# **NIH funding opportunities**

## 15 April 2024 (#11)



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



#### See all Important Notices, Parent Announcements and Notice of Special Interest below

Plan your application. Before starting your application attend

1) Generic Grant Writing Workshop and then the

2) NIH Grant Writing Workshop

To prepare an application can take 4-18 months.

From submission to receiving a Notice of Award can take 10 months

### **Important Notices**

#### **NOT-OD-24-084** Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025.

This notice provides the research and research training community an overview of application and peer review changes impacting grant applications submitted for due dates on or after January 25, 2025, including:

- Simplified Review Framework for Most Research Project Grant Applications
- Revisions to the NIH Fellowship Application and Review Process
- Updates to Reference Letter Guidance
- Updates to NRSA Training Grant Applications
- Updated Application Forms (FORMS-I)
- Common Forms for Biographical Sketch and Current and Pending (Other) Support

Although each of these initiatives has specific goals, they are all meant to simplify, clarify, and/or promote greater fairness towards a level playing field for applicants throughout the application and review processes.

NIH will release additional details and guidance on these initiatives throughout 2024 which will be cross-referenced in this notice as well. NIH will host a series of webinars covering many of the changes. Details will be announced through the NIH Guide. Each webinar will be recorded for later viewing.

<u>NOT-OD-24-085</u> Simplified Review Framework for NIH Research Project Grant Applications - Update and Implementation Plans. This notice provides an update and implementation plans for the simplified framework for peer review for most research project grant applications. Implementation of the framework will be for application due dates on or after January 25, 2025.

<u>NOT-OD-24-086</u> New NIH "FORMS-I" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2025. This notice informs the applicant and recipient communities of changes to grant application forms and application guide instructions for due dates on or after January 25, 2025.

NOT-NS-24-068 Notice of National Institute of Neurological Disorders and Stroke (NINDS) Participation and Interests in NOT-AI-24-007 "Notice of Special Interest (NOSI): RNA Delivery Technologies to Allow Specific Tissue Target Homing (RNA-DASH)"

NOT-HD-24-018 Notice of Intent to Publish a Funding Opportunity Announcement for Archiving and Documenting Child Health and Human Development Data Sets (R03 Clinical Trial Not Allowed) The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) intends to publish a Notice of Funding Opportunity (NOFO) to solicit applications to support the archiving and documentation of existing data sets within the scientific mission of the NICHD in order to enable secondary analysis of these data by the scientific community. The highest priority is to archive original data collected with NICHD funding. This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects. First Estimated Application Due Date: October 01, 2024.

<u>NOT-OD-24-089</u> Notice of Participation of the Office of Research on Women's Health (ORWH) in <u>PAR-23-097</u>, "Mood and Psychosis Symptoms during the Menopause Transition (R01 Clinical Trial Optional" The purpose of this NOFO 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).

<u>NOT-OD-24-090</u> Notice of Participation of the Office of Research on Women's Health (ORWH) in <u>PAR-23-102</u>, "Mood and Psychosis Symptoms during the Menopause Transition (R21 Clinical Trial Optional)". 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.

<u>NOT-HD-24-014</u> Notice of Eunice Kennedy Shriver National Institute of Child Health and Human Development (<u>NICHD</u>) Participation in <u>NOT-HL-23-110</u> "Notice of Special Interest (NOSI): Data Informed, Place-Based Community-Engaged Research to Advance Health Equity"

#### **Parent Announcements**

#### <u>NOT-OD-24-099</u> Notice to Extend Parent R01/R03/R21 Parent Notices of Funding Opportunities. Current Key Dates Modified Expiration Date: January 8, 2025

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)
- <u>PA-20-200</u> NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
- PA-20-195 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-AI-24-028** Research to Stimulate Development of Diagnostics, Therapeutics, and Vaccines for Herpes Simplex Virus (HSV). This NOSI encourages applications which are focused on development of diagnostics, therapeutics, and vaccines for herpes simplex virus (HSV). In September 2023, the NIH released the <u>NIH Strategic Plan for HSV Research</u>. The strategic plan focuses on four strategic priorities: HSV virology basic research, better HSV diagnostics, strategies to address HSV treatment and cure, and research to prevent HSV infection. This NOSI focuses on furthering the development of new products for prevention of HSV infection, as well as improving the diagnosis and treatment of patients living with herpes, addressing three of these four strategic priorities. This notice applies to due dates on or after June 5, 2024 and subsequent receipt dates through April 5, 2027.

**NOT-AI-24-024** Inborn Errors of Immunity/Primary Immunodeficiencies. The purpose of this NOSI is to support research on the discovery and characterization of Inborn Errors of Immunity (IEIs), also referred to as Primary Immunodeficiencies, to understand the causes and mechanisms of disease, enable early detection and molecular diagnosis, and support the development of strategies to treat and eventually cure these disorders. Innovations in whole genome sequencing and other high throughput technologies have led to more rapid discovery of novel genes and molecular pathways responsible for aberrant or sub-optimal immune responses, leading to enhancement of infection or other immune-mediated diseases. Identification of genes and pathways associated with IEIs should inform discovery and development of novel diagnostic methods to inform personalized approaches for therapies. his notice applies to due dates on or after June 5, 2024, and subsequent receipt dates through March 16, 2027.

NOT-DC-24-025 Development of Imaging Techniques for High Resolution and Functional Scanning of In Vivo Human Sensory and Communication Systems. Purpose: To improve existing, and discover new, imaging techniques in terms of resolution and functional capabilities to provide accurate and timely diagnoses for humans in the clinic. Objectives: This NOSI aims to encourage grant applications that propose innovative approaches to developing high-resolution imaging technologies for structures such as the inner ear, olfactory epithelium, taste buds, and vocal production structures during disordered speech. Proposed projects should focus on improving the resolution of current imaging techniques or developing new imaging techniques that can visualize cellular, sub-cellular, and molecular structures and functions. New imaging developments should consider reducing the burden of imaging procedures on cost, invasiveness, and procedure time. The new and improved techniques must have the potential to be translated to use with humans in the clinic, preferably in an awake state. This notice applies to due dates on or after May 7, 2024, and subsequent reissues with receipt dates through May 7, 2027.

**NOT-OD-24-079** Women's Health Research. This NOSI applies to due dates on or after May 6, 2024, and subsequent receipt dates through November 4, 2027. In alignment with the <u>White House Initiative on Women's Health Research</u>, the National Institutes of Health (NIH) is issuing this Notice of Special Interest to highlight interest in receiving research applications focused on diseases and health <u>conditions</u> that predominantly affect women (e.g., autoimmune diseases; depressive disorders, Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD), gender-based-violence), present and progress differently in women (e.g., cardiovascular disease; HIV; reproductive aging and its implications), or are female-specific (e.g., uterine fibroids; endometriosis; menopause). For consideration under this NOSI, applications must have a central focus on the health of women, as demonstrated through specific aims that *EITHER* explicitly address a particular condition in women *OR* focus on one of the high priority topics below. In either approach, <u>intersectional</u> and/or multidimensional approaches that consider the health of women in context (e.g., projects accounting for social and structural variables—including <u>race</u>, <u>ethnicity</u>, <u>socioeconomic</u> status, and <u>State</u> and <u>Federal policies</u>— that affect women's health) are strongly encouraged. For consideration under this NOSI, projects are not required to exclusively focus on women. However, studies that include more than one sex or gender should be designed and powered to make generalizable conclusions about women and enable sex or gender difference comparison. High priority topics across NIH include but are not limited to:

- Projects that investigate the influence of sex-linked biology, gender-related factors, or their intersections on health.
- Projects that investigate how physical, mental, and psychological health outcomes interact with structural factors to either mitigate or exacerbate health disparities, and aim to create behavioral interventions to address these issues.
- Projects that advance the translation of research advancements and evidence in women's health into practical benefits for patients and providers
- Projects to inform and develop multi-sector partnerships to advance innovation in women's health research
- Research to increase public awareness of the need for greater investment in and attention to women's health research, as well as women's health outcomes across the lifespan
- Projects that advance research to reduce health disparities and inequities affecting women's health, including those related to race, ethnicity, age, socioeconomic status, disability, and exposure to environmental factors and contaminants that can directly affect health
- Dissemination and implementation research to increase uptake of evidence-based interventions\_that advance women's health
- Projects addressing topics identified in the <u>Women's Health Innovation Opportunity Map</u>

<u>NOT-MH-24-165</u> School Mental Health: Innovative Approaches to Expand Access to Evidence-Based Interventions and Services. The National Institute of Mental Health (NIMH) is issuing this Notice of Special Interest (NOSI) to outline priorities for school-based intervention and services research. This NOSI encourages applications that incorporate: (1)

end-user/community-engaged approaches with systematic attention to challenges related to gaining access to schools, competing demands/workload issues, workforce shortages, and privacy concerns; (2) research-practice partnerships that leverage existing practice infrastructure (e.g., Project AWARE [Advancing Wellness and Resiliency in Education],Certified Community Behavioral Health Clinics [CCBHCs]); (3) plans to quantify the resources necessary to implement the intervention, tool, or strategy (e.g., provider qualifications, training and supervision requirements, provider administration/delivery time and burden); and (4) strategies that promote health equity. This notice applies to due dates on or after June 5, 2024, and subsequent receipt dates through March 17, 2026.

<u>NOT-OD-24-078</u> Supporting the Exploration of Cloud in NIH-supported Research. Applications must be submitted as <u>Revision</u> applications to the parent awards by using <u>PA-23-317</u> "Competing Revisions to Existing NIH Single Project Research Grants and Cooperative Agreements (Clinical Trial Optional)", or any reissues of <u>PA-23-317</u> through the expiration date of this notice. The following activity codes are ELIGIBLE: R01, R15, R24, R33, R35, R37, R61, RF1, U01 and U24. Applicants are strongly encouraged to consult the program officer of the parent award to confirm eligibility. Due dates: June 18, 2024; June 18, 2025; and June 18, 2026.

**NOT-AG-24-004 U.S. Health in the International Perspective**. This NOSI expresses National Institute on Aging (NIA) interest in research that examines mechanisms and causes behind the increasing U.S. health disadvantage, which refers to worsening life expectancies and health outcomes in the U.S. compared to other countries. The complex, multifactorial pathways across the life course leading to these proximate causes of death warrant further investigation. This NOSI encourages research that leverages differences between macro- and meso-level social and environmental factors at the country, region, and/or state-level to elucidate. This notice applies to due dates on or after June 5, 2024 and subsequent receipt dates through May 8, 2027.

**NOT-AT-24-035** Interventions to Reduce Chronic Inflammation and Inflammation-Related Morbidity in People Living with HIV/AIDS. The National Center for Complementary and Integrative Health (NCCIH) and other participating National Institutes of Health (NIH) Institutes, Centers, and Offices (ICOs) are soliciting projects to evaluate and elucidate interventions to prevent, reduce, and/or reverse chronic systemic inflammation and inflammation-related comorbidities and complications in people living with HIV/AIDS (PWH). The main objective of this NOSI is to encourage applications for clinical and basic and mechanistic research to develop, refine, and/or test interventions that reduce or prevent chronic HIV-associated inflammation, and evaluate whether this ultimately reduces the sequelae of that inflammation. This notice applies to due dates on or after June 5, 2024 and subsequent receipt dates through November 13, 2024.

**NOT-CA-24-037** Epidemiologic Studies to Assess the Impact of Incretin Mimetics on New and Recurrent Cancer Risk. The purpose of this notice of special interest (NOSI) is to solicit submission of innovative epidemiologic research designed and focused on facilitating and enhancing our understanding of the impact of long-term incretin mimetic use on cancer risk and outcomes among individuals with and without comorbid conditions. Cancer types vary in latency after exogenous exposure(s). As such, latency/temporal issues (long term exposure to incretin mimetic use of one (1) year is required. In this NOSI we seek applications using large clinical data sets. Investigators are strongly encouraged to use one of various epidemiologic study designs in response to this NOSI. These may include leveraging existing population-based data sources, such as cohorts and registries, and data from available randomized clinical trials. Applicants are also encouraged to incorporate real-world data (e.g., electronic health records) when possible, or may propose new data collection as warranted. This NOSI expires May 09, 2026.

# Notice of Funding Opportunity (NOFO)

1. <u>RFA-AI-24-010</u> Feasibility of Novel Diagnostics for TB in Endemic Countries (FEND for TB) (R01 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to support the evaluation of early-stage diagnostics and novel diagnostic strategies for Tuberculosis (TB) in the context of existing clinical algorithms in TB endemic countries. Evaluation studies should: 1) perform proof-of principle studies of novel diagnostic tests and strategies for TB, including among people living with HIV (PLWH) and 2) provide feedback to diagnostic developers and policy makers on the performance of the technologies and most effective strategies for use of the diagnostic technologies in an endemic setting.

**Due date:** June 28, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIAID intends to commit \$5,500,000 in FY 2025 to fund 1-2 awards. Application budgets are not limited but are not expected to exceed \$3,500,000 in direct costs per year and need to reflect the actual needs of the proposed project. The project period must be 5 years.

2. PAR-24-160 New Approaches for Measuring Brain Changes Across Longer Timespans (R01 Clinical Trial Optional). The purpose of this funding opportunity is to encourage multidisciplinary investigators to develop new approaches or apply existing approaches in novel ways to measure brain activity, connectivity, genomics, or other aspects across the age spectrum of neurodevelopment. The overarching goal is to extend our understanding of brain development and aging, including studies of the neurodevelopmental origins of later health and disease. Research can include healthy human participants of any age; specific clinical groups such as those with cognitive, motor, or affective regulation challenges; and/or animal research on these domains of function. The studies can focus on longitudinal neuroanatomical or functional changes at any level, including genetics/genomics, single cells, connectomics, neural population activity patterns, and others. This funding opportunity is intended to encourage technological and conceptual innovation to improve repeated measures across longer epochs of the lifespan, to better predict outcomes at later ages.

**Due dates:** June 05, 2024 through to February 05, 2027. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** Application budgets are not limited but need to reflect the actual needs of the proposed project. he 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 8 weeks before submitting the application.

**3.** PAR-24-161 New Approaches for Measuring Brain Changes Across Longer Timespans (R21 Clinical Trial Optional). The purpose of this funding opportunity is to encourage multidisciplinary investigators to develop exploratory, highly novel new approaches, or innovative applications of existing approaches, to measure brain activity, connectivity, genomics, or other aspects across the age spectrum of neurodevelopment. The overarching goal is to extend our understanding of brain development and aging, including studies of the neurodevelopmental origins of later health and disease, by improving repeated measures across longer epochs of the lifespan to better predict outcomes at later ages. Research can include healthy human participants of any age; specific clinical groups such those with cognitive, motor, or affective regulation challenges; and/or animal research on these domains of function. The studies can focus on longitudinal neuroanatomical or functional changes at any level, including genetics/genomics, single cells, connectomics, neural population activity patterns, and others. This funding opportunity is intended to encourage technological and conceptual innovation through this high risk, high reward funding mechanism to develop highly innovative ideas that either lack preliminary data or need additional preliminary data.

**Due dates:** June 16, 2024, through to February 16, 2027. 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. **Letter of Intent:** 30 days prior to the application due date. **Budget:** Direct costs are limited to \$275,000 over the two-year project period. No more than \$200,000 in direct costs are allowed in any single year.

4. <u>RFA-AT-24-007</u> Limited Competition: Research Resource for Natural Product Nuclear Magnetic Resonance Data (R24 Clinical Trial Not Allowed). The National Center for Complementary and Integrative Health (NCCIH) with the Office of Dietary Supplements (ODS) solicit applications for continuation of an established nuclear magnetic resonance (NMR) research resource consisting of raw and meta-data from natural products ranging from crude extracts to purified substances; with the capacity to upload, download, store, search and analyze raw NMR data. The purpose of this limited competition is to promote sustainability, scaling and wider community inclusiveness of the established NMR research resource. This notice of funding opportunity (NOFO) is part of the Consortium Advancing Research on Botanicals and Other Natural Products (CARBON) Program. Other elements of this Program include the <u>RFA-OD-24-014</u> Botanical Dietary Supplements Translational Research Teams (RM1) and <u>RFA-AT-24-008</u> Leveraging Big Data to Understand Natural Product Impacts on Whole Person Health (R01).

**Due date:** July 08, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NCCIH and partner components intend to commit an estimated total of \$500,000 per year to fund one award. Application budgets are limited to less than \$350,000 in direct costs per year but need to reflect the actual needs of the proposed project. Support may be requested for up to five years.

#### 5. <u>RFA-HD-25-004</u> Optimizing Health of Children and Adolescents with Perinatal HIV Exposure (U19 Clinical

**Trial Optional).** This NOFO invites applications to participate in a research program cooperative agreement to support the Optimizing Health of Children and Adolescents with Perinatal HIV Exposure Initiative. The objective of this NOFO is to generate information needed to develop and to test interventions for the early detection and reduction of long-term effects of in utero/perinatal exposure to antiretroviral therapy (ART) and/or HIV among individuals who are HIV exposed but uninfected (IHEU). Investigators with innovative thinking and new approaches to address the public health issues facing IHEUs are encouraged to apply. A multi-program project grant is proposed to answer questions not easily addressed in an R01 or U01. The applications should answer important fundamental questions related to long-term health outcomes for IHEUs. Proposed projects should 1) have a scope that is well matched to the resources and the research objectives, 2) be scientifically meritorious, and 3) complement one another, be synergistic, and support the program's overall theme.

**Due date:** July 30, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NICHD intends to commit \$9.48M in FY 2025 to fund 1-2 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.

6. <u>**RFA-MH-25-110</u>** BRAIN Initiative: Data Archives for the BRAIN Initiative (R24 Clinical Trial Optional). This Notice of Funding Opportunity (NOFO) solicits applications to develop web-accessible data archives to capture, store, and curate data related to the Brain Research Through Advancing Innovative Neurotechnologies<sup>®</sup> (BRAIN) Initiative activities. The data archives teams will work with the research community to incorporate software tools that allow users to analyze and visualize the data, and will use appropriate standards to describe the data, but an application with major focus on the creation of such software tools and data standards is not responsive to this NOFO. A goal of this program is to advance research by creating a data archive with appropriate standards and summary information that is broadly available and accessible to the research community for furthering research. This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP), which will be assessed as part of the scientific and technical peer review evaluation. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn. Applicants are strongly encouraged to read the NOFO instructions carefully and view the available PEDP guidance material.</u>

**Due date:** June 24, 2024; June 24, 2025; June 24, 2026. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** Issuing IC and partner <u>components</u> intend to commit an estimated total of \$4 million to fund 3-4 awards at each receipt date. It is expected that costs will be substantially higher after the first year of these 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.

7. <u>RFA-RM-24-007</u> Technologies and Assays for Therapeutic Genome Editing INDs (U01, Clinical Trial Not Allowed). The purpose of this NOFO is to solicit applications on the optimization and characterization of technologies and assays with the potential for utilization and adoption in regulatory submissions of genome editing therapeutics. **Due date:** July 26, 2024. 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. Letter of Intent: 30 days prior to the application due date.

**Budget:** The NIH Common Fund intends to commit approximately \$2,000,000 per year for three years. Approximately four awards are anticipated, contingent upon availability of funds and receipt of a sufficient number of meritorious applications. Application budgets should reflect the actual needs of the proposed project. The maximum budget period is 3 years (FY 2025-2027).

8. <u>RFA-AG-25-017</u> Exploring Proteogenomic Approaches to Unravel the Mechanisms of Mis-Folded Protein Accumulation in Tauopathies (R01 Clinical Trial Not Allowed). This notice of funding opportunity (NOFO) invites innovative research proposals to explore the accumulation of misprocessed proteins in Tauopathies within specific brain regions and cell types. NIA encourages collaborative efforts to create advanced single-cell or single-cell type proteogenomic platforms. These platforms aim to shed light on dynamic changes in protein-misfolding responses in

neuronal proteomes and their potential biological consequences during aging and the development of Alzheimer's Disease (AD) and AD-Related Dementias (ADRD).

**Due Date:** June 10, 2024. 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. Letter of Intent: 30 days prior to the application due date.

**Budget:** NIA intends to commit \$4,000,000 in FY 2024 to fund 4-6 awards. Application budgets may not exceed \$500,000 in direct costs per year. Budgets must reflect the actual needs of the proposed project. The maximum project period is 5 years.

9. <u>RFA-DA-25-004</u> Research on the Neuro-Immune Axis in the context of HIV and Substance Use (R01 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to support research towards identifying and characterizing neuroimmune networks, communication pathways, and targets that reside within neuroimmune axes, in the context of HIV and substance use. This NOFO will also support research on the discovery of novel modulatory probes/tools that can advance our knowledge of the regulatory mechanisms by which neuroimmune interactions contribute to HIV and substance use disorder comorbidity. Applications testing a fully conceptualized premise founded with adequate preliminary data are appropriate for this NOFO.Exploratory research projects should consider applying to the companion R21 announcement <u>RFA-DA-25-005</u>.

**Due date:** November 13, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIDA intends to commit \$2M in FY 2025 to fund up to six awards in response to <u>RFA-DA-25-004</u> and the companion NOFO <u>RFA-DA-25-005</u>. Application budgets are not limited but need to reflect the actual needs of the proposed project. The award project period must be appropriate for the scope of the proposed research and cannot exceed 5 years.

10. <u>RFA-AI-24-006</u> Centers for Research in Emerging Infectious Diseases (CREID) Network (U01 Clinical Trial Not Allowed). The purpose of this NOFO is to invite applications for the Centers for Research in Emerging Infectious Diseases (CREID) Network Research Centers (RCs). The CREID Network, comprised of all recipients under this NOFO and the companion NOFO [<u>RFA-AI-24-016</u>], serves to expand knowledge on re-emerging and emerging infectious diseases (re/EIDs) around the globe where outbreaks are most likely to occur while developing expertise, capacity, and readiness to address outbreak-related research. Multi- and interdisciplinary teams of domestic and international investigators will conduct innovative, collaborative, hypothesis-driven One Health (approach that recognizes the health of humans is interconnected with that of animal health and the shared environment) based research, will undertake outbreak-related research, when necessary, in their geographical areas, and will work across the CREID Network in a coordinated, collaborative, and cooperative fashion.

**Due date:** June 21, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIAID intends to commit \$13.5M in FY 2025 to fund 6-8 awards. Application budgets are not expected to exceed \$850,000 in direct costs per year and need to reflect the actual needs of the proposed project. Project period must be 5 years in length.

11. <u>RFA-AI-24-016</u> Centers for Research in Emerging Infectious Diseases (CREID) Network Coordination Center (U01 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to invite applications for the Centers for Research in Emerging Infectious Diseases (CREID) Network Coordination Center (CC). The CREID Network, comprised of all recipients under this NOFO and the companion NOFO [<u>RFA-AI-24-006</u>], serves to expand knowledge on re-emerging and emerging infectious diseases (re/EIDs) around the globe where outbreaks are most likely to occur while developing expertise, capacity, and readiness to address outbreak-related research. The CC will serve to lead, advance, facilitate, and coordinate critical and collaborative scientific, data and resource management, communication, and administrative activities during both outbreak and non-outbreak periods among the CREID Network research centers in a coordinated, collaborative, and cooperative fashion.

**Due date:** June 21, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

Budget: NIAID intends to commit \$2M in FY 2025 to fund 1 award. Application budgets are not expected to exceed \$1,500,000 in direct costs per year and should reflect the actual needs of the proposed project. Project period must be 5 years in length.

#### 12. <u>RFA-AI-24-008</u> Strategies for Controlled Release of HIV Vaccines (SCORE-H) (R01 Clinical Trial Not Allowed).

The purpose of this Notice of Funding Opportunity (NOFO) is to support product-focused research to advance controlled release vaccine strategies to improve immune responses for HIV prevention, treatment, and cure and develop simplified or single-shot vaccination formulations. Timelines with measurable milestones are required.

**Due date:** July 30, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** The following NIH components intend to commit the following amounts in FY25: NIAID, \$3,000,000 and NIMH, \$300,000 to fund 3-5 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum requested project period is 5 years.

#### 13. <u>RFA-DK-24-002</u> Adaptation of Diabetes Control Technologies for Older Adults with T1D (R01 Clinical Trial

**Optional).** The main objective of this NOFO is to foster development and testing of technologies adaptable to agingrelated changes in older adults (aged 65 years or older) with T1D to improve diabetes management and quality of life. Older adults may have increased vulnerability to hypoglycemia, cognitive impairment and/or multiple co-morbidities which may affect the risks and benefits of these technologies in this population. Projects will be funded to a) develop and test new technologies and b) to adapt and test existing technologies. It is expected that aging-adaptive diabetes technologies that address barriers for use among older adults with T1D will improve usability, adoption and adherence decreasing the risk of hypoglycemia (and hypoglycemia unawareness) while enhancing glycemic control, facilitating better diabetes management, and improving quality of life for these individuals and their caregivers.

**Due date:** July 17, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIDDK intends to commit \$1 million in FY 2024 to fund 2-3 awards and up to \$1 million in FY2025 to fund 2-3 awards. Application budgets are limited to \$500,000 direct costs per year, exclusive of indirect costs on subcontracts, per year. Budgets are expected 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.

14. RFA-MH-25-190 Precision Mental Health: Develop Tools to Inform Treatment Selection in Depression (UG3/UH3 Clinical Trial Optional). The purpose of this phased NOFO is to create a pipeline to accelerate the development and early validation of predictive tools and/or biomarkers to inform individual-level treatment selection among two or more existing therapeutics for depression. This phased inter-agency program will be milestone-based and provide support from multi-disciplinary teams to address scientific, technical, clinical, regulatory, and commercialization requirements. In the first phase (UG3), investigators are expected to identify potential tools and/or biomarker(s) that can predict whether a patient will differentially respond to one well-established depression treatment versus another. This could be accomplished using secondary analysis of data from completed clinical trials or using real-world clinical data, or by conducting small, efficient pilot feasibility studies to assess promising new tools or biomarkers to predict individual treatment response to a specific therapeutic for depression. In the second phase (UH3), investigators will conduct independent, prospective clinical trials to initially validate the utility of the tool/biomarker for predicting differential response to established treatments for depression. The overall goal of this NOFO is to support the testing of various tools/biomarkers as predictors of response to well-established depression treatments and halt the development of those tools that do not meet sufficient performance characteristics to justify further testing. Ultimately, tools that are successful in early-stage studies could be further evaluated for future use in decision-making in clinical practice settings.

**Due date:** October 18, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIMH intends to commit a total of \$5,000,000 in FY 2025 to fund up to 10 awards. Application budgets are limited to \$500,000 in direct costs per year for the UG3 phase and up to \$1,500,000 in direct costs per year of the UH3 phase. Applicants may seek one-two years of funding for the UG3 phase and up 5 years in total for the UG3/UH3 phase. The actual duration of individual projects will depend on successful achievement of milestones and conditions as described in Milestones Section of the program overview.

**15.** <u>**RFA-AI-24-018**</u> Interaction between ARVs and Hormones in HIV and Coinfections (R01 Clinical Trial Optional). The purpose of this NOFO is to support research to identify and characterize the interaction between hormone therapy and antiretroviral drugs (ARVs) used for treatment and prevention of HIV and co-infections.

**Due date:** July 30, 2024. 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. Letter of Intent: 30 days prior to the application due date.

**Budget:** The issuing IC and partner components intend to commit an estimated total of \$4.8 M to fund 4-7 awards in FY2025. 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 requested project period is five years.

16. <u>**RFA-AT-24-008</u>** Leveraging Data at Scale to Understand Natural Product Impacts on Whole Person Health</u>

**(R01 Clinical Trial Not Allowed).** This NOFO will support development, adaptation, and/or applications of computational tools to aggregate and analyze orthogonal chemical and/or biological data sets related to natural products with the aim of generating novel testable hypotheses regarding their biological activity and role in the context of whole person health research. Projects must leverage and merge multiple compatible or interoperable sources and/or types of data. Use of artificial intelligence and machine learning approaches is encouraged. This NOFO is part of the Consortium Advancing Research on Botanicals and Other Natural Products (CARBON) Program. Other components of this Program include the Botanical Dietary Supplements Translational Research Teams (RM1) and <u>RFA-AT-24-007</u> Limited Competition: Research Resource for Natural Product Nuclear Magnetic Resonance Data (R24).

**Due dates:** June 28, 2024. 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. **Letter of Intent:** 30 days prior to the application due date.

**Budget**: Application budgets are limited to less than \$500K in Direct Costs 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

17. <u>**RFA-FD-24-037</u>** Use of Digital Health Technologies in Clinical Investigations to Support Drug and Biological **Product Development (U01) Clinical Trials Optional.** The purpose of this notice of funding opportunity (NOFO) is to address topics related to the use of digital health technologies (DHTs) for remote data acquisition in clinical investigations to support drug development.</u>

**Due dates:** May 20, 2024. 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. **Letter of Intent to NIH:** 30 days prior to the application due date.

**Budget:** FDA/ CDER intends to commit \$1.1 million in fiscal year 2024 and \$860,000 in 2025 to fund 1 (one) award. The scope of the proposed project should determine the project period. The maximum project period is 2 (two) years.

**18.** <u>PAR-24-203</u> Neuropathological Interactions Between COVID-19 and ADRD (R01 - Clinical Trial Not Allowed). This NOFO is to solicit applications that propose studies in animal, cell culture, and/or human tissue models to elucidate the mechanisms by which COVID-19 interacts with and/or modulates ADRD-relevant phenotypes. The NOFO intends to support studies that are disease mechanistic in nature and must incorporate ADRD outcomes, risk factors, pathologies, or relevant comorbidities.

**Due date: October 04, 2024** 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. **Letter of Intent to NIH:** 30 days prior to the application due date.

**Budget:** NIH intends to commit up to \$3,750,000 in FY 2025 to fund up to five awards. Application budgets are limited to \$500,000 in direct costs/year and need to reflect the actual needs of the proposed project. The maximum project period is five years.

19. **RFA-DA-25-039** Education Activities for Responsible Analyses of Complex, Large-Scale Data (R25- Clinical Trial Not Allowed). The NIH Research Education Program (R25) supports research education activities in the mission areas of the NIH. The overarching goal of this R25 program is to support educational activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs. To accomplish the stated over-arching goal, this NOFO will support educational activities with a primary focus on: Courses for Skills Development & Curriculum or Methods Development. The goal of this NIDA R25 program is to support training and educational activities for responsible analyses of complex large-scale data involving brain, behavioral, genomic, and socioenvironmental data that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral, and clinical research needs. This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP), which will be assessed as part of the scientific and technical peer review evaluation. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn. Applicants are strongly encouraged to read the NOFO instructions carefully and view the available <u>PEDP guidance material</u>.

**Due date:** December 18, 2024. 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. **Letter of Intent to NIH**: 30 days prior to the application due date.

**Budget:** NIDA intends to commit \$500,000 in FY 2025 to fund up to 3 awards. Application budgets must reflect the actual needs of the proposed project and are limited to \$300,000 direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is 3 years.

20. <u>**RFA-AI-24-021</u>** Partnerships for the Development of Tools to Advance Therapeutic Discovery for Select Antibiotic-Resistant Gram-Negative Bacteria (R01 Clinical Trial Not Allowed). The purpose of this Notice of Funding Opportunity (NOFO) is to support milestone-driven projects focused on developing and utilizing novel predictive models, assays, tools, and/or platforms based on penetration and efflux of small molecules to facilitate therapeutic discovery for select Gram-negative bacterial pathogens: carbapenem-resistant Acinetobacter, carbapenem-resistant Enterobacterales (CRE), and multidrug-resistant Pseudomonas aeruginosa.</u>

**Due date:** August 20, 2024. 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. **Letter of Intent to NIH:** 30 days prior to the application due date.

**Budget:** NIAID intends to commit \$7.25 million in FY2025 to fund 7-9 awards. Application budgets are not expected to exceed \$750,000 in direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is five years.

Faculty of Medicine and Health Sciences Research & Internationalisation Development & Support (RIDS) & Grants Management Office (GMO) 009 K <sup>th</sup> Floor, Teaching Block, Tygerberg Campus.	Stellenbosch Campus Division for Research Development (DRD) 2041 Krotoa Building, Ryneveld Street
Enquiries: <u>cdevries@sun.ac.za</u> / <u>fmhsgmo@sun.ac.za</u>	Enquiries: <u>research@sun.ac.za</u>
Add "Interest in NIH opportunity" in the subject line. Add the notice number in the text of the email.	