NIH funding opportunities

17 January 2025 (#03)



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 the2) 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-HS-25-006 New "FORMS-I" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2025. The following application forms include substantive form changes (i.e., new/deleted/modified fields). All other forms include only an OMB expiration date change.

- PHS 398 Research Training Program Plan
- PHS Fellowship Supplemental Form
- PHS Assignment Request Form
- PHS 398 Cover Page Supplement Form

Application guides for FORMS-I application packages will be posted to the <u>How to Apply - Application Guide</u> page in November 2024.

NOT-OD-25-044 Updates to NIH Training Grant Application Data Tables for Application Due Dates on or After January 25, 2025. This notice serves as a reminder regarding updates to the NIH Institutional Training Program application required training data tables. These changes take effect starting with submissions for due dates on or after January 25, 2025. The overall goals of these changes are to: (1) reduce applicant and reviewer burden and (2) promote consistent information collection across training programs. The following activity codes are affected: International Institutional Training – D43, D71, U2R.

Parent Announcements

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-25-301 NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- PA-25-303 Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)
- PA-25-305 Research Project Grant (Parent R01 Clinical Trial Required)
- PA-25-302 NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)

- PA-25-304 NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)
- PA-25-306 NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)
- <u>PA-25-307</u> NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

Notice of Special Interest (NOSI)

<u>NOT-AI-24-085</u> Somatic Cell Gene Editing Therapies to Improve Transplantation. The National Institute of Allergy and Infectious Diseases (NIAID) is interested in supporting research that applies somatic cell gene editing (SCGE) approaches in animal models or human tissues or organs excluded from clinical use to improve graft survival and outcomes for recipients of allogenic or xenogeneic solid organ or pancreatic islet transplants, or vascularized composite allografts (VCA). This notice applies to due dates on or after February 5, 2025 and subsequent receipt dates through November 16, 2027.

NOT-AG-24-074 Innovative Interdisciplinary Research on Female Reproductive Aging. NIA is issuing this notice to encourage innovative interdisciplinary research on the molecular, cellular, and physiological processes involved in female reproductive aging, with the goal to identify and understand key biological pathways involved in aging associated health outcomes in women across the lifespan. Interdisciplinary research that integrates knowledge, expertise, and perspectives from different disciplines may help to give a more complete understanding of the biological drivers of female reproductive aging, as well as provide novel insights into the complexity of overall aging in females. This notice applies to due dates on or after February 5, 2025 and subsequent receipt dates through May 8, 2028.

Notice is to inform potential applicants of NCI's interest in receiving applications focused on survivorship research for people living with advanced and metastatic cancers. NCI is interested in applications proposing observational or intervention studies. Applications may focus on cancer survivors diagnosed at any age (childhood through adulthood) and may focus on a single cancer type or multiple cancer types. Applicants must adequately describe the population proposed in the study, including a justification for how this is a population living with likely incurable cancer. NCI strongly encourages applicants to include a plan for survivor engagement during the development, planning, and conduct of the proposed research project. This notice applies to application due dates on or after February 5, 2025 through to January 7, 2028.

NOT-HL-24-036 Cardiorespiratory and Sleep Complications of the Muscular Dystrophies. Patients with muscular dystrophies and their caregivers, including families and clinical teams, face significant challenges. These individuals often experience progressive difficulties in breathing and sleeping, along with decreased exercise tolerance due to cardiorespiratory insufficiency. Research is needed to better understand upper airway obstruction and central ventilatory control mechanisms, given the heterogeneity in pulmonary decline among different dystrophies and individuals. Racial and ethnic disparities in outcomes highlight the need for equitable care and research addressing these disparities, and for encouraging participation from understudied populations. This notice applies to application due dates on or after February 5, 2025 through to February 5, 2028.

NOT-MH-25-045 Molecular and Cellular Computational Tools Supporting Fundamental Neuroscience Research in Health, Mental Illness and Developmental Processes. This NOSI encourages computational approaches in fundamental neuroscience research investigating the molecular and cellular mechanisms that drive the structure and function of cells and circuits supporting cognitive, affective, and social domains, in both health and mental illness, during early development and across the lifespan. This NOSI invites rigorous, hypothesis-driven studies that integrate the development of biophysically based models of neuronal and glial processes with an experimental component to test model predictions. Use of precise, state-of-the-art experimental techniques that offer high spatial and/or temporal resolution of molecular and cellular processes, as well as advanced methods to manipulate these processes, is encouraged. This NOSI supports studies conducted in vitro, ex vivo, and in vivo toward the goal of uncovering mechanistic links across biological scales. To promote this interdisciplinary research, collaborations between investigators with complementary theoretical/computational and experimental expertise are essential. These partnerships can drive innovative research and address scientific and technical challenges that might be intractable otherwise. This notice applies to due dates on or after February 5, 2025, and subsequent receipt dates through May 10, 2028.

NOT-MH-25-050 Al/ML in Pre-Clinical Drug Development for Psychiatric Disorders. The purpose of this NOSI is to encourage the use of artificial intelligence (AI)/ machine learning (ML) methods to accelerate any of the steps of preclinical Drug Discovery (DD): target identification, lead identification, and lead optimization. The focus of this NOSI is on preclinical drug discovery. Investigational New Drug (IND)-enabling studies, scale-up for manufacturing, and clinical research and development are out of the scope of this NOSI. Team science approaches where the strength and knowledge of multiple individuals across computational sciences, biology, and clinical expertise in psychiatric diseases, among others, are strongly encouraged. For this NOSI, Al/ML refers to AI and its subsets (machine learning, deep learning, neural networks, natural language processing). Applications must include experimental testing of the predictions made by the model. Studies focusing on computational tools and models for molecular and cellular mechanisms underlying brain processes should consider NOT-MH-25-045. This notice applies to due dates on or after January 25, 2025, and subsequent receipt dates through January 8, 2029.

Notice of Funding Opportunity (NOFO)

RFA-AI-24-023 U.S.-South Africa Program for Collaborative Biomedical Research – Phase 3 (HIV/AIDS) (R01 Clinical Trial Optional). The purpose of this Notice of Funding Opportunity (NOFO) is to support research projects under Phase 3 of the U.S.-South Africa Program for Collaborative Biomedical Research. Research areas supported under this program include HIV/AIDS, HIV/AIDS co-morbidities and co-infections, HIV/AIDS-associated implementation science, and HIV/AIDS-associated data science. The hallmark of the U.S.-South Africa program is the development of collaborative partnerships between South African investigators and United States (U.S.) investigators. Through international collaboration, this research will advance scientific discoveries, promote sharing of technologies and approaches, and serve local public health needs and priorities in support of global HIV/AIDS research.

AIDS Date: March 12, 2025. All applications are due by 5:00 PM local time of applicant organization. **Letter of Intent:** 30 days prior to the application due date.

Budget: Issuing IC and partner components intend to commit an estimated total of \$3.8 million to fund 8-10 awards. Application budgets are not expected to exceed \$400,000 in direct costs per year and should 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.

<u>Important Notice:</u> All potential applicants <u>MUST</u> inform the Grants Management Office <u>before</u> 12 January 2025 of their intention to apply. This must include the specific aims, participating institutions and list of all key personnel and consultants. Only after receiving this internal letter of intent, meetings with the PI will be scheduled and project plans will be prepared. <u>Please also contact the Scientific Program officials</u> listed in the NOFO to ensure that your application is responsive to the call.

PAR-25-242 Mobile Health: Technology and Outcomes in Low and Middle Income Countries (R21/R33 - Clinical Trial Optional). The purpose of this Notice of Funding Opportunity (NOFO) is to encourage exploratory/developmental research applications that propose to study the development, validation, feasibility, and effectiveness of innovative mobile health (mHealth) interventions or tools specifically suited for low- and middle-income countries (LMICs) that utilize new or emerging technology, platforms, systems, and/or analytics. The overall goal of the program is to catalyze innovation through multidisciplinary research that addresses global health problems, develop an evidence base for the use of mHealth technology to improve clinical and public health outcomes, and strengthen mHealth research capacity in LMICs. This NOFO provides support for up to two years (R21 phase) for technology development and feasibility studies, followed by a possible transition to expanded research support (R33 phase) for validation, larger-scale feasibility, and effectiveness studies. Transition to the R33 depends on the completion of applicant-defined milestones, as well as program priorities and the availability of funds. All applicants must address both the R21 and R33 phases.

Date: March 21, 2025 & March 20, 2026. All applications are due by 5:00 PM local time of applicant organization. **Budget:** The R21 phase may not exceed \$125,000 in direct costs in any single year of the R21 phase. The R33 phase may not exceed \$200,000 in direct costs in any single year of the R33 phase. The project period is limited to 2 years for the R21 phase and up to 3 years for the R33 phase. The total project period may not exceed 5 years.

<u>PAR-25-100</u> Pilot Health Services and Economic Research on the Treatment of Drug, Alcohol, and Tobacco Use Disorders (R34 Clinical Trial Optional). The purpose of this notice of funding opportunity (NOFO) encourages pilot and preliminary research in preparation for larger-scale services research effectiveness trials. Relevant trials may test a wide range of approaches, including interventions, practices, and policies designed to optimize access to, and the quality, effectiveness, affordability and utilization of tobacco or substance use disorder treatments and related services, as well as services for comorbid medical and mental disorder conditions. Relevant approaches may include

both those that are novel, and those that are commonly used in practice but lack an evidence base. This NOFO provides resources for assessing the feasibility, acceptability, and utility of these approaches, in addition to usual trial preparation activities.

Date: May 07, 2025 through to May 07, 2027. All applications are due by 5:00 PM local time of applicant organization. **Budget:** The Direct costs are limited to \$450,000 over the 3-year project period, with no more than \$225,000 in direct costs allowed in any single year. The total project period for an application submitted may not exceed three years.

PAR-25-265 Innovative Screening Approaches and Therapies for Screenable Disorders in Newborns (R01 - Clinical Trial Optional). This NOFO encourages research relevant to the development of novel screening approaches and/or therapeutic interventions for conditions for which newborn screening has already been implemented, as well as for potentially fatal or disabling genetic conditions that could benefit in the near future from the early detection made possible by newborn screening. This research is especially critical given that accurate screening tests and demonstrable benefits of early intervention are often prerequisites for new conditions to be added to newborn screening panels.

Date: June 05, 2025 through to October 05, 2027. All applications are due by 5:00 PM local time of applicant

Date: June 05, 2025 through to October 05, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: The 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.

PAR-25-266 Innovative Screening Approaches and Therapies for Screenable Disorders in Newborns (R21 - Clinical Trial Optional). This NOFO encourages research relevant to the development of novel screening approaches and/or therapeutic interventions for conditions for which newborn screening has already been implemented, as well as for potentially fatal or disabling genetic conditions that could benefit in the near future from the early detection made possible by newborn screening. This research is especially critical given that accurate screening tests and demonstrable benefits of early intervention are often prerequisites for new conditions to be added to newborn screening panels.

Date: June 16, 2025 through to October 16, 2027All applications are due by 5:00 PM local time of applicant organization.

Budget: 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 total project period may not exceed 2 years. The scope of the proposed project should determine the project period.

<u>PAR-25-300</u> Targeting Cell Surface HIV Envelope for Cell Elimination (R01 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to support the investigation of HIV-1 Envelope (Env) cell surface expression, the structural mechanism of biologic-mediated cell killing, and the development of novel approaches to enhance the recognition and elimination of Env-expressing, HIV-1 infected cells. These studies are expected to inform the development of immunotherapies and targeted vaccines for HIV-1 prevention and cure.

Date: May 07, 2025 through to January 07, 2028. All applications are due by 5:00 PM local time of applicant organization.

Budget: The 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 five years.

RFA-DA-26-003 Research to Address Systemic and Structural Barriers and Facilitators to Improve the HIV Pre-Exposure Prophylaxis (PrEP) Care Continuum for People Who Use Substances (R01 Clinical Trials Required). This notice of funding opportunity (NOFO) invites applications for research to address systemic and structural factors that impede or facilitate the pre-exposure prophylaxis (PrEP) uptake and persistence among people who use substances in the U.S. and worldwide. Research projects supported by this NOFO will develop, implement, and evaluate system/structural-directed strategies that meet the needs of people who use substances to improve the PrEP uptake and persistence. Particular emphasis is placed on strategies designed to benefit populations disproportionately affected by substance use and human immunodeficiency viruses (HIV), including but not limited to: women, transgender people, people with a history of criminal legal involvement, sex workers, and men who have sex with men, for whom PrEP uptake and persistence rates are the lowest. This NOFO requires an intersectional perspective. Projects should focus on equitable, scalable, and sustainable approaches for accelerating the improvement of the PrEP uptake and persistence for marginalized and underserved people who use substances.

Date: March 12, 2025 .All applications are due by 5:00 PM local time of applicant organization.

Budget: The Application budgets are not limited but need to reflect the actual needs of the proposed project. Unless well-justified, it is strongly recommended that applicants not request a budget of more than \$500,000 in direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

RFA-DA-26-004 Research to Address Systemic and Structural Barriers and Facilitators to Improve the HIV Pre-Exposure Prophylaxis (PrEP) Care Continuum for People Who Use Substances (R34 Clinical Trials Required). This notice of funding opportunity (NOFO) invites applications for research to address systemic and structural factors that impede or facilitate the pre-exposure prophylaxis (PrEP) uptake and persistence among people who use substances in the U.S. and worldwide. Research projects supported by this NOFO will develop, implement, and evaluate system/structural-directed strategies that meet the needs of people who use substances to improve the PrEP uptake and persistence. Particular emphasis is placed on strategies designed to benefit populations disproportionately affected by substance use and human immunodeficiency viruses (HIV), including but not limited to: women, transgender people, people with a history of criminal legal involvement, sex workers, and men who have sex with men, for whom PrEP uptake and persistence rates are the lowest. This NOFO requires an intersectional perspective. Projects should focus on equitable, scalable, and sustainable approaches for accelerating the improvement of the PrEP uptake and persistence for marginalized and underserved people who use substances.

Date: March 12, 2025 All applications are due by 5:00 PM local time of applicant organization.

Budget: This R34 is limited to direct costs requests of up to \$450,000 over the entire project period. Although variations from year to year are permissible, in no case may any year be more than \$225,000 in direct costs. The scope of the proposed project should determine the project period. The maximum project period is 3 years.

RFA-DA-26-055 Accelerating the Pace of Substance Use Research Using Existing Data (R01 Clinical Trial Not Allowed)

The purpose of this notice of funding opportunity (NOFO) is to invite applications proposing innovative analysis of existing social science, behavioural, administrative, and neuroimaging data to study the etiology and epidemiology of substance using behaviours (defined as alcohol, tobacco, prescription, and other substances) and related disorders, prevention of substance use and HIV, and health service utilization. This NOFO encourages the analyses of public use and other extant community-based or clinical datasets to their full potential in order to increase our knowledge of etiology, trajectories of substance using behaviours and their consequences including morbidity and mortality, risk and resilience in the development of psychopathology, strategies to guide the development, testing, implementation, and delivery of high quality, effective and efficient services for the prevention and treatment of substance use disorder and HIV. Primary data collection is not allowed for applications in response to this NOFO.

Date: July 17, 2025 through to December 03, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: The NIDA intends to commit \$2 million in FY 2026 to award 2-4 applications, with an additional \$2 million for 2-4 applications focused on HIV research, in response to this and the companion R21 RFA RFA-DA-26-056. 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

RFA-DA-26-056 Accelerating the Pace of Substance Use Research Using Existing Data (R21 Clinical Trial Not Allowed).

The purpose of this notice of funding opportunity (NOFO) is to invite applications proposing innovative analysis of existing social science, behavioural, administrative, and neuroimaging data to study the etiology and epidemiology of substance using behaviours (defined as alcohol, tobacco, prescription, and other substances) and related disorders, prevention of substance use and HIV, and health service utilization. This NOFO encourages the analyses of public use and other extant community-based or clinical datasets to their full potential in order to increase our knowledge of etiology, trajectories of substance using behaviours and their consequences, including morbidity and mortality, risk and resilience in the development of psychopathology, strategies to guide the development, testing, implementation, and delivery of high quality, effective and efficient services for the prevention and treatment of substance use disorder and HIV. Primary data collection is not allowed for applications in response to this NOFO.

Date: July 17, 2025 through to December 03, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: 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 period is 2 years.

RFA-ES-25-003 Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trials Not

Allowed). This Notice of Funding Opportunity (NOFO) is intended to support novel environmental health research in which an unpredictable event or policy change provides a limited window of opportunity to collect human biological samples or environmental exposure data. The primary motivation of the NOFO is to understand the consequences of natural and human-made disasters, emerging environmental public health threats, and policy changes in the U.S. and abroad. A distinguishing feature of an appropriate study is the need for rapid review and funding, substantially shorter than the typical NIH grant review/award cycle, for the research question to be addressed and swiftly implemented.

The shortened timeframe will be achieved by more frequent application due dates and expediting peer review, council concurrence and award issuance. The entire cycle, from submission to award, is expected to be within 4–6 months.

Date: April 01, 2025 though to December 01, 2025. All applications are due by 5:00 PM local time of applicant organization.

Budget: The NIEHS intends to commit \$800,000 in FY 2025 to fund 4-5 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum period may not exceed 2 years.

RFA-HG-25-007 Informatics Tools for the Pangenome (U01 Clinical Trial Not Allowed). This NOFO seeks applications for the development of informatics tools to facilitate uptake and scientific use of the human pangenome reference being developed and maintained by the NHGRI Human Genome Reference Program (HGRP). Emphasis for this RFA will be on development of tools to advance compelling use cases that are relevant to different broad sectors of the genomics community, e.g., clinical, population, or functional genomics. These tools will use pangenome datasets and build on systems developed by the Human Pangenome Coordinating Center (see below), which will support general computational infrastructure for pangenome use. This informatics tools RFA will fund one component of an overall HGRP, which will also include two other components: High Quality Reference Genomes (herein called "Genomes Center"), and a Human Pangenome Coordinating Center (Herein called "Coordinating Center"). (See Companion Funding Opportunities). Awardees under all three RFAs will work collaboratively within a consortium towards production and community adoption of the human pangenome reference.

Date: March 03, 2025. All applications are due by 5:00 PM local time of applicant organization.

Budget: The Participating components intend to commit \$3M in FY2026 to fund up to 6 awards. Application budgets are limited to \$400,000 direct costs per year, but need to reflect the actual needs of the proposed project. The maximum project period is 3 years.

RFA-OD-25-001 High-Priority Research in Tobacco Regulatory Science (R01 Clinical Trial Optional). The purpose of this Notice of Funding Opportunity (NOFO) is to invite R01 applications to support new high-priority biomedical and behavioral research that will provide scientific data to inform the regulation of tobacco products to protect public health. Research Projects must address the new high-priority research topics related to the regulatory authority of the Food and Drug Administration (FDA) Center for Tobacco Products (CTP). The awards under this NOFO will be administered by NIH using funds that have been made available through FDA CTP and the Family Smoking Prevention and Tobacco Control Act (FSPTCA), P.L. 111-31. Research results from this NOFO are expected to generate findings and data that are directly relevant in informing the FDA's regulation of the manufacture, distribution, and marketing of tobacco products to protect public health.

Date: June 06, 2025. All applications are due by 5:00 PM local time of applicant organization. Letter of Intent **due 60** days prior to the application due date.

Budget: The NIH, via support from the FDA Center for Tobacco Products (CTP), intends to fund up to 5 R01s, corresponding to a total of up to \$4 million, for fiscal year 2026. Future year amounts will depend on the availability of funds. Application budgets are limited to \$500,000 in direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

PAR-25-028 Single-Site Investigator-Initiated Clinical Trials (R61/R33 Clinical Trial Required). This Notice of Funding Opportunity (NOFO) supports applications to develop and implement investigator-initiated single site clinical trials including efficacy, comparative effectiveness, pragmatic and/or implementation research clinical trials. Trials using innovative designs such as platform trials, adaptive, and Bayesian designs are encouraged. These trials may include ones that test different therapeutic, behavioural, and/or prevention strategies. Trials for which this NOFO applies must be relevant to the research mission of the NHLBI and meet the NIH definition of a clinical trial (see NOT-OD-15-015). For additional information about the mission, strategic vision, and research priorities of the NHLBI, applicants are encouraged to consult the NHLBI website. This NOFO will utilize a bi-phasic, milestone-driven mechanism of award. The objective of the application is to present the scientific rationale for the clinical trial and a comprehensive scientific and operational plan that describes it. The application should address project management, subject recruitment and retention, performance milestones, scientific conduct of the trial, and dissemination of results. The multiple PD/PI model is strongly encouraged but not required. Applicants are encouraged to include a PD/PI with expertise in biostatistics, clinical trial design, and coordination. The application should also describe its approaches to increasing community engagement and reducing health inequities and disparities.

Date: June 11, 2025.All applications are due by 5:00 PM local time of applicant organization.

Budget: The 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 requested project award period. The maximum period of the combined R61 and R33 phases is 5 years, with up to 1 year for the R61 phase and up to 4 years for the R33 phase.

PAR-25-321 Exploratory/Developmental Bioengineering Research Grants (EBRG) (R21 Clinical Trial Optional). The purpose of this engineering-oriented notice of funding opportunity (NOFO) announcement is to encourage submissions of exploratory/developmental Bioengineering Research Grant (EBRG) applications to demonstrate feasibility and potential utility of new capabilities or improvements in quality, speed, efficacy, operability, costs, and/or accessibility of solutions to problems in basic biomedical, pre-clinical, or clinical research, clinical care delivery, or accessibility. This NOFO will support clinical trials that test functionality or validate performance in the chosen setting. Applications that propose phase III clinical trials are not sought by and will not be supported through this NOFO. The overall goals of this NOFO are to identify cancer risks and risk reduction strategies, to identify factors that cause cancer in humans, and to discover and develop mechanisms for cancer prevention and preventive interventions in humans.

Date: June 16, 2025 through to October 16, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: 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.

PAR-25-325 Integrating Biospecimen Science Approaches into Clinical Assay Development (U01 Clinical Trial Not Allowed). Through this Notice of Funding Opportunity (NOFO), the National Cancer Institute (NCI) intends to support extramural research to investigate and mitigate challenges in clinical assay development and subsequent analytical validation due to preanalytical variability in tumour tissue biopsies, blood biospecimens utilized as "liquid biopsies", or other biospecimens as described in this NOFO. Extramural research funded under this NOFO may include investigations of preanalytical variability associated with the procurement and study of small biopsies (core biopsies, small excision samples), blood utilized for "liquid biopsies", tissue swabs, tissue secretions, pleural and oesophageal aspirates, faeces, or bodily fluids like sweat, urine, CSF, breast milk and saliva. Investigator-designed experiments will explore how different biospecimen preanalytical conditions affect emerging and clinically relevant biomarkers quantified by a variety of testing platforms. The results from this research program will improve the understanding of how analytical quantification of clinically relevant biomarkers is affected by variation in biospecimen collection, processing, and storage procedures. The overall goal is to expedite biomarker clinical assay development through evidence-based standardization of biopsy handling practices.

Date: June 04, 2025 through to September 10, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: The Application budgets are limited to \$250,000 direct costs per year. The maximum period is 5 years.

<u>PAR-25-330</u> Role of Defective Proviruses in HIV Persistence (R01 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to support research to define the impact of defective HIV proviruses on mechanisms of HIV persistence and pathogenesis during antiretroviral treatment and their potential deleterious effects on HIV cure strategies and interference with HIV-specific molecular assays.

Date: May 07, 2025 through to January 07, 2028. All applications are due by 5:00 PM local time of applicant organization.

Budget: The Application budgets are not expected to exceed \$500K in direct costs per year and 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 five years.

PAR-25-346 Exploratory/Developmental Bioengineering Research Grants (EBRG) (R21 Clinical Trial Not Allowed).

The purpose of this engineering-oriented notice of funding opportunity announcement (NOFO) is to encourage submissions of exploratory/developmental Bioengineering Research Grant (EBRG) applications to demonstrate feasibility and potential utility of new capabilities or improvements in quality, speed, efficacy, operability, costs, and/or accessibility of solutions to problems in basic biomedical, pre-clinical, or clinical research, clinical care delivery, or accessibility.

Date: June 16, 2025 through to October 16, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: 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.

<u>RFA-AI-25-006</u> Molecular Mechanisms of Combination Adjuvants (MMCA) (R01 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to support research studies of two or more vaccine adjuvants (combination adjuvants) in order to understand the mechanisms by which they work in concert. All adjuvants considered must have previously demonstrated immune modulating activity. The long-term goal of this research

program is to improve the rational design of vaccines by predicting the immune profile elicited by combination adjuvants.

Date: June 10, 2025. All applications are due by 5:00 PM local time of applicant organization.

Budget: The NIAID intends to commit \$2.56 million in FY 2026 to fund 4-6 awards. Application budgets need to reflect the actual needs of the proposed project and are expected to be less than \$500K in direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is five years.

PAR-25-315 Elucidating Immuno-metabolic Responses to HIV Infection that Increase TB or HBV Risk (R01 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to support research to elucidate how HIV-induced immune-metabolic alterations, in a host suppressed on combination antiretroviral therapy (cART-suppressed), impact the immune response and increase risk for poor outcomes due to a second, potentially long-term, infection such as Mycobacterium tuberculosis (Mtb) or hepatitis B virus (HBV). This NOFO aims to support research to define how HIV-driven alterations to immune-metabolism affect immune cell regulation, cell-cell interactions, response to treatment, and, ultimately, tuberculosis (TB) and HBV disease progression.

Date: May 07, 2025 through to January 07, 2028. All applications are due by 5:00 PM local time of applicant organization.

Budget: The 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 five years.

PAR-25-316 Elucidating Immuno-metabolic Responses to HIV Infection that Increase TB or HBV Risk (R21 Clinical Trial Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to support research to elucidate how HIV-induced immune-metabolic alterations, in a host suppressed on combination antiretroviral therapy (cART-suppressed), impact the immune response and increase risk for poor outcomes due to a second, potentially long-term, infection such as Mycobacterium tuberculosis (Mtb) or hepatitis B virus (HBV). This NOFO aims to support research to define how HIV-driven alterations to immune-metabolism affect immune cell regulation, cell-cell interactions, response to treatment, and, ultimately, tuberculosis (TB) and HBV disease progression.

Date: May 07, 2025 through to January 07, 2028. All applications are due by 5:00 PM local time of applicant organization.

Budget: The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 in direct costs may be requested in any single year.

<u>PAS-25-236</u> D-START: Data Science Track Award for Research Transition (D/START) (R03-Clinical Trial Optional). This NOFO seeks to support investigators interested in applying cutting-edge data science techniques to address timely and challenging research questions related to substance use and/or substance use disorder (SUD) in all areas of research supported by the National Institute on Drug Abuse (NIDA). This NOFO requests Small Research Grant (R03) applications to support research projects that can be carried out in a short period of time with limited resources.

Date: February 16, 2025 through to September 07, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: Six to seven awards, corresponding to a total of \$1,000,000 per year for fiscal year 2025, 2026 and 2027. Budgets for direct costs of up to \$100,000 per year for up to 2 years, may be requested. The maximum project period is 2 years

RFA-CA-25-001 Innovative Molecular and Cellular Analysis Technologies for Basic and Clinical Cancer Research (R61 Clinical Trial Not Allowed). Through this NOFO, the National Cancer Institute (NCI) solicits grant applications proposing exploratory research projects focused on the early-stage development of highly innovative technologies offering novel molecular or cellular analysis capabilities for basic, clinical, or epidemiological cancer research. The emphasis of this NOFO is on supporting the development of novel capabilities involving a high degree of technical innovation for targeting, probing, or assessing molecular and cellular features of cancer biology. The goals of this NOFO are:

- to identify cancer risks and risk reduction strategies, to identify factors that cause cancer in humans, and to discover and develop mechanisms for cancer prevention and preventive interventions in humans;
- to improve screening and early detection strategies and to develop accurate diagnostic techniques and methods for predicting the course of disease in cancer patients;
- to develop the means to cure as many cancer patients as possible and to control the disease in those patients who are not cured;
- to provide fundamental information on the cause and nature of cancer in people;
- to reduce cancer risk, incidence, morbidity, and mortality and enhance quality of life in cancer survivors.

Date: April 04, 2025 & October 03, 2025. All applications are due by 5:00 PM local time of applicant organization.

Budget: The NCI intends to fund an estimate of 17 awards, corresponding to a total of \$4,200,000, for fiscal year 2026. Future year amounts will depend on annual appropriations. Application budgets are limited to \$150,000 per year (direct costs). The total project period request may not exceed 3 years.

RFA-CA-25-002 Advanced Development and Validation of Emerging Molecular and Cellular Analysis Technologies for Basic and Clinical Cancer Research (R33 Clinical Trial Not Allowed). Through NOFO, the National Cancer Institute (NCI) invites grant applications proposing exploratory research projects focused on further development and validation of emerging technologies offering novel capabilities for targeting, probing, or assessing molecular and cellular features of cancer biology for basic, clinical, or epidemiological cancer research. This NOFO solicits R33 applications where major feasibility gaps for the technology or methodology have been overcome, as demonstrated with supportive preliminary data, but still requires further development and rigorous validation to encourage adoption by the research community. Well-suited applications must offer the potential to accelerate and/or enhance research in the areas of cancer biology, early detection and screening, clinical diagnosis, treatment, cancer control, epidemiology, and/or address issues associated with cancer health disparities. Technologies proposed for development may be intended to have widespread applicability but must be focused on improving molecular and/or cellular characterizations of cancer. Projects proposing the application of existing technologies where the novelty resides in the biological or clinical target/question being pursued are not responsive to this solicitation and will not be reviewed. The goals of this NOFO are:

- to identify cancer risks and risk reduction strategies, to identify factors that cause cancer in humans, and to discover and develop mechanisms for cancer prevention and preventive interventions in humans;
- to improve screening and early detection strategies and to develop accurate diagnostic techniques and methods for predicting the course of disease in cancer patients;
- to develop the means to cure as many cancer patients as possible and to control the disease in those patients who are not cured;
- to provide fundamental information on the cause and nature of cancer in people;
- to reduce cancer risk, incidence, morbidity, and mortality and enhance quality of life in cancer survivors.

Date: April 04, 2025 & October 03, 2025. All applications are due by 5:00 PM local time of applicant organization. **Budget:** The NCI intends to fund an estimate of 10 awards, corresponding to a total of \$4,300,000, for the fiscal year 2026. Future year amounts will depend on annual appropriations. Application budgets are limited to \$300,000 per year (in direct costs). The total project period request may not exceed 3 years.

RFA-CA-25-003 Innovative Biospecimen Science Technologies for Basic and Clinical Cancer Research (R61 Clinical Trial Not Allowed). Through this NOFO, the National Cancer Institute (NCI) solicits grant applications proposing exploratory research projects focused on the early-stage development of highly innovative technologies that improve the quality and handling of samples used for cancer research or clinical care. NCI will support the development of tools, devices, instrumentation, and associated methods for the collection, handling, processing, preservation, or storage of cancer-relevant biospecimens and their derivatives. This includes tools with new capabilities to preserve or protect sample integrity, establish verification criteria for quality assessment/quality control, and address issues related to pre-analytical degradation of targeted analytes. The overall goal is to support the development of highly innovative technologies capable of maximizing or interrogating the quality and utility of biological samples used for downstream analyses. These technologies are expected to accelerate and/or enhance research in cancer biology, early detection and screening, clinical diagnosis, treatment, epidemiology, and/or address issues associated with cancer health disparities. Projects proposing the application of existing technologies where the novelty resides in the biological or clinical target/question being pursued rather than the technical innovation are not responsive to this solicitation and will not be reviewed. This funding opportunity is part of a broader NCI-sponsored Innovative Molecular Analysis Technologies (IMAT) Program.

Date: April 04, 2025 & October 03, 2025. All applications are due by 5:00 PM local time of applicant organization. **Budget:** The NCI intends to fund an estimate of 4 awards, corresponding to a total of \$1,000,000, for the fiscal year 2026. Application budgets are limited to \$150,000 per year (in direct costs). The total project period request may not exceed 3 years.

RFA-CA-25-004 Advanced Development and Validation of Emerging Biospecimen Science Technologies for Basic and Clinical Cancer Research (R33 Clinical Trial Not Allowed. Through this NOFO, NCI will support the development of tools, devices, assays, and associated methods for the collection, handling, processing, preservation, or storage of cancer-relevant biospecimens and their derivatives. This includes tools with new capabilities to preserve or protect sample integrity or establish verification criteria for quality assessment/quality control and address issues related to pre-analytical degradation of targeted analytes. NCI solicits R33 applications where major feasibility gaps for the

technology or methodology have been overcome, as demonstrated with supportive preliminary data, but still require further development and rigorous validation to encourage adoption by the research community. These technologies are expected to accelerate and/or enhance research in cancer biology, early detection and screening, clinical diagnosis, treatment, or epidemiology, or address issues associated with cancer health disparities. Projects proposing to use existing technologies where the novelty resides in the application of the technology or the biological or clinical question being pursued, and not the technical capabilities being developed, are not appropriate for this NOFO and will not be reviewed. This funding opportunity is part of a broader NCI-sponsored Innovative Molecular Analysis Technologies (IMAT) Program.

Date: April 04, 2025 & October 03, 2025. All applications are due by 5:00 PM local time of applicant organization. **Budget:** The NCI intends to fund an estimate of 2 awards, corresponding to a total of \$900,000, for fiscal year 2026. Future year amounts will depend on annual appropriations. Application budgets are limited to \$300,000 per year (in direct costs). The total project period request may not exceed 3 years.

RFA-DC-25-002 National Institute on Deafness and Other Communication Disorders (NIDCD) Research Grants for Translating Basic Research into Clinical Practice (R01 Clinical Trial Optional). This NOFO provides an avenue for basic scientists, clinicians, and clinical scientists to jointly initiate and conduct research projects that translate basic research findings into clinical practice for better human health. The scope of this NOFO includes a range of activities that will impact the diagnosis, treatment, and prevention of disorders within NIDCD's scientific mission. Connection to the clinical condition must be clearly established and the outcomes of the proposed work must have the potential for practical clinical impact in the near term. Given the emphasis on translation to clinical practice, early engagement with end users (e.g., practicing clinicians, patients) in real-world environments in which these approaches will be employed is expected.

Date: February 13, 2025 through to October 12, 2027. All applications are due by 5:00 PM local time of applicant organization.

Budget: The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. NIDCD anticipates funding an estimated 2-3 awards in FY25 for \$2M. The maximum funding per grant must be less than \$500,000 direct costs per year, unless prior approval from NIDCD is obtained. Application budgets need to reflect the actual needs of the proposed project. 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. The scope of the proposed project should determine the project period. The maximum period is 5 years.

Faculty of Medicine and Health Sciences
Research & Internationalisation Development & Support (RIDS) & Grants Management Office (GMO)

009 Kth Floor, Teaching Block, Tygerberg Campus.

Enquiries: fmhsgmo@sun.ac.za

Add "Interest in NIH opportunity" in the subject line.

Add the notice number with hyperlink in the text of the email.