ค. 2565 13/12/65

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

Funding Opportunity Title

Investigating the Effects of Addictive Substances on Brain Developmental Trajectories Using Innovative Scalable Methods for Quantification of Cell Identity, Lineage and Connectivity (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

New

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

RFA-DA-23-036

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.279

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) will support projects that investigate the effects of addictive substances on developmental trajectories of molecularly-defined central nervous system (CNS) cells and circuits. Emphasis is on carrying out systematic and highly granular quantitative characterizations of the impact of in utero and/or postnatal substance exposure on the numbers, spatial distribution and

connectivity of molecularly-defined cells, across whole brains or within distributed circuits of clinical relevance. The ultimate goals of the program are to identify critical developmental windows and cellular mechanisms mediating the protracted developmental impact of addictive substances, and to inform clinical practice, by complementing the data from human longitudinal neuroimaging studies such as the HEALthy Brain and Child Development (HBCD) Study and the Adolescent Brain Cognitive Development (ABCD) Study.

Key Dates

Posted Date

November 08, 2022

Open Date (Earliest Submission Date)

January 02, 2023

Letter of Intent Due Date(s)

January 02, 2023

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 02, 2023	Not Applicable	Not Applicable	July 2023	August 2023	December 2023

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 03, 2023

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=RFA-DA-23-036) 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

Scientific Gap and Opportunity

In utero and/or prepubertal exposures to a range of addictive substances, including nicotine/tobacco products, opioids, marijuana/cannabinoids, and psychostimulants have been associated with disruptions in the emergence of sensorimotor, cognitive and affective neurobehavioral milestones and with an enhanced susceptibility to develop psychiatric and substance use disorders. While large prospective longitudinal studies, such as the HEALthy Brain and Child Development (HBCD) Study and the Adolescent Brain Cognitive Development (ABCD) Study, are providing growing insights into normative development and the neurobehavioral impact of developmental exposures, opportunities to gain knowledge into the cellular underpinnings of these observations remain limited from clinical studies.

Studies using tissue culture systems and animal models have provided complementary indications that addictive substance exposures can interfere with a range of cellular processes pivotal for brain development, including cell proliferation, migration/positioning, neurotransmitter specification, axonal pathfinding and pruning. However, it remains unclear how heterogeneous and distributed such effects are across brain systems, cell types and developmental time-points. It is also unclear which of these effects, if any, are causal of the protracted volumetric and functional sequelae described in patients and certain animal models. To date, studies designed to address these questions have remained relatively rare and have focused on only a few target brain regions and candidate cell-types often defined based on a single or a small number of molecular markers. Such approaches are susceptible to multiple confounds and can overlook effects implicating functionally critical but less abundant specialized cell subclasses or developmental intermediates.

In recent years the field of developmental neuroscience has been transformed by the progress and growing availability of two main classes of scalable technologies:(i) single-cell and spatial omics technologies, which enable large scale granular molecular maps and inventories of cell types and their developmental intermediates and (ii) DNA barcoding or editing that enable cell tagging and tracking of clonal /lineage relationships, as well as the quantification of cell connectivity and cell-cell relationships, in a scalable manner. These technologies are now being applied extensively in the context of initiative such as the BRAIN initiative cell census (https://biccn.org (https://biccn.org)) and developmental GTEX (https://www.genome.gov/Funded-Programs-Projects/Developmental-Genotype-Tissue-Expression (https://www.genome.gov/Funded-Programs-Projects/Developmental-Genotype-Tissue-Expression)) to define normative brain developmental trajectories and generate public reference datasets and other key resources, such as repositories, atlases and common coordinate frameworks (CCF) of developing brains. The time is right to now leverage these innovative technologies and resources to begin to systematically identify and map the in vivo developmental effects of addictive substances on a larger scale.

Research objectives and requirements

This FOA will support projects that investigate the effects of addictive substances on developmental trajectories of molecularly-defined central nervous system (CNS) cells and circuits. Emphasis is on carrying out systematic and highly granular quantitative characterizations of the impact of *in utero* and/or postnatal substance exposures on the numbers, spatial distribution, connectivity and states of molecularly-defined cells and cell classes, across whole brains or large spatially-defined structures and distributed circuits of clinical relevance.

Projects should leverage state-of-the-art molecular profiling, imaging, atlasing approaches and/or scalable cell tagging, tracing, barcoding technologies with single-cell resolution. They should apply time-series sampling strategies and implement specialized computational and statistical pipelines to experimentally test whether quantifiable spatiotemporal shifts in the molecular identities, patterning, connectivity and lineages/trajectories of specific cells result from developmental substance exposures at particular windows or branchpoints, and mediate protracted structural and/or functional sequelae. Projects should focus on exposure to any addictive substance with strong public health relevance (including but not limited to nicotine/tobacco products, alcohol, opiates, psychostimulants and marijuana/cannabinoids) and may sample any relevant period of embryonic and/or postnatal brain development leading to and including adulthood.

Applicants should adopt previously validated experimental mammalian models that apply substance exposure regimens with strong public health relevance, and result in alterations that can be quantified using translationally-relevant morphological and/or functional readouts, proximal to target circuits and amenable to causality testing. Although it is expected the bulk of proposed research will use rodents due to the greater availability of validated molecular tools and reference data, the use of other model species and cross-species comparisons, including with human tissues, are encouraged when relevant to strengthen the translational relevance of the studies. Examples of relevant animal models include but are not limited to: rodent models of the neonatal opioid withdrawal syndrome (NOWS), rodent models of adolescent cannabis exposure, models of prenatal tobacco smoke inhalation or nicotine exposure in rodents or NHPs, rodent or NHP models of gestational cocaine exposure. Important differences that exist in brain developmental trajectories between humans and animals should be considered. For example, the third trimester of human pregnancy is more analogous to the postpartum period in rodents. Applications should address these differences in their experimental design and exposure regimens to maximize translational relevance.

Applications aiming to map rodent whole-brains or large brain volumes in mainly comparative/descriptive series of experiments are acceptable, however such applications should also select defined developmental exposure windows/branchpoints and/or circumscribed neuroanatomical systems as test beds for causal hypotheses testing, and demonstration of scalability to broader brain systems.

The ultimate goals of the program are to identify cellular mechanisms mediating the functional developmental effects of addictive substances by applying scalable paradigms. The research is expected to inform clinical practice by complementing data from human longitudinal studies, such as the HEALthy Brain and Child Development (HBCD) Study and the Adolescent Brain Cognitive Development (ABCD) Study.

Examples of relevant research topics include, but are not limited to:

- Comparative brain-wide spatial transcriptomics studies (e.g., Starmap, Slideseq or others) of the effects of prenatal exposure to opioids (or other substances) on the numbers and spatial patterning of peptidergic neuronal cell subtypes, followed by causal tests in regions mediating drug-induced sensitization
- Single-cell muliomics studies of sex-specific effects of chronic gestational cannabis inhalation (or other substances) on brain-wide glial lineage trajectories, with causal tests of specific regional/developmental subtypes in the ontogenesis of social behaviors
- Investigation using viral tracing and barcoding of the effects of postnatal cannabinoid exposure (or other substances) on the timing of pruning and connectivity maturation of inhibitory neuronal classes in sensory cortices, and causal relationship to the protracted effects of cannabinoids on forms of sensory plasticity
- Brain wide time-series using spatial transcriptomics and cell-tagging of the effect of developmental tobacco exposure (or other substances) on vascular and endothelial cell lineages, with causal tests in circuits relevant to autonomic/cardiovascular sequelae of tobacco exposure, such as increased risk of sudden infant death syndrome (SIDS)

Applications Not Responsive to this FOA

Applications with the following specifics will be considered non-responsive and will not be reviewed:

- Projects aimed at validating new models of developmental exposure to addictive substances
- Projects investigating a single developmental time-point rather than time-sampling
- Projects applying profiling methods that lack sufficient (single cell) resolution
- Projects that concentrate on a single or a very limited array of molecularly-defined cell types/subtypes
- Projects that categorize cells or cell classes based on a single or a small number of molecular markers
- Projects that do not investigate cells and tissues from the CNS
- Projects that do not incorporate rodents or NHPs as investigated species or focus on non mammalian models
- Projects that do not propose exposure to an addictive substance or that propose to investigate alcohol as sole addictive substance exposure
- Projects that do not propose to investigate an *in utero,* perinatal and/or adolescent substance exposure

Prior Consultation with Scientific/Research Staff

Consultation with Scientific/Research Contact staff is strongly recommended, preferably well before the Letter of Intent due date. If requested by the applicants, staff can advise whether the proposed project meets the goals of this FOA and the mission of NIDA, and discuss responsiveness questions. Staff will not evaluate the technical and scientific merit of the proposed project; technical and scientific merit will be determined during peer review using the review criteria indicated in this FOA. During the consultation phase, if the proposed project does not meet the programmatic needs of this FOA, applicants will be strongly encouraged to consider other Funding Opportunities.

Applicants considering molecular profiling studies or developmental studies that may not meet the requirements for this FOA (e.g., focus on placental biology or the immune system) should consider other NIDA FOAs, and in particular the following:

- HEAL Initiative: Opioid Exposure and Effects on Placenta Function, Brain Development, and Neurodevelopmental Outcomes RFA-HD-23-032 (https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-23-032.html), RFA-HD-23-030 (https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-23-030.html) , RFA-HD-23-031 (https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-23-031.html), RFA-HD-23-03 (https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-23-033.html)

Other points to consider when developing a research application:

- Applicants should have strong technical preliminary data showing the proposed profiling and barcoding/tagging experiments can be performed in a developmental context. However, specific pilot data with these tools in the context of substance exposure is not required

- Applicants are encouraged to leverage public reference datasets and resources being generated in the context of the BRAIN initiative cell census and dGTEX, such as mouse brain normative development datasets and CCFs
- It is recommended that applications document reliable substance exposure by including quantitative PK/PD readouts
- We anticipate that the most compelling projects will be proposed by interdisciplinary teams and encourage applicants to assemble interdisciplinary teams with expertise in all appropriate areas, including models of developmental substance exposure and their clinical relevance and statistical/computational experts in atlasing technologies and bioinformatics pipelines relevant to cell trajectory analyses such as pseudotime and velocity analyses
- Data generated must be made available to the scientific community for data mining through the NIDA-funded SCORCH data coordination center (RFA-DA-20-027 (https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-20-027.html))
- Applicants should propose a timeline and yearly quantitative milestones for their projects. If selected for funding, applicants will work with NIH staff to develop more granular milestones which will be included in their Notice of Award. Progress towards completion of these milestones will be assessed yearly
- Applicants should plan for the PDs/PIs and essential team members to travel domestically for a yearly face to face meeting with other NIDA researchers for the entire funding period

Plan for Enhancing Diverse Perspectives (PEDP):

The NIH and NIDA recognize 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.

NIDA encourages inclusivity in research and supports the formation of diverse research teams that represent an array of perspectives, backgrounds, disciplines, eligible institutions and geographic locations (see NOT-OD-20-031 and NOT-OD-22-019). Applications from researchers with diverse backgrounds underrepresented across roles and positions in research, including underrepresented racial and ethnic groups, persons with disabilities, and women are strongly encouraged in response to this Funding Opportunity Announcement.

All projects submitted under this FOA must provide a Plan for Enhancing Diverse Perspectives (PEDP) submitted as a 1-page attachment under Other Project Information. The PEDP is a summary of strategies used by the team to advance the scientific and technical merit of the proposed project through expanded inclusivity. Detailed instructions for completing the PEDP are provided in Section IV. of this announcement. The PEDP will be assessed as part of the scientific and technical peer review evaluation and will be considered among programmatic matters informing funding decisions. Applicants are strongly encouraged to read the FOA instructions carefully and view the available PEDP guidance material (https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp). Applications submitted without a PEDP will be considered incomplete and will be administratively withdrawn.

Special Considerations

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding.

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

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

NIDA intends to commit $2M in FY2023 to fund 1-3 awards.

Award Budget

Applications may not request more than $700,000 direct costs for any one year.

Award 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 Government

- 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 registration; 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.

Letter of Intent

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

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

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

The letter of intent should be sent to: NIDALetterofIntent@mail.nih.gov (mailto:NIDALetterofIntent@mail.nih.gov).

Page Limitations

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

Instructions for Application Submission

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

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.

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 underrepresented 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 https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp (https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp).

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.

PEDP implementation costs:

- Applicants may include allowable costs associated with PEDP implementation (as outlined in the Grants Policy Statement section 7: 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)).

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:

Provide a summary of the overall goals for the proposal, explaining how the different research components will be developed and implemented over the project period to (1) evaluate whether quantifiable spatiotemporal shifts in molecular identities, patterning, connectivity or lineages/trajectories of specific cells result from developmental substance exposures at particular windows or branchpoints,(2) test whether these effects mediate protracted structural and/or functional sequelae of developmental exposure.

Research Strategy:

- Provide a compelling justification for how the proposed work will dramatically improve our understanding of the developmental impact of addictive substance exposure and underlying cellular mechanisms
- Summarize the different components of the project and how they will integrate and synergize towards the goal of investigating the effects of addictive substances on developmental trajectories of molecularly-defined CNS cells and circuits
- Describe how the chosen strategies will leverage state-of-art technologies, resources and analytic pipelines to address current gaps and challenges, and why the approaches, toolsets, models or treatment regimen implemented offer advantages over alternative methods
- Explain how the project will inform clinical practice, by complementing the data from human longitudinal neuroimaging studies such as the HEALthy Brain and Child Development (HBCD) Study and the Adolescent Brain Cognitive Development (ABCD) Study
- Justify the choice of the substance, doses and the exposure model adopted, including prior validation and means to optimize the translational relevance and document in vivo exposure parameters
- Justify the abilities of the investigative team to carry out the proposed studies
- If proposing single cell transcriptomic or other molecular assays, please include a power estimate justifying the proposed number of individuals to be tested as well as the proposed number of single cells to be assayed from each individual
- A timeline and yearly quantitative milestones for the entire proposed funding period. If selected for funding, applicants will work with NIH staff to develop more granular milestones

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

- All applications, regardless of the amount of direct costs requested for any one year, mustshould address a Data Sharing Plan.
- A primary goal of this FOA is to facilitate discoveries by the broad scientific community. Restrictive sharing practices and licensing terms for user-generated data and resources could substantially diminish their value and public benefit. Accordingly, awardees are expected to manage data, resources, protocols, and software in a way that achieves this goal.
- Applicants should indicate their willingness to submit the metadata and data they generate to the SCORCH Data Center using data formats established by the SCORCH Data Center (RFA-DA-20-027 (https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-20-027.html)).
- Applicants should indicate their willingness to work with the SCORCH Data Center to submit metadata and data they generate to appropriate public data repositories. Applicants should identify such repositories and describe plans for deposition. For datatypes that lack suitable public repositories, applicants should indicate their willingness to identify an appropriate alternative solution consistent with achieving the goals of the program.
- Genomic Data Sharing Plan: If applicants propose to generate genomic data, they must indicate their willingness to abide by the NIH Genomic Data Sharing Policy (https://gds.nih.gov/ (https://gds.nih.gov/))
- Applicants are expected to register resources supported by this FOA in the Neuroscience Information Frameworkhttps://scicrunch.org/ (https://scicrunch.org/) and use Research Resource Identifiers (RRID) assigned byhttp://scicrunch.com/resources (http://scicrunch.com/resources)in any publication supported by this FOA.

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.

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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/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 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 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 NIDA (https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-20-025.html#_Components_of_Participating), NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

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.

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 compelling is the justification for how the proposed work will dramatically improve our understanding of the developmental impact of addictive substance exposure and inform clinical practice, by complementing the data from human studies such as the ABCD study ?

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:

Does the investigative team have appropriate expertise in rodent models of opioid exposure and/or single cell assays and/or anatomical mapping and registration of CNS ensembles?

Innovation

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

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators 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?

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.

Specific to this FOA:

- 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?

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

Not Applicable.

Renewals

Not Applicable.

Revisions

Not Applicable.

Additional Review Considerations

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

Applications from Foreign Organizations

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

Select Agent Research

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

Resource Sharing Plans

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.

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 NIDA, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications 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.

Appeals (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 to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Council on Drug Abuse. 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 (https://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.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (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 (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) and https://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 $25,000. 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 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: 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)

Olivier Berton, PhD
National Institute on Drug Abuse (NIDA)
Telephone: 301-827-7771
Email: olivier.berton@nih.gov (mailto:olivier.berton@nih.gov)

John Satterlee, Ph.D.
National Institute on Drug Abuse (NIDA)
Telephone: 301-435-1020
Email: satterleej@nida.nih.gov (mailto:satterleej@nida.nih.gov)

Peer Review Contact(s)

Dharmendar Rathore, PhD
National Institute on Drug Abuse (NIDA)
Telephone: 301-402-6965
Email: dharmendar.rathore@nih.gov (mailto:dharmendar.rathore@nih.gov)

Financial/Grants Management Contact(s)

Aida Vasquez
National Institute on Drug Abuse (NIDA)
Telephone: 301-480-2154
Email: vasquez@mail.nih.gov (mailto:xxxx@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.

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

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):

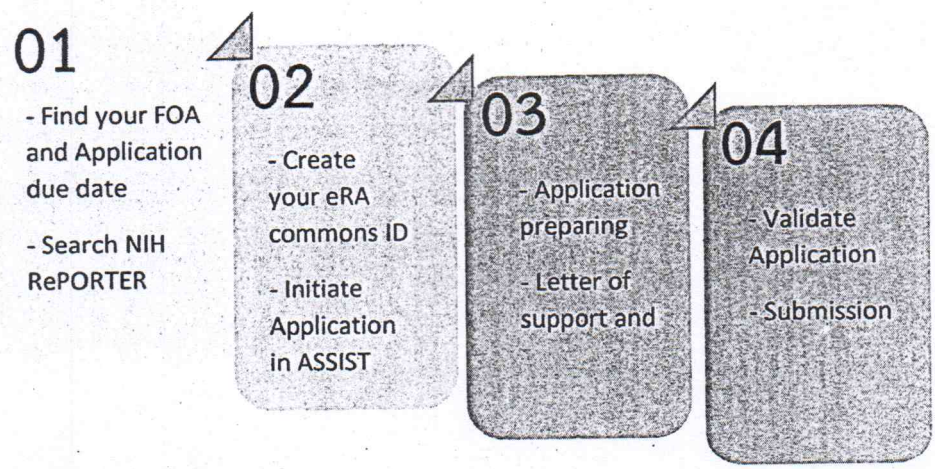
   Funding Opportunity Announcement (FOA) Number:

   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)