NIH funding opportunities

20 January 2025 (#04)



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-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.

<u>Keep Your eRA Personal Profile Updated</u>: The Personal Profile module in eRA Commons is where you — as a principal investigator, award recipient, trainee, reviewer or other Commons user — tell NIH and other awarding agencies about yourself. Awarding agencies need to know about you to grant awards, process those awards and more. Here are a few reasons that it is extremely important to keep your Personal Profile updated.

<u>NOT-CA-25-028</u> Notice of Intent to Publish a Notice of Funding Opportunity for Global Training for Research and Equity in Cancer (GlobTREC) (U2R Clinical Trial Optional). National Cancer Institute (<u>NCI</u>) intends to publish a Notice of Funding Opportunity (NOFO) as a Request for Applications (RFA) that will invite applications from institutions who

propose research training programs to strengthen capacity to conduct global cancer research. The overarching goal of this research training program is to provide investigators and health professionals with the scientific expertise, mentorship, and leadership skills needed to conduct innovative and collaborative global research projects that will contribute to the advancement of basic, clinical, translational, and population-based cancer research. This Notice is being provided to allow potential applicants time to develop responsive projects and meaningful collaborations. **The NOFO will utilize the U2R activity code, which is an NIH cooperative agreement mechanism for international research training. First Estimated Application Due Date:** July 14, 2025. Estimated Award Ceiling: U2R application direct costs are limited to \$275,000 per year over a five-year period, Indirect costs are capped at 8%

NOT-CA-25-022 Notice of Intent to Publish a Funding Opportunity Announcement for U.S. and Low- and Middle-Income Countries (LMICs) HIV Associated Malignancy Research Centers (U54 Clinical Trial Optional). The office of HIV and AIDS Malignancy (OHAM) at NCI is planning to issue a new Notice of Funding Opportunity announcement (NOFO) to solicit applications from eligible institutions of higher educations for specialized centers to conduct research on malignancies in people with HIV in Low- and Middle-Income Countries (LMICs) and to support early- and mid-career investigators from the United States (U.S.) and LMICs interested in malignancies in people with HIV. The NOFO (RFA) will use a U54 mechanism and it will be Clinical Trials Optional. First Estimated Application Due Date: September 01, 2025. Each HIV Associated Malignancy Research Centers (HAMRCs) will be able to request up to \$800,000 Direct Costs if partnering with two LMICs and \$700,000 if partnering with LMIC per year for five years.

NOT-OD-25-064 An Introduction to the NIH Fellowship Program for Prospective Candidates - Registration Open for February 11, 2025, Webinar. This webinar is designed for individuals preparing their first NIH fellowship or those seeking a refresher on the process. Don't miss this opportunity to gain valuable insights and enhance your application strategy. Visit the *An Introduction to the NIH Fellowship Program for Prospective Candidates* for presenters, additional resources, and registration link.

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)

NOT-AG-24-039 Human Cell Biology of Alzheimer's Disease Genetic Variants. The goal of this NOSI is to encourage research that assesses the function of AD genetic variants and other age- and disease-modifying factors contributing to AD using human cell reprogramming (e.g., iPSCs and iNeurons) and genomic editing approaches. The impact of aging and approaches to induce or recapitulate brain aging in these human cell models should be considered, as aging is a major risk factor for AD. Assessment of variants and other risk factors should include an unbiased, comprehensive molecular phenotyping approach, for example via genomics, transcriptomics, epigenomics, and/or proteomics. Consideration should be given to not only the variants to study, but the neural cell type and stage of maturation (i.e., aging) of the reprogrammed and edited human cells. Functional analysis (e.g., maturation, cell morphology, metabolism, electrophysiology, synaptic activity, and/or connectivity) should be considered in the overall characterization of genotype-phenotype relationships. Development of high-throughput genetic, molecular, and functional assays and 3D or organoid cell systems would be complementary and important approaches to reach the goal of this NOSI. Comprehensive functional annotation of risk variants, causality of genotype-phenotype relationships of AD gene variants and other age or disease factors, and the generation of unbiased molecular datasets that can be integrated with genomic and physiological data in human cells could be an outcome of these studies. This notice applies to due dates on or after March 11, 2025 and subsequent receipt dates through November 17, 2027.

<u>NOT-CA-25-002</u> Mechanisms Driving Obesity and Prostate Cancer Risk. The purpose of this NOSI is to promote studies examining the mechanisms by which obesity drives aggressive prostate cancer (PCa) risk. About 80% of overall PCa is non-aggressive. The biologic mechanisms driving both overall and aggressive PCa are uncertain. The identification of differences in the mechanisms driving aggressive vs. overall (mostly non-aggressive) disease are critical to optimizing clinical care among men who develop the disease. Studies should determine if the biologic mechanism(s) driving aggressive vs. non-aggressive PCa are different through the investigation of preclinical models and/or human prostate studies. This NOSI applies to Application Due Dates on or after February 5, 2025, and subsequent receipt dates through January 7, 2028.

NOT-CA-25-010 Research on rare cancers across the cancer control continuum. The NCI defines a rare cancer as one having an age-adjusted incidence of fewer than 15 cases per 100,000 per year. Despite their rarity, these cancers collectively account for approximately 25% of all new cases of adult cancers each year and all paediatric cancers in the United States. This purpose of this NOSI is to stimulate observational and intervention research focused on rare cancers that is within the mission of NCI's Division of Cancer Control and Population Sciences (DCCPS). DCCPS has several broad areas of interest: development and validation of methods, technologies, and tools in surveillance, statistics, epidemiology, health care delivery, and the behavioral sciences; identification of modifiable risk factors or host susceptibility factors associated with cancer etiology, cancer prevention, and treatment outcomes; and clinical and translational science to reduce risk, incidence, and death from cancer, as well as to enhance the quality of life for cancer survivors. This notice applies to due dates on or after February 5, 2025 and subsequent receipt dates through January 7, 2028.

NOT-HL-24-037 Bold New Bioengineering Research for Heart, Lung, Blood and Sleep Disorders. This NOSI issued by the National Heart, Lung, and Blood Institute (NHLBI) aims to encourage early-stage innovative bioengineering projects that could lead to preclinical and translational research and potential funding from federal and non-federal sources. The program is distinct from the NHLBI Catalyze Program and is focused on investigator-initiated ideas and concepts that may eventually contribute to the Catalyze pipeline. This NOSI invites discovery- and design-driven bioengineering research ideas that are important across the Institute and critical for future hypothesis-generating projects. Notably, this program emphasizes first-generation prototype development and initial feasibility studies. The NHLBI is interested in the development of new ideas for diagnostics, therapeutics, surgical technologies, artificial intelligence/machine learning/computational modelling tools, smart biomaterials for self-adjusting implants, molecular imaging, synthetic biology, and nanotechnologies, as applied to HLBS-related issues. Research funding under this NOSI will be limited to early-stage concept development that can ultimately feed into other translational program funding, such as the NHLBI Catalyze Program, for further development. This notice applies to due dates on or after February 5, 2025 and subsequent receipt dates through January 7, 2028.

<u>NOT-AG-24-030</u> Novel Approaches to Characterizing and Diagnosing Alzheimer's Disease and Related Dementias. The goal of this NOSI is to encourage the development of novel approaches to characterizing, diagnosing, and predicting outcomes in AD/ADRD. Both clinical and preclinical studies may be supported by this NOSI. Applications proposing clinical trials on this topic would not be considered a high priority. This notice applies to due dates on or after March 11, 2025 and subsequent receipt dates through November 17, 2027.

NOT-AG-24-033 Selective Cell and Network Vulnerability in Aging and Alzheimer's Disease. The goal of this NOSI is to stimulate research to define and characterize neural cell populations (e.g., neurons and glia), neural activity and circuits, structural and functional networks, and brain regions that are vulnerable (or resistant) in brain aging and AD as well as the mechanisms underlying such selective vulnerability. Genetic and molecular signatures of different types of neurons and glial cells across the adult lifespan, in AD compared to other dementias of aging as well as in different stages of AD, will implicate cell processes and pathways mediating selective vulnerability in AD. Defining cell types by physiological measures such as electrophysiology and connectivity and manipulating neural activity in circuits and networks will provide a functional index of selective vulnerability. Applicants are encouraged to use new approaches to generate sophisticated data on molecular signatures of brain cells and on structure and function of brain circuits and networks. Understanding the mechanisms underlying selective therapies. This notice applies to due dates on or after March 11, 2025 and subsequent receipt dates through November 17, 2027.

NOT-AG-24-042 Major Opportunities for Research in Epidemiology of Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD) and Cognitive Resilience. This Notice of Special Interest (NOSI) encourages investigator-initiated research on all aspects of cognitive epidemiology relevant to Alzheimer's disease (AD) and ADrelated dementias (ADRD) and cognitive resilience, and identifies specific areas that build on current efforts supported by NIA as well as gaps and opportunities identified in the <u>2018</u> and <u>2021</u> Alzheimer's Disease Research Summits. This NOSI is a reissue of <u>NOT-AG-21-045</u>. Applications proposing exploratory or developmental projects for which there are insufficient preliminary data as well as certain focused secondary analysis projects should consider applying to <u>PAR-</u> <u>25-331</u>. This notice applies to due dates on or after March 11, 2025 and subsequent receipt dates through November 17, 2027.

NOT-AG-24-029 Genetic Underpinnings of Endosomal Trafficking as a Pathological Hub in Alzheimer's Disease (AD) and AD-Related Dementias (ADRD). The goal of this NOSI is to encourage basic and translational research focused on the molecular, cellular, physiological, and pathological processes associated with the endosomal compartment in AD and AD-related dementias (ADRD). Studies funded under this topic will support research into AD/ADRD pathogenesis related to enhancing our understanding of how the genetic underpinnings of endosomal trafficking in AD/ADRD may act as a hub in the pathophysiological changes associated with the disease. The impact of changes in endosomal genetics on functional events, for example upon the generation of amyloid Beta (Aß) cellular processing, are important factors to be evaluated. This notice applies to due dates on or after March 11, 2025 and subsequent receipt dates through November 17, 2027.

<u>NOT-AG-24-031</u> Common Mechanisms and Interactions Among Neurodegenerative Diseases. This NOSI encourages research to enhance our understanding of how different neurodegenerative diseases interact clinically and physiologically. There is a need to identify, more precisely, which neurodegenerative process, or processes, are active in individuals. At the same time, there needs to be better understanding of how different neurodegenerative diseases resemble and differ from one another at the molecular, cellular, and organismic levels. Cellular and animal models for investigating concurrent neurodegenerative processes need to be developed if these questions are to be answered. This notice applies to due dates on or after March 11, 2025 and subsequent receipt dates through November 17, 2027.

NOT-AG-24-032 Understanding Alzheimer's Disease in the Context of the Aging Brain. This NOSI invites applications that aim to establish the role and underlying mechanisms by which brain aging impacts the development and progression of AD. A comprehensive and integrative characterization of brain aging, including its crosstalk with peripheral systems and factors, will help to define the mechanisms underlying the shift from normal aging to pathological processes in the etiology of AD. To gain a deeper understanding of the complex biology and physiology of healthy and pathologic brain aging, cross-disciplinary, systems-based approaches using newly developed tools and technology to integrate findings on AD with research on the basic biology and neurobiology of aging are encouraged. Animal and human studies are appropriate for this NOSI. This notice applies to due dates on or after March 11, 2025 and subsequent receipt dates through November 17, 2027.

NOT-CA-25-035 Addressing Cancer-Related Financial Hardship to Improve Patient Outcomes. This notice invites research applications that propose to develop and/or test interventional approaches to prevent and/or mitigate financial hardship in individuals diagnosed with cancer. Intervention targets may include the patient, caregiver, clinician, healthcare team, and/or healthcare delivery system, with multi-level research encouraged. Proof of concept and studies testing the efficacy of interventions are acceptable; however, proposed studies should address the potential for intervention sustainability and scalability. Research studies that integrate expertise from diverse scientific and clinical areas (e.g., health services, health economics, outcomes research, health communications, social work, pharmacy, nursing, and oncology) are of particular interest. Studies that target populations identified to be at risk for health disparities are strongly encouraged. This notice applies to due dates on or after February 05, 2025, and subsequent receipt dates through January 08, 2028.

NOT-HL-24-032 Understanding and Addressing Weight Stigma, Bias, and Discrimination to Promote Health Equity. The objective of this NOSI is to encourage research and career development training applications to elucidate the mechanisms and consequences of weight stigma, bias, and discrimination in children and adults with overweight or obesity. A secondary objective is to evaluate the effects of obesity-related interventions or policies that address weight bias and/or its consequences (e.g., weight stigma and discrimination) in affected groups. Applications may propose observational studies or clinical trials utilizing quantitative, qualitative, and/or community-based research methods. Intervention research may address mechanisms of action, mechanisms of prevention, implementation strategies, or evaluation of interventions or policies to address weight stigma, bias, or discrimination. This notice applies to due dates on or after February 12, 2025 and subsequent receipt dates through May 08, 2028.

Notice of Funding Opportunity (NOFO)

<u>RFA-AI-24-023</u> 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.

Important Notice: All potential applicants MUST inform the Grants Management Office before 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. Please also contact the Scientific Program officials 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.

PAR-25-056 Secondary Analysis of Existing Datasets in Heart, Lung, and Blood Diseases and Sleep Disorders (R21 Clinical Trial Not Allowed). This NOFO encourages R21 applications that propose to conduct secondary analyses using existing human datasets in areas relevant to the National Heart, Lung, Blood Diseases and Sleep Disorders Institute (NHLBI) scientific mission. The NOFO aims to stimulate the use of existing human datasets to investigate novel scientific ideas, and/or generate new models, systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioural research. Generation of new primary data is not allowed.

for the R21 phase and up to 3 years for the R33 phase. The total project period may not exceed 5 years.

Date: May 07, 2025 through to January 07, 2026. All applications are due by 5:00 PM local time of applicant organization.

Budget: The NHLBI intends to commit up to \$2,187,000 per year in total costs for new awards in Fiscal Year2026 to fund up to eighteen new awards. Application budgets may request up to \$75,000 in direct costs per year. Investigators are encouraged to request what is well-justified for their proposed research. The total project period may not exceed 2 years.

<u>PAR-25-099</u> Planning for Product Development Strategy (R34 Clinical Trial Not Allowed). The purpose of this NOFO is to support the development of a comprehensive and well-defined product development strategy for next-generation treatments for HIV and HIV-associated comorbidities, coinfections and complications and preventive strategies for HIV, as well as facilitating the translation of research findings into drug products that enables submission of an Investigational New Drug (IND) application to the FDA.

Date: March 13, 2025 through to December 04, 2026. All applications are due by 5:00 PM local time of applicant organization.

Budget: NIH intends to fund an estimate of 2-3 awards, corresponding to a total of \$1,000,000, for fiscal year 2025. Future year amounts will depend on annual appropriations. Application budgets are limited to \$225,000/year in direct costs. The maximum project period is 1 year.

PAR-25-101 Cutting-Edge Basic Research Awards (CEBRA) (R21 Clinical Trial Optional). National Institute on Drug Abuse (NIDA) Cutting-Edge Basic Research Award (CEBRA) is designed to foster highly innovative or conceptually creative research related to the etiology, pathophysiology, prevention, or treatment of substance use disorders (SUDs). It supports high-risk and potentially high-impact research that is underrepresented or not included in NIDA's current portfolio that has the potential to transform SUD research. The proposed research should: 1. develop, and/or adapt, revolutionary techniques or methods for addiction research or that show promising future applicability to SUD research; and /or 2. test an innovative and significant hypothesis for which there are scant precedent or preliminary data and which, if confirmed, would transform current thinking.

Date: March 10, 2025 through to August 11, 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 \$150,000 in direct costs may be requested in any single year. The maximum project period is 2 years.

PAR-25-283 Innovative Mental Health Services Research Not Involving Clinical Trials (R01 Clinical Trials Not Allowed). The purpose of this notice of funding opportunity (NOFO) is to encourage innovative research that will inform and support the delivery of high-quality, continuously improving mental health services to benefit the greatest number of individuals with, or at risk for developing, a mental illness. This announcement invites applications for nonclinical trial R01-level projects that address NIMH strategic priorities that strengthen the public health impact of NIMHsupported research as described in Goal 4 of the NIMH Strategic Plan. This NOFO solicits research projects including, but not limited to the following: (a) research identifying mutable factors that impact access, continuity, utilization, quality, value, and outcomes, including disparities in outcomes, or scalability of mental health services, which may serve as targets in future service delivery intervention development, (b) research that develops and tests new research tools, technologies, measures, or methods and statistical approaches to study these issues, and/or (c) research that integrates and analyzes large data sets to understand factors affecting mental health services outcomes using advanced computational and predictive analytic approaches. Wherever possible, projects should leverage existing infrastructure and partnerships to accomplish these goals. Companion funding opportunity: <u>PAR-25-284</u>, <u>R34</u> Planning Grant.

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

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

<u>PAR-25-328</u> Grand Opportunity in Medications Development for Substance-Use Disorders (U01 Clinical Trial Optional). The purpose of this funding opportunity is to support research to advance the development of safe and effective medications for the treatment of Substance Use Disorders (SUD). It includes preclinical and/or clinical research projects, from lead optimization all the way Phase I, Phase II, and Phase III clinical trials. The goal is to fund studies that will have high impact and quickly yield the necessary results to advance medications closer to FDA approval.

Date: April 10, 2025 & August 11, 2025All applications are due by 5:00 PM local time of applicant organization.

Budget: NIH intends to fund an estimate of five awards per year. Application budgets are limited to \$5 million per year for direct costs and need to reflect the actual needs of the proposed project. The maximum period of support is 3 years.

PAR-25-329 Development of Medications to Prevent and Treat Substance Use Disorders and Overdose (UG3/UH3 -

Clinical Trial Optional). National Institute on Drug Abuse (<u>NIDA</u>) seeks research for the discovery and development of medications to prevent and treat substance use disorders (SUDs) and overdose. The UG3/UH3 Phased Innovation Awards Cooperative Agreement funding mechanism involves 2 phases. The UG3 is to support a project with specific milestones to be accomplished by the end of the 2-year period. The UH3 is to provide funding for 3 years to a project that successfully completed the milestones set in the UG3. UG3 projects that have met their milestones will be administratively considered by NIDA and prioritized for transition to the UH3 phase. Investigators responding to this FOA must address both UG3 and UH3 phases. Application may include preclinical or clinical research studies that will

have high impact and quickly yield the necessary results to advance closer to or to FDA approval. The compounds to be evaluated can be small molecules or biologic and may focus on the development of new chemical entities, new formulations of marketed medications available for other indications, or combinations of medications.

Date: April 10, 2025 & August 11, 2025. All applications are due by 5:00 PM local time of applicant organization. **Budget:** Application budgets are limited to \$3 million per year for direct costs. The maximum period of support is 5 years.

PAR-25-331 Research on Current Topics in Alzheimer's Disease and Its Related Dementias (R21 Clinical Trial Optional). The purpose of this NOFO is to invite applications proposing new tests, animal models, techniques, etc. to advance research on Alzheimer's disease (AD) and its related dementias (ADRD) that need additional preliminary data with broader dissemination to establish them for more general use in this research field. The priority topics will be announced through a series of Notices published subsequent to this NOFO.

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 in direct costs may be requested in any single year. The scope of the proposed project should determine the project period. The maximum project period is 2 years.

<u>PAR-25-332</u> Research on Current Topics in Alzheimer's Disease and Its Related Dementias (R01 Clinical Trial **Optional).** The purpose of this NOFO is to invite applications proposing research on current topics in Alzheimer's disease (AD) and its related dementias (ADRD). Further information on the high-priority topics of interest will be announced through a series of Notices published subsequent to this NOFO.

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

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

PAR-25-337 Academic-Industrial Partnerships for Translation of Technologies for Diagnosis and Treatment (R01 -**Clinical Trial Optional).** The purpose of this Notice of Funding Opportunity (NOFO) Announcement is to stimulate efforts to translate scientific discoveries and engineering developments into methods or tools that address problems in basic research to understand disease, or in applied research to assess risk, detect, prevent, diagnose, treat, and/or manage disease. The rationale is to deliver new capabilities to meet evolving requirements for technologies and methods relevant to the advance of research and delivery of care in pre-clinical, clinical and non-clinical settings, domestic or foreign, for conditions and diseases within the missions of participating institutes. This NOFO specifies a partnership structure that is expected to help bridge gaps in knowledge and experience by engaging the strengths of academic, industrial, and other investigators. The partners on each application should establish an inter-disciplinary, multi-institutional research team to work in strategic alliance to implement a coherent strategy to develop and translate a solution to their chosen problem. They are expected to plan, design, and validate that the solution will be suitable for end users. Each partnership should include at least one academic and one industrial organization. Each partnership should plan to transition a technology, method, assay, device, and/or system from a demonstration of possibility to a status useful in the chosen setting. Funding may be requested to enhance, adapt, optimize, validate, and otherwise translate technologies that address problems in biology, pathology, risk assessment, diagnosis, treatment, and/or monitoring of disease status.

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

Budget: Application budgets are limited to \$499,000 (direct costs) per year. The maximum project period is 5 years.

<u>PAR-25-338</u> Academic-Industrial Partnerships for Translation of Technologies for Diagnosis and Treatment (R01 - Clinical Trial Not Allowed). The purpose of this Notice of Funding Opportunity (NOFO) is to stimulate efforts to translate scientific discoveries and engineering developments into methods or tools that address problems in basic research to understand disease, or in applied research to assess risk, detect, prevent, diagnose, treat, and/or manage disease. The rationale is to deliver new capabilities to meet evolving requirements for technologies and methods relevant to the advance of research and delivery of care in pre-clinical, clinical and non-clinical settings, domestic or foreign, for conditions and diseases within the missions of participating institutes. This NOFO specifies a partnership structure that is expected to help bridge gaps in knowledge and experience by engaging the strengths of academic, industrial, and other investigators. The partners on each application should establish an inter-disciplinary, multi-institutional research team to work in strategic alliance to implement a coherent strategy to develop and translate a

solution to their chosen problem. They are expected to plan, design, and validate that the solution will be suitable for end users. Each partnership should include at least one academic and one industrial organization. Each partnership should plan to transition a technology, method, assay, device, and/or system from a demonstration of possibility to a status useful in the chosen setting. Funding may be requested to enhance, adapt, optimize, validate, and otherwise translate technologies that address problems in biology, pathology, risk assessment, detection, diagnosis, treatment, and/or monitoring of disease status.

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

Budget: Application budgets are limited to \$499,000 (direct costs) per year. The maximum project period is 5 years.

PAR-25-357 National Eye Institute (NEI) Research Grant for Vision-Related Secondary Data Analysis (R21 Clinical Trial Not Allowed). The purpose of this Notice of Funding Opportunity (NOFO) is to conduct secondary data analyses using existing data collected from humans participating in vision-related clinical trials, epidemiologic, and other clinical research studies or represented in clinical and health care database resources (e.g., electronic health records). This NOFO may be used to develop new statistical methodologies or test hypotheses using existing data, but this NOFO must not be used to support the collection of new data. This NOFO encourages applications from institutions/organizations that propose to conduct vision-related secondary analyses of data collected from humans. Applications may be related to, but must be distinct from, the specific aims of the original data collection. The NEI supports an extensive portfolio of clinical trials and large-scale epidemiologic research projects wherein numerous data collection activities are required to meet each project's specific aims. The resultant wealth of data generated by these studies often provides unique, cost-effective opportunities to investigate additional research questions or develop new analytical approaches secondary to a project's originally intended purpose. Data are not limited to those collected under NEI support, but such data are of the highest programmatic interest.

Date: June 16, 2025 through to January 07, 2028. All applications are due by 5:00 PM local time of applicant organization.

Budget: The NEI permits direct costs up to \$275,000 for the entire two-year project period, plus applicable F&A for consortia. No more than \$200,000 in direct costs may be requested in any single year. The total project period for an application submitted in response to this funding opportunity may not exceed two years.

<u>PAR-25-362</u> Early Immune System Development and Ontogeny (R01 Clinical Trial Optional). The purpose of this Notice of Funding Opportunity (NOFO) is to further elucidate the mechanisms of early immune development in utero, during the early post-natal period and during early childhood in neonates, infants, and children and adolescents with or without in-utero exposure to HIV or Anti-Retroviral Therapeutics (ART). This initiative aims to understand intricate mechanisms of immune cells at the maternal-fetal interface, T and B cell development and maturation in offspring, and local immune responses and the role of systemic immunity.

Date: May 07, 2025 through to January 07, 2029. All applications are due by 5:00 PM local time of applicant organization.

Budget: Application budgets are limited to \$400,000/year Directs Costs exclusive of consortium F&A costs. A maximum project period of four years is allowed.

<u>PAR-25-374</u> Translational Bioinformatics and Experimental Approaches to Advance Drug Repositioning and Combination Therapy Development for Alzheimer's Disease and Related Dementias (R01 Clinical Trial Not Allowed).

This Notice of Funding Opportunity (NOFO) invites applications that combine computational and experimental approaches to enable rigorous preclinical testing of drugs or drug combinations currently used for other conditions, as well as investigational drugs at various stages of clinical development, predicted to be efficacious in Alzheimer's Disease (AD) and AD-related dementias (ADRD). This initiative will also support preclinical testing of repurposable or investigational drug candidates in combination with non-pharmacologic interventions leading to robust translational outcomes. The central goal of this NOFO is to establish robust proof of concept in mouse models or cell-based models of AD/ADRD that will enable rational drug repositioning and the development of precision combination therapies for the treatment and prevention of AD/ADRD.

Date: June 09, 2025 through to February 07, 2028. All applications are due by 5:00 PM local time of applicant organization.

Budget: NIA intends to commit \$6 million in FY 2026 to fund 4 - 5 awards. Application budgets are capped at \$1 million in direct costs per year. 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.

<u>RFA-DA-25-074</u> Ex Vivo Models for Studies at the Intersection of HIV and Addictive Substance Use (R01 Clinical Trial

Not Allowed). This notice of funding opportunity (NOFO) invites grant applications aimed at elucidating neuroimmune and neuronal-glial pathophysiological mechanisms underlying the interaction between addictive substances and HIV-associated neurological disorders (HAND) using ex vivo culturing platforms derived from human induced pluripotent stem cells (hiPSC).

Date: August 13, 2025. All applications are due by 5:00 PM local time of applicant organization.

Budget: NIDA intends to commit \$2,000,000 in FY 2026 to fund a total of three to four awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

PA-25-150 Joint NINDS/NIMH Exploratory Neuroscience Research Grant (R21 Clinical Trial Not Allowed). The Joint NINDS/NIMH Exploratory Neuroscience Research Grant program supports exploratory and innovative research projects, which fall within the missions of the NINDS and NIMH. Awards will provide support for the early and conceptual stages of projects. These studies often assess the feasibility of a novel avenue of investigation and involve considerable risk but have the potential to bring about breakthroughs in the understanding of important areas of neuroscience, or to the development of novel techniques, agents, methodologies, or models, of high value to the neuroscience community. No clinical trials will be accepted with this NOFO.

Date: May 07, 202 through to January 07, 2028All applications are due by 5:00 PM local time of applicant organization.

Budget: Direct costs are limited to \$275,000 over a two-year period, with no more than \$200,000 in direct costs allowed in any single year. The maximum project period is two years.

<u>PAR-24-329</u> Development & Testing of Novel Interventions to Improve HIV Prevention, Treatment, and Program Implementation for People Who Use Substances (R34 Clinical Trial Required). This notice of funding opportunity (NOFO) encourages formative research, intervention development, and pilot-testing of interventions for people who use drugs. Primary outcomes of interest include the feasibility, acceptability and safety of novel or adapted interventions that target HIV prevention, treatment or services research. Interventions here may include behavioral, social, or structural approaches, as well as combination biomedical and behavioral approaches that prevent the acquisition or transmission of HIV infection, or improve clinical outcomes for persons living with HIV.

Date: May 07, 2025 through to May 07, 2027. All applications are due by 5:00 PM local time of applicant organization. **Budget:** Applicants may request direct costs of up to \$450,000 for three years. Although variations from year to year are permissible, in no case may any year be more than \$225,000 in direct costs, and total direct costs for the entire project period may not exceed \$450,000. The maximum period is 3 years.

<u>PAR-25-048</u> Prospective Observational Comparative Effectiveness Research in Clinical Neurosciences (UG3/UH3 Clinical Trial Not Allowed). The purpose of this Notice of Funding Opportunity (NOFO) is to encourage grant applications for investigator-initiated prospective observational comparative effectiveness research (CER) to the National Institute of Neurological Disorders and Stroke (NINDS) (note: only prospective observational studies will be considered). The study must address questions within the mission and research interests of the NINDS and may evaluate preventive strategies, diagnostic approaches, or interventions including drugs, biologics, and devices, or surgical, behavioral, and rehabilitation therapies. NINDS is particularly interested in pragmatic study designs that utilize a cost-effective means of prospectively collecting observational data important to current clinical practice.

Date: May 07, 2025, June 18, 2025, September 07, 2025. All applications are due by 5:00 PM local time of applicant organization.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. Up to 2 years for the UG3; up to 5 years for the UH3.

<u>PAR-25-318</u> Advancing HIV/AIDS Research within the Mission of the NIDCD (R21 Clinical Trial Optional). The purpose of this Notice of Funding Opportunity (NOFO) is to stimulate HIV/AIDS research within the scientific mission areas of the National Institute on Deafness and Other Communications Disorders (NIDCD). Applications should address high priority HIV/AIDS research outlined by the NIH Office of AIDS Research (OAR) (<u>https://www.oar.nih.gov/hiv-policyand-research/research-priorities</u>) in the areas of hearing, balance, taste, smell, voice, speech, and language. For applications proposing a clinical trial, only low risk clinical trials will be supported. **Companion funding:** <u>PAR-25-319</u>. **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 may be requested in any single year.

PAR-25-324 Method to Extend Research in Time (MERIT) Award Extension Request (Type 4 eSubmission Clinical Trial Optional). National Cancer Institute (NCI). Method to Extend Research in Time (MERIT) (R37) Award provides extended grant support to Early Stage Investigators (ESIs) who qualify for conversion based on receiving a percentile within the NCI payline for established investigators on their R01 applications. By providing longer term support to ESIs who qualify, the NCI intends to offer flexibility and opportunity for creativity and innovation and additional time to successfully launch their careers and to become more established before having to submit renewal applications (NOT-CA-18-037). The objective of the NCI's ESI MERIT Award is to allow eligible investigators the opportunity to obtain up to 7 years of support in two segments: 1) The initial approved duration of the award; and 2) A second phase, providing an additional two years of support. This funding opportunity announcement is specifically for currently funded NCI ESI MERIT recipients to request the second phase of the initial award.

Date: The first Application Due Date is March 3, 2025. All applications are due by 5:00 PM local time of applicant organization.

Budget: The funding instrument will be the same as the parent award. Budget is limited to the committed Direct Costs on the final year of the initial project period. Project period is limited to 2 years.

<u>PAR-25-354</u> Multidisciplinary Studies of HIV/AIDS and Aging (R01 Clinical Trial Optional). This NOFO invites applications at the intersection of HIV and aging by proposing research that aims to meet the following objectives: 1) Improve the understanding of biological, clinical, and socio-behavioral aspects of aging through the lens of HIV infection and its treatment; and 2) Improve approaches for testing, preventing, and treating HIV infection, and managing HIV-related comorbidities, co-infections, and complications in different populations and cultural settings by applying current aging science approaches. Proposed research must be consistent with the HIV/AIDS Research Priorities outlined by NIH's Office of AIDS Research (OAR), as described in <u>NOT-OD-20-018</u>. Companion Funding: <u>PAR-25-355</u>

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

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

PAR-25-358 National Eye Institute (NEI) Clinical Research Study Planning Grant Program (R34 Clinical Trial Not Allowed) The NEI supports large-scale clinical vision research projects, including randomized clinical trials and epidemiologic studies on eye/vision conditions. At the time of submission, applications requesting support for these activities are expected to provide detailed information regarding the study rationale, design, analytic techniques, protocols and procedures, facilities and environment, organizational structure, and collaborative arrangements. This information is best conveyed in a Manual of Procedures (MOP), the development of which represents a costly and time-consuming activity. This clinical research planning grant funding opportunity supports applicants in their planning efforts to conduct collaborative clinical research. The grant may be used to support the development of a MOP, as well as to conduct preliminary studies to refine study procedures or document recruitment potential. The grant must not be used to generate data on the effects of a proposed intervention. This NEI FOA is applicable to both epidemiologic and clinical trial research studies.

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

Budget: The NEI permits direct costs up to \$150,000 per year plus applicable F&A for consortia. The scope of the proposed project should determine the project period. The maximum period is two year

PAS-25-073 Priority HIV/AIDS Research within the Mission of National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (R01 Clinical Trial Optional). This NOFO seeks to stimulate HIV/AIDS research within the mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) that aligns with the HIV/AIDS research priorities outlined by the NIH Office of AIDS Research (OAR). These priorities were most recently described in NOT-OD-20-018 UPDATE: NIH HIV/AIDS Research Priorities and Guidelines for Determining HIV/AIDS Funding.

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

Budget: NIDDK intends to fund an estimate of 3 to 5 awards, corresponding to a total of \$2,000,000, for fiscal year 2026. Future year amounts will depend on annual appropriations. 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-DC-25-003 Cooperative Agreement for In Vivo High-Resolution Imaging for Inner Ear Visualization (U01 Clinical Trial Required) This funding opportunity aims to support high risk clinical trials for the development of in vivo high-resolution structural and functional imaging technologies for the living human inner ear. Proposed projects should focus on improving the resolution of current imaging techniques or developing new imaging techniques that can visualize inner ear structures in vivo with significantly greater detail and accuracy than currently possible. Structural and functional aspects, including visualizing dynamic elements, are important to developing new and improved techniques. Projects may also focus on developing new imaging probes or contrast agents that can enhance visualization of the inner ear structures. Research supported in response to this funding opportunity is expected to significantly advance the ability to visualize auditory and vestibular components, such as hair cells, otoliths, membranes, ions, and vasculature, in detail in awake patients in a clinical setting using non-invasive techniques. To achieve this goal, a multidisciplinary team approach that takes advantage of the expertise of each team member is highly encouraged. Studies in humans must be proposed to develop, advance, or test the needed technology. Any intermediate studies must articulate a clear path of the proposed methodology to application in awake humans or define the limitations and the usefulness in anesthetized humans.

Date: June 03, 2025 through to October 01, 2026All applications are due by 5:00 PM local time of applicant organization.

Budget: NIDCD intends to commit \$3 million in FY 2025 to fund 2-4 awards including the companion announcement RFA-DC-25-005 Future year amount will depend on annual appropriations with \$2 million planned in both FY 2026 and FY 2027. The maximum funding per grant must be less than \$500,000 direct costs per year, unless prior approval from NIDCD is obtained. Requests for prior approval for applications that exceed \$500,000 direct costs per year should be made at least six weeks prior to the submission due date, Application budgets 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-DC-25-005 In Vivo High-Resolution Imaging for Inner Ear Visualization (R01 Clinical Trial optional). This funding opportunity aims to support the development of in vivo high-resolution structural and functional imaging technologies for the living human inner ear. Proposed projects should focus on improving the resolution of current imaging techniques or developing new imaging techniques that can visualize inner ear structures in vivo with significantly greater detail and accuracy than currently possible. Both structural and functional aspects, including visualizing dynamic elements are important to the development of new and improved techniques. Projects may also focus on developing new imaging probes or contrast agents that can enhance visualization of the inner ear structures. Research supported in response to this funding opportunity is expected to significantly advance the ability to visualize auditory and vestibular components, such as hair cells, otoliths, membranes, ions, and vasculature, in detail in awake patients in a clinical setting using non-invasive techniques. To achieve this goal, a multidisciplinary team approach that takes advantage of the expertise of each team member is highly encouraged. Studies in humans and intermediate studies in mammalian animal models may be proposed to develop or advance the needed technology. Any intermediate studies must articulate a clear path of the proposed methodology to application in awake humans or define the limitations and the usefulness in anesthetized humans.

Date: June 03, 2025 through to October 01, 2026. All applications are due by 5:00 PM local time of applicant organization.

Budget: NIDCD intends to commit \$3 million in FY 2025 to fund 4-6 awards combined for this NOFO and the companion RFA-DC-25-003. Future year amounts will depend on annual appropriations with \$2 million planned in both FY 2026 and FY2027. 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. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

<u>PAR-25-369</u> Ethical, Legal and Social Implications (ELSI) Exploratory/Developmental Research Grant (R21 Clinical Trial Optional). This Notice of Funding Opportunity (NOFO) invites Exploratory/Developmental Research Grant (R21) applications that propose to study the ethical, legal and social implications (ELSI) of human genetic or genomic research. Applications may propose studies using either single or mixed methods, that break new ground, extend previous discoveries in new directions, or develop preliminary data in preparation for larger studies. Approaches may include but are not limited to empirical qualitative and quantitative methods, and conceptual, legal, and normative analyses. Applied research designed to address ELSI issues in genetics and genomics will also be considered responsive. Direct engagement with communities and other stakeholders is encouraged, but not required.

Date: June 17, 2025 through to October 20, 2026All applications are due by 5:00 PM local time of applicant organization.

Budget: Application budgets are limited to a combined total of no more than \$275,000 in direct costs for the two or three-year project period with no more than \$200,000 in direct costs in a single year. The scope of the proposed project should determine the project period. The maximum project period is 3 years.

<u>PAR-25-370</u> Ethical, Legal and Social Implications (ELSI) Small Research Grant (R03 Clinical Trial Optional). This NOFO invites Small Research Grant (R03) applications that propose to study the ethical, legal and social implications (ELSI) of human genetic or genomic research. These applications should be for small, self-contained research projects, such as those that involve single investigators. Of particular interest are projects that propose normative or conceptual analyses, including focused legal, economic, philosophical, anthropological, or historical analyses of new or emerging issues. This mechanism can also be used for the collection of preliminary data or the secondary analysis of existing data. Applications may propose studies using either single or mixed methods. Applied research designed to address ELSI issues in genetics and genomics will also be considered responsive. Direct engagement with communities and other stakeholders is encouraged but not required.

Date: June 17, 2025 through to October 16, 2026All applications are due by 5:00 PM local time of applicant organization.

Budget: Application budgets are limited to no more than \$50,000 in direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is 2 years.

<u>PAR-25-371</u> Ethical, Legal and Social Implications (ELSI) Research (R01 Clinical Trial Optional). This NOFO invites Research Project Grant (R01) applications that propose to study the ethical, legal and social implications (ELSI) of human genetic or genomic research. Applications may propose studies using either single or mixed methods. Approaches may include but are not limited to empirical qualitative and quantitative methods, and conceptual, legal, and normative analyses. Applied research designed to address ELSI issues in genetics and genomics will also be considered responsive. Direct engagement with communities and other interested groups is encouraged but not required. This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP).

Date: June 17, 2025 through to October 20, 2026. All applications are due by 5:00 PM local time of applicant organization.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 5 years, but given how quickly the field changes, it is expected that some projects will be no more than 4 years in duration.

<u>**RFA-AI-25-006</u>** Molecular Mechanisms of Combination Adjuvants (MMCA) (R01 Clinical Trial Not Allowed). The purpose of this 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.</u>

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

Budget: 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.

<u>**RFA-DK-26-007</u>** Collaborative Research Using Biosamples and/or Data from Type 1 Diabetes Clinical Studies (R01 - Clinical Trial Not Allowed). This NOFO invites applications for studies of type 1 diabetes etiology and pathogenesis using data and samples from clinical trials and studies. This opportunity is intended to fund investigative teams collaborating to answer important questions about disease mechanisms leading to improved delay and durable prevention of type 1 diabetes. This NOFO is associated with the Special Diabetes Program (https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/type-1-diabetes-special-statutory-funding-</u>

program/about-special-diabetes-program) which funds research on the prevention, treatment, and cure of type 1 diabetes and its complications, including unique, innovative, and collaborative research consortia and clinical trials networks.

Date: A June 26, 2025 & March 06, 2026. All applications are due by 5:00 PM local time of applicant organization.

Budget: NIDDK intends to commit \$5.5 million in Fiscal Year 2026 to fund 3-4 awards and \$5.5 million in FY 27 to fund 3-4 awards. The number of awards is contingent upon the submission of a sufficient number of meritorious applications. Application budgets are limited to no more than \$1,200,000 direct costs per year, exclusive of facilities and administrative (F&A) costs. Budgets are expected to reflect the actual needs of the proposed project. The maximum project period is 3 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.