

**NIH funding opportunities** 

Faculty of Medicine and Health Sciences: Research Development and Support 18 Apr 2023 (#15)

Confirm your intent to apply ASAP, but not later than **60 days** before the submission date. Tygerberg Campus: <u>cdevries@sun.ac.za</u> • Stellenbosch Campus <u>lizelk@sun.ac.za</u>

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**

<u>NOT-HG-23-034</u> Notice of Intent to Publish a Notice of Funding Opportunity for Advancing Genomic Medicine Research (R01 Clinical Trial Optional). The National Human Genome Research Institute intends to issue a Notice of Funding Opportunity (NOFO) to solicit applications that stimulate innovation and advance understanding of when, where and how best to implement the use and sharing of genomic information and technologies in clinical care in all persons including populations or communities that experience health disparities, such as racial or ethnic minority groups, people with lower socioeconomic (SES) status, underserved rural communities, and sexual and gender minority groups. First Estimated Application Due Date: October 06, 2023. Related Announcements: Notice of Intent to Publish a Notice of Funding Opportunity for Advancing Genomic Medicine Research (R21 Clinical Trial Optional). See Notice <u>NOT-HG-23-035</u>. Non-domestic (non-U.S.) Entity (Foreign Organization) = Anticipated Eligible Organization.

### **Parent Announcements**

<u>NOT-OD-23-105</u> Notice to Extend Parent R01/R03/R21 Parent Notices of Funding Opportunities. Current Key Dates Expiration Date: May 8, 2023 Modified Key Dates Expiration Date: May 8, 2024

Parent Announcements (PA) for unsolicited are broad funding opportunity announcements allowing applicants to submit investigator-initiated applications. They are open for up to 3 years and use standard due dates.

- PA-20-185 NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- PA-20-184 Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)
- PA-20-183 Research Project Grant (Parent R01 Clinical Trial Required)
- PA-20-200 NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
- <u>PA-20-195</u> NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)
- PA-20-194 NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)
- <u>PA-20-196</u> NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

## **Notice of Special Interest (NOSI)**

**NOT-DA-24-007** Assembling the Addiction Organelle Interactome. This Notice of Special Interest (NOSI) encourages innovative studies on the role of organelle interactions and communications, and how organelle dynamics affect cellular homeostasis in the context of addiction. This notice applies to due dates on or after June 5, 2023 and subsequent receipt dates through September 8, 2026.

**NOT-EB-23-002** Synthetic Biology for Biomedical Applications. The purpose of this Notice of Special Interest (NOSI) is to announce that the National Center for Complementary and Integrative Health (NCCIH), the National Cancer Institute (NCI), the National Heart, Lung and Blood Institute (NHLBI), the National Institute on Aging (NIA), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), and the National Institute of General Medical Sciences (NIGMS) are encouraging new applications to advance research activities relevant to synthetic biology. This notice applies to due dates on or after May 16, 2023 and subsequent receipt dates through May 17, 2026.

NOT-OD-23-112 EXposome in Autoimmune Disease Collaborating Teams PLANning Awards (EXACT-PLAN) (Clinical Trials Not Allowed). This Notice of Special Interest (NOSI) invites applications for exploratory, early, and conceptual stage research projects aimed at the design, development, and implementation of a future national, interdisciplinary, collaborative, team science research network that will advance the study of the exposome in autoimmune diseases (Exposome in Autoimmune Diseases Collaborating Teams, EXACT). The future EXACT Network will conduct research to discover the environmental exposures that influence disease susceptibility, onset, and outcomes and will develop a systems- level approach to understanding the mechanisms underlying how exposures perturb cellular, organ, and tissue function across autoimmune diseases (AID). The exploratory, developmental grants requested under this NOSI are intended to enable institutions to plan research strategies and develop partnerships, infrastructure, and goals capabilities needed to address the major of a future collaborative EXACT network and to develop a research framework and strategies to support coordination among studies, collaborative research projects, and sites. This Notice is a collaborative effort between ORWH, NIAMS, NIEHS and NIH Institutes, Centers, and Offices engaged in AID research. The research focus addresses one of the key gap areas identified by the National Academies of Science, Engineering and Medicine Report: Enhancing NIH Research on Autoimmune Disease (2022) (NASEM Report) (Enhancing NIH Research on Autoimmune Disease |The National Academies Press). The objectives reflect the NASEM Report's emphasis on planning, collaboration, and innovation and address the Consolidated Appropriations Act, 2023, (Public Law 117-328) directives to the NIH Office of the Director, Office of Research in Women's Health, to enhance coordination and collaboration regarding autoimmune disease research activities across Institutes and Centers. The exploratory and developmental grant will not be a prerequisite for submission of any future application. This notice applies to the due date of June 16, 2023.

## **Notice Funding Opportunity (NOFO)**

1. Fundamental Research to Understand the Mechanisms of Neurotropic Virus-mediated Disease (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due dateHyperlink: RFA-AI-23-028Type: R01Application Due Date: August 25, 2023. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to<br/>apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.Announcement: The purpose of this Notice of Funding Opportunity (NOFO) is to promote basic research to better understand the mechanisms<br/>underlying viral invasion of the central nervous system (CNS), virus- and/or host immune-mediated neuropathogenesis, and the associated<br/>clinical manifestations for emerging and re-emerging neurotropic viruses.

**Budget:** NIAID intends to commit \$2.8 million in FY 2024 to fund 5-6 awards. 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.

# 2. Catalytic Tool and Technology Development in Kidney, Urologic, and Hematologic Diseases (R21 Clinical Trial Not Allowed) Letter of Intent: 30 days prior to the application due date Hyperlink: PAR-23-119 Type: R21

Application Due Date: June 16, 2023 through to January 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.

Announcement: The purpose of this Funding Opportunity Announcement is to promote development of innovative, enabling tools and technologies in the areas of kidney, urologic, and hematologic diseases.

**Budget:** NIDDK intends to fund approximately 10 awards, corresponding to a total of \$2.0 million per fiscal year. Future year amounts will depend on annual appropriations. The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year. The maximum project period is 2 years.

#### 3. Understanding Expectancies in Cancer Symptom Management (R01 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date

Hyperlink: PAR-23-155 Type: R01

**Application Due Date: June 15, 2023 through to March 05, 2026.** 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.

Announcement: This Notice of Funding Opportunity (NOFO) will solicit mechanistic research that aims to understand how and why expectancy effects occur in a cancer context, elucidate their role in cancer symptom management, and identify patients, symptoms, cancer sites, and contexts in which expectancy effects can be leveraged to improve cancer outcomes. Expectancies are defined in this context as beliefs about future outcomes, including one's response to cancer or cancer treatment. Expectancies can be evoked by social, psychological, environmental, and systemic factors. Expectancy effects are the cognitive, behavioral, and biological outcomes caused by expectancies. Expectancy effects can be generated by expectancies held by patients, clinicians, family members, caregivers, and/or dyadic/social networks. Program is particularly interested in applications that enroll individuals and groups from populations historically underrepresented or excluded from biomedical and behavioral research.

Budget:

#### 4. Exploratory Clinical Neuroscience Research on Substance Use Disorders (R61/R33 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date

Hyperlink: PAR-23-157

Type: R61/R33

Application Due Date: June 21, 2023 through to May 07, 2026 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.

**Announcement:** This Notice of Funding Opportunity (NOFO) uses a R61/R33 Phased Innovation Award activity code to support clinical research applications that are exploratory and developmental in nature and focus on understanding the neurobiological mechanisms underlying substance use disorders (SUD), including fundamental circuitry and behavior relevant to substance use. Note: For basic science experimental studies involving humans, referred to in <u>NOT-OD-18-212</u> as "prospective basic science studies involving human participants" please use the companion NOFO - Exploratory Clinical Neuroscience Research on Substance Use Disorders (R61/R33 Basic Experimental Studies with Humans (BESH)) <u>PAR-23-282</u>. For projects not requiring a phased research approach, applicants are encouraged to apply under a different funding activity code (e.g., <u>PA-20-183</u> "Research Project Grant (Parent R01 Clinical Trial Required)".

**Budget:** For the R61 planning phase, the combined budget for direct costs for up to two years may not exceed \$500,000. For the R33 phase, budgets are not limited, but need to reflect the actual needs of the proposed project. Applicants requesting \$500,000 or more in direct costs during the R33 phase in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application, as specified in Section IV.7. The maximum period of the combined R61 and R33 phases is 5 years, with up to 2 years for the R61 phase and up to 3 years for the R33 phase. The scope of the proposed project should determine the requested project period.

#### 5. International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date

Hyperlink: RFA-AI-23-023

Type: R01

Application Due Date: August 02, 2023, August 02, 2024, August 01, 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.

Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to support applications for high-priority, regionally relevant infectious diseases research by international investigators in resource-constrained countries. Applicant organizations must be headquartered in foreign (non-U.S.) resource-constrained countries (i.e. low-income economies, lower-middle-income economies, and upper-middle-income economies by World Bank Classification). Applicant organizations headquartered in low- and lower-middle income economy countries are particularly encouraged to apply. Eligibility status of applicant organizations will be determined by the World Bank Classification list at the time of application submission.

**Budget:** NIAID intends to commit \$1,360,000 in FY 2024 to fund 7-8 awards. Application budgets should not exceed \$125,000 in direct costs per year, and should reflect the actual needs of the project. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

# 6. Strengthening Global Competency and Capacity in Inspectional Approaches for the Oversight of Human and Animal Pharmaceutical Products (U01) Clinical Trials Not Allowed

Letter of Intent: 30 days prior to the application due dateHyperlink: RFA-FD-23-022Type: U01Application Due Date: June 20, 2023, by 11:59 PM Eastern Time. Applicants are encouraged to apply early to allow adequate time to make any<br/>corrections to errors found in the application during the submission process by the due date.Type: U01

Announcement: The Cooperative Agreement will build upon the extensive experience of an institution with well-established and globally recognized expertise and quality standards for drug inspectorates of National Regulatory Authorities (NRAs) around the globe in support of data-driven and science-based regulatory public health strategies and approaches. The organization's best practices should align with the FDA domestic and global priority of assuring of the integration of pharmaceutical good manufacturing practice (GMP) inspections and risk assessment activities including data modeling for a risk-based inspection prioritization and workplan. The funding will catalyze and support the institution's activities that are focused on building a global consensus on criteria for an optimal good manufacturing practice inspection, the core competencies for Inspectors or investigators, and planning, prioritizing and conducting inspections based on well informed risk assessments within the context of the increasingly complex and evolving science and innovation in the manufacturing of pharmaceutical products. Based on such consensus, the institution and its network of NRA Inspectorates will work toward a systems-approach and sustainable alignment across NRA Inspectorates in training inspectors and regulatory experts in best practices for maintaining oversight of pharmaceutical supply chains.

**Budget:** Application budgets need to reflect the actual needs of the proposed project. and should not exceed the total costs \$150,000 per year. The scope of the proposed project should determine the project period. The maximum project period is FIVE (5) years.

#### 7. Individually Measured Phenotypes to Advance Computational Translation in Mental Health (IMPACT-MH) (U01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date

Hyperlink: RFA-MH-23-105 Type: U01

Application Due Date: June 14, 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.

Announcement: This Notice of Funding Opportunity (NOFO) is intended to stimulate and support research that will use behavioral measures and computational methods to define novel clinical signatures that can be used for individual-level prediction and clinical decision making in mental disorders. A multi-component approach is proposed in which grantees will (1) identify and/or develop behavioral tasks (and other types of measures, as appropriate) that are optimized for measurement of individual differences in individuals with or at risk of developing mental disorders; (2) collect the data from novel clinical cohorts and/or identify existing datasets that include behavioral data and other data that are typically available in the clinical record; (3) derive novel clinical signatures that incorporate behavioral measures and information derived from the clinical record, and are informative for clinical purposes; and (4) partner with a Data Coordinating Center (DCC) as described in funding opportunity RFA-MH-23-106 which will coordinate the harmonization of methods, aggregation of data, analysis of combined data, and creation of a data infrastructure to support data sharing with the scientific community. Applicants may propose new cohorts from one or more populations targeted to specific clinical groupings (e.g., mood/anxiety disorders, disorders of behavior regulation, psychosis) and/or care delivery settings, may leverage data from existing clinical research cohorts that have appropriate data structures, or may use a combination of approaches with new and existing data.

Budget: NIMH intends to commit \$30 million total in FY 2024 for this NOFO and the companion NOFO, RFA-MH-23-106, to fund up to 8 U01 awards and 1-2 U24 awards. Application budgets are limited to no more than \$2,500,000 direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

#### 8. BRAIN Initiative: Integration and Analysis of BRAIN Initiative Data (R01 Clinical Trial Not Allowed)

Hyperlink: RFA-MH-23-270 Type: R01

Letter of Intent: 30 days prior to the application due date Application Due Date: June 09, 2023, October 13, 2023, June 07, 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.

Announcement: This Notice of Funding Opportunity (NOFO) solicits applications to develop informatics tools for analyzing, visualizing, and integrating data related to the BRAIN Initiative or to enhance our understanding of the brain. As part of programs of building the informatics infrastructure for the BRAIN Initiative, the NOFO supports several different, but related activities. These include modifying existing analysis and visualization tools to deal with BRAIN Initiative data and integrating different types of BRAIN Initiative datasets. Proposing the development of new tools to deal with BRAIN Initiative data is also permitted. The tools supported under this NOFO will make use of relevant data standards and will be built so that they can be integrated into the data repositories, both of which are created in awards under the other NOFOs of the BRAIN initiative informatics program. The tools must be user-friendly in accessing and analyzing data from appropriate data archives, and should analyze/visualize data without requiring users to download data. The tools should also allow data to be combined for analysis/visualization from multiple locations.

Budget: NIMH and partner components intend to commit an estimated total cost of \$4 million to fund 4-7 awards for each round of funding. 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 3 years.

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