NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 09 Jan 2023 (#02)

Confirm your intent to apply ASAP, but not later than 60 days before the submission date.

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To prepare an application can take 4-18 months, depending on many factors:

1. Mechanism for which you will apply e.g. U54, R01, D43, K43

2. Requirement of preliminary data

3. Time to assemble the research team

4. Time available to work on the grant, taking into consideration other responsibilities

5. Time for internal review

Important Notices

Gearing Up for Transition to FORMS-H Application Forms: As announced over the summer, NIH requires the use of updated application forms (FORMS-H) for due dates **on or after January 25, 2023**. The How to Apply – Application Guide was updated on October 25 with FORMS-H application form instructions to prepare for the transition. Also see **Guide Notice NOT-OD-23-012.** All form changes are listed in High-level Grant Application Form Change Summary: FORMS-H.

- **A key change in FORMS-H is support for the implementation of the 2023 NIH Data Management and Sharing Policy.** NIH expects applicants to submit a plan for how they will manage and share their data and allows applicants to include certain costs associated with data management and sharing in their budget.
    - **Writing a Data Management & Sharing Plan.** Learn what NIH expects Data Management & Sharing plans to address.
    - **Budgeting for Data Management & Sharing.** Find out what data sharing related costs may be requested in an application for funding.

NOT-OD-23-047 Updates to the Non-Discrimination Legal Requirements for NIH Recipients. NIH complies with all federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and applicable conscience protections. Effective immediately, NIH is updating and implementing HHS language on the Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance. All Notices of Funding Opportunity (NOFOs) (i.e. Funding Opportunity Announcements) and Notices of Award (NoAs) will include the updated non-discrimination language.

Notices of Special Interest (NOSI)

NOT-DC-23-001 Fundamental Science Research on the Neural Circuits Underlying Sensory Processing. The National Institute on Deafness and Other Communication Disorders (NIDCD) is issuing this Notice to highlight priorities from its new strategic plan, in basic and mechanistic research on neural circuits underlying sensory processing in hearing, balance, taste and smell. NIDCD encourages multidisciplinary and innovative projects, from diverse teams, to advance a mechanistic understanding of the behavior of neural circuits at cellular and sub-second temporal resolution by integrating cutting-edge technologies and approaches for recording and modulation of cells and circuits (e.g., electrophysiology, optical imaging, optogenetics, chemogenetics, sonogenetics, magnetogenetics, pharmacologic

modulation). Applications are expected to integrate appropriate domains of expertise, including but not limited to biological, chemical and physical sciences, engineering, computational modeling, statistical analysis, and bioethics, as appropriate. Mechanistic human studies and comparative, cross-species projects are highly encouraged. This notice applies to due dates on or after February 5, 2023 and subsequent receipt dates through January 8, 2026. Submit applications for this initiative using one of the following funding opportunity announcements (FOAs) listed. Potential applicants to this NOSI are strongly encouraged to contact Scientific/Research staff prior to submission.

NOT-OD-23-044 Support for existing data repositories to align with FAIR and TRUST principles and evaluate usage, utility, and impact. The goal of this NOSI is to strengthen NIH-funded biomedical data repositories to better enable data discoverability, interoperability, and reuse by aligning with the FAIR and TRUST principles and using metrics to measure their effectiveness. This NOSI provides an opportunity for existing repositories to increase "FAIR"-ness and "TRUST"-worthiness to improve their usage, utility, and impact throughout the data resource lifecycle. Prospective applicants are required to conduct a self-assessment to identify gaps or deficiencies in "FAIR"-ness and "TRUST"-worthiness that are unique to their data resource and consider which metrics could be implemented for evaluation of usage, utility, and impact. Based on the self-assessment, applicants must identify how they would improve the impact of their unique data resource. To be responsive to this NOSI, applications must:

- Propose work for an existing biomedical data repository
- Include a self-assessment that identifies, lists, and describes the gaps or deficiencies to be addressed in and maps to one or more of the following areas: "FAIR"-ness, "TRUST"-worthiness, and/or metrics

Applications for this initiative must be submitted using the following opportunity or its subsequent reissued equivalent. Application Due Date(s) – **February 15, 2023** by 5:00 PM local time of applicant organization.

Funding Opportunity Announcements (FOA)

1. Revision Applications for Validation of Biomarker Assays Developed Through NIH-Supported Research Grants (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-088** **Type: R01**

Application Due Date: February 28, 2023; July 10, 2023; October 27, 2023. 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.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage revision applications (formerly called "competing revisions") from currently funded NCI R01 research projects. The applicants should propose projects that are expected to accelerate the pace of translation of NCI-supported methods/assays/technologies (referred to as "assays") to the clinic. Specifically, the focus of applications submitted in response to this FOA should be on the adaption and clinical validation of molecular/cellular/imaging markers (referred to as "markers" or "biomarkers") for cancer detection, diagnosis, prognosis, monitoring, and prediction of response in treatment, as well as markers for cancer prevention and control. Applications may support the acquisition of well-annotated specimens from NCI-supported or other clinical trials or observational cohorts/consortia for the purpose of clinical validation of the assay. Research projects proposed in response to this FOA encourage multi-disciplinary interaction among scientific investigators, assay developers, clinicians, statisticians, and clinical laboratory staff. Clinical laboratory scientist(s) and statistical experts are highly encouraged to comprise integral parts of the application. This FOA is not intended to support early-stage development of technology or the conduct of clinical trials, but rather the adaption and validation of assays to the point where they could be integrated into clinical trials as investigational assays/tools/devices.

Budget: Application budgets are limited to $150,000 in direct costs in any single year. The parent grant must be active when the application is submitted. There must be a minimum two years of support remaining on the parent award (not to include a no cost extension) at the estimated time of award. If a no-cost extension is needed on the parent grant, it must be in place before the revision application is submitted. The maximum project period is 3 years.

2. Building in vivo Preclinical Assays of Circuit Engagement for Application in Therapeutic Development (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-091** **Type: R01**

Application Due Date: February 05, 2023 through to September 07, 2025. 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.

Funding Opportunity Announcement: The goal of this FOA is to identify, in animals, in vivo neurophysiological and behavioral measures for use as assays in the early screening phase of treatment development. This FOA will support efforts to optimize and evaluate measures of neurophysiological and behavioral processes that may serve as pharmacokinetic/pharmacodynamic (PK/PD) markers of neural processes of clinical interest based on available knowledge of the neurobiology of mental illnesses. The screening assays developed from this FOA are expected to build upon systems neurobiology and clinical neuroscience to enhance the scientific value of preclinical animal data contributing to a therapeutic development pipeline in which treatment candidates and therapeutic targets can be evaluated for their ability to impact neurobiological mechanisms of potential clinical relevance to mental illnesses. The objectives of this FOA will be accomplished by supporting basic neuroscience aimed at improving the efficiency and scientific value of the therapeutic development pipeline by advancing the discovery of in vivo physiological and behavioral measures reflecting circuit engagement as tools for early phase target validation and therapeutic

screening for mental illness treatment development. The efforts supported by this initiative focus on measures in animals as a first step in generating translational assay measures that are adaptable across early therapeutic screens in animals to evaluation in humans. The FOA may be considered a prequel to build a suite of assays that are evaluated in future projects for coherence of assay performance between the preclinical species and healthy humans. In summary, this FOA will support efforts to improve the tool kit of assays available for early phase testing of novel therapeutic agents by incorporating measures proximal to neural systems that impact mental health.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. It is expected that budgets of $250,000 direct costs per year or less will be adequate for most projects proposing to optimize just one measure. The scope of the proposed project should determine the project period. The maximum period is 5 years.

3. Utilizing Invasive Recording and Stimulating Opportunities in Humans to Advance Neural Circuitry Understanding of Mental Health Disorders (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-093** **Type: R01**
Application Due Date: 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.
Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage applications to pursue invasive neural recording studies focused on mental health-relevant questions. Invasive neural recordings provide an unparalleled window into the human brain to explore the neural circuitry and neural dynamics underlying complex moods, emotions, cognitive functions, and behaviors with high spatial and temporal resolution. Additionally, the ability to stimulate, via the same electrodes, allows for direct causal tests by modulating network dynamics. This FOA aims to target a gap in the scientific knowledge of neural circuit function related to mental health disorders. Researchers should target specific questions suited to invasive recording modalities that have high translational potential. Development of new therapies is outside the scope of this FOA, though development of novel tools/methods to enable relevant mental health studies is encouraged. This FOA uses the R01 grant mechanism, encouraging longer-term projects, whereas its companion R21 FOA, PAR-21-288, seeks grant applications encouraging shorter, higher-risk studies.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

4. Innovative Mental Health Services Research Not Involving Clinical Trials (R01 Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-095** **Type: R01**
Application Due Date: February 05, 2023 through to July 05, 2024 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.
Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage innovative research that will inform and support the delivery of high-quality, continuously improving mental health services to benefit the greatest number of individuals with, or at risk for developing, a mental illness. This announcement invites applications for non-clinical trial R01-level projects that address NIMH strategic priorities that strengthen the public health impact of NIMH-supported research as described in Goal 4 of the NIMH Strategic Plan. Proposed research should seek to:

1. Identify mutable factors that impact access, continuity, utilization, quality, value, and outcomes, including disparities in outcomes, or scalability of mental health services, which may serve as targets in future service delivery intervention development;
2. Develop and test new research tools, technologies, measures, or methods and statistical approaches to study these issues;
3. Integrate and analyze large data sets to understand factors affecting mental health services outcomes using advanced computational and predictive analytic approaches;
4. Wherever possible, leverage existing infrastructure and partnerships to accomplish these goals.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed budget. However, 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. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

5. Laboratories to Optimize Digital Health (R01 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-096** **Type: R01**
Application Due Date: February 05, 2023 through to March 05, 2025. 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.
Funding Opportunity Announcement: NIMH seeks applications for innovative research projects to test strategies to increase the reach, efficiency, effectiveness, and quality of digital mental health interventions which may impact mental health outcomes, including suicide behaviors and serious mental illness. This FOA is intended to support the development of digital health test beds that leverage well-established digital mental health platforms and infrastructure to rapidly refine and optimize existing evidence-based digital health interventions and to conduct clinical research testing digital mental health interventions that are statistically powered to provide a definitive answer regarding the intervention's effectiveness particularly in populations who experience health disparities and vulnerable populations.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. **The maximum project period is 4 years.**

6. Mood and Psychosis Symptoms during the Menopause Transition (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-097** **Type: R01**

Application Due Date: February 05, 2023 through to October 05, 2024. 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.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage applications that will advance mechanistic and translational research on the onset and worsening of mood and psychotic disorders during the menopausal transition (or perimenopause). In particular, NIMH seeks research that will advance understanding of the underlying neurobiological and behavioral mechanisms of mood disruption and psychosis during the menopausal transition and that will identify novel targets for future mental health interventions or prevention efforts. This FOA uses the R01 grant mechanism, while the companion FOA (PAR-22-036) uses the R21 mechanism. Investigators proposing high risk/high reward projects, projects that lack preliminary data, or studies that utilize existing data may wish to apply using the R21 mechanism, while applicants with preliminary data who seek longer-term funding may wish to apply using the R01 mechanism.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 5 years. 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.

7. BRAIN Initiative: Transformative Brain Non-invasive Imaging Technology Development (UG3/UH3 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-EB-22-003** **Type: UG3/UH3**

Application Due Date: October 13, 2023. 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.

Funding Opportunity Announcement: This FOA solicits applications for team-centric development and validation of innovative non-invasive imaging technologies that could have a transformative impact on the study of brain function/connectivity. Applications are expected to turn a novel concept into a functional prototype using this phased grant mechanism. The feasibility should be established by the end of its first phase and serve as a foundation for the transition to its second phase. Fully developing the technology into a functional prototype and validating it by in-vivo animal or human function/connectivity imaging are anticipated in the second phase. The research plan should provide a realistic timeline and tangible milestones to support the proposed development effort. Awards will be integrated into the BRAIN Non-Invasive Imaging Consortium, as a coordinated network on brain function/connectivity imaging.

Budget: The BRAIN Initiative intends to commit $18M to fund an estimated up to 4 awards each fiscal year. Application budgets are limited to $300,000 in direct costs excluding consortium F&A in any year for the UG3 phase. Applications should rarely exceed $750,000 in direct costs excluding consortium F&A in any year for the UH3 phase. The proposed project period for the UG3 phase must not exceed 3 years. The proposed project period for the UH3 phase must not exceed 4 years. The total combined duration of the UG3 and UH3 must not exceed 5 years.

8. Development and Validation of a Multi-functional, Multi-purpose Quantitative Tool for Dermal Physiologically-Based Pharmacokinetic (PBPK) Modeling (U01) Clinical Trial Optional

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-015** **Type: U01**

Application Due Date: March 20, 2023 by 11:59 PM Eastern Time. 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.

Funding Opportunity Announcement: The purpose of this funding opportunity is to develop and validate an enhanced mechanistic PBPK model to reliably describe the skin permeation of active pharmaceutical ingredients in topical drug products applied on the skin surface of virtual subjects by accounting for the drug product quality attributes and the metamorphosis these products undergo post application. The goal is to develop an in silico tool and to assess its capability to predict skin absorption for reference listed drug and test drug products considering their potentially different formulation compositions and quality attributes and the dynamic changes they undergo post application. This in silico tool (validated using appropriate datasets) is intended to identify parameters that may impact therapeutic equivalence between a reference listed drug and a test drug product applied on the skin and to inform decisions on generic drug development for these products.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide ONE (1) year of support and include future recommended support for TWO (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/CDER intends to commit up to $500,000 in FY 2023 to fund up to TWO (2) awards. Application budgets need to reflect the actual needs of the proposed project. and should not exceed the following in total costs (direct and indirect) per award: YR 01: $250,000; YR 02: $250,000; YR 03: $250,000. The scope of the proposed project should determine the project period. The maximum project period is THREE (3) years.

9. Cooperative Agreement to Support the Food and Agriculture Organization (FAO) (U01) Clinical Trials Not Allowed

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-020** **Type: U01**

Application Due Date: March 7, 2023, by 11:59 PM Eastern Time. 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.

Funding Opportunity Announcement: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for award of a cooperative agreement in fiscal year 2023 (FY23) to the Food and Agriculture Organization (FAO) of the United Nations to support global strategies that address food safety and public health.

The purpose of this Cooperative Agreement is to:

1. Contribute to the knowledge base of and development of food safety systems globally due to the increasingly diverse and complex food supply.
2. Enhance and broaden FDA's ability to address global food safety and public health issues associated with food.

3. Provide opportunities to leverage additional resources of other countries.
4. Support implementation of the FDA Food Safety Modernization Act (FSMA) and FDA's International Food Safety Capacity Building Plan, which emphasizes the concept of preventing food safety-related problems before they occur and the importance of establishing strong relationships and mutual support among all stakeholders, including multilateral organizations, to improve worldwide food safety.
5. Support food safety, nutrition and public health programs that align with FDA's mission.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/Center for Food Safety and Applied Nutrition (CFSAM) intends to commit up to $750,000 in FY 2023 to fund one award. Application budgets need to reflect the actual needs of the proposed project. and should not exceed the following in total costs (direct and indirect): YR 01: $750,000; YR 02: $750,000; YR 03: $750,000; YR 04: $750,000; YR 05: $750,000.

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