# NIH funding opportunities

**20 Nov 2023 (#37)**

National Institutes of Health

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

Stellenbosch University iYunivesithi Universiteit

**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-NS-24-021 Notice of Intent to Publish a Funding Opportunity Announcement for Translational Neural Devices (R61/R33 - Clinical Trial Optional).** The purpose of this Notice is to announce the intention of National Institutes of Neurological Disorders and Stroke (NINDS) to reissue RFA-NS-21-021 to solicit applications for research pursuing translational activities and small clinical studies to advance the development of low risk therapeutic and diagnostic devices for disorders that affect the nervous or neuromuscular systems. Activities that would be supported in this reissue include implementation of clinical prototype devices, non-clinical safety and efficacy testing, design verification and validation activities, obtaining Institutional Review Board (IRB) approval for a Non-Significant Risk (NSR) study (R61 phase), as well as a subsequent small clinical study (R33 phase). This reissue will use a milestone-driven R61/R33 Phased Innovation Award activity code to support clinical research applications that are exploratory and developmental in nature. Support will be provided for up to 5 years, which includes initial support of up to 2 years for the R61 phase, followed by up to 3 years of support for the R33 phase upon successfully meeting R61 milestones. First Estimated Application Due Date: May 28, 2024.

## Parent Announcements

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

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

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

- PA-20-196 NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

## Notice of Special Interest

**NOT-DE-24-003 Applications of Data Science in Translational Dental, Oral, and Craniofacial Research.** This NOSI calls for a variety of data science-oriented projects focused on developing and using data and data science resources, methods, and tools for dental, oral, and craniofacial (DOC) research. Investigators and trainees who are currently active in DOC, non-DOC, and disease agnostic data science spaces are strongly encouraged to apply. An application can respond to any Notice of Funding Opportunity (NOFO), and subsequent reissues, listed under Related Announcements seeking support for research, research training, career development, product development, or conferences. Overall, the initiative will promote research, research training, and career development projects that develop and use state of the art data science resources, methods, and tools in biomedical and behavioral DOC research spanning the full translational continuum from basic to clinical. In particular, applicants are strongly encouraged to develop and disseminate standards and tools to make retrospective and prospective biomedical and behavioral DOC data FAIR (findable, accessible, interoperable and reusable), use the data to discover disease prevention and treatment targets, and translate discoveries into evidence-based clinical applications. This notice applies to due dates on or after January 1, 2024, and subsequent receipt dates through May 8, 2026.

**NOT-MH-24-290 Adopting Techniques and Tools Developed from the BRAIN Initiative Toward NIMH Strategic Research Priorities.** The Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative is aimed at revolutionizing neuroscience through the development and application of innovative technologies to map neural circuits, monitor and modulate their activity, and understand how they contribute to thoughts, sensations, emotions, and behavior. To date, large-scale investment of resources and time through BRAIN has made significant progress in deepening the knowledge about the brain circuits that underlie mental health-relevant domains of function such as cognition, learning and memory, and social processing. Given remarkable progress in technology development, the neuroscience community is poised to apply these new technologies, and accumulated knowledge, to further understand these complex systems-level processes and how their dysfunction might be implicated in mental health illnesses. This NOSI encourages studies seeking to apply innovative BRAIN technologies to understand brain functions in the service of cognition, executive function, reward and motivation, social, or affective processing. This notice applies to due dates on or after February 5, 2024, and subsequent receipt dates through May 10, 2027.

**NOT-AI-23-063 Using Targeted Degradation of Protein and non-Protein Targets for the Development of Novel Anti-Infectives**. The purpose of this Notice is to inform the extramural community that NOT-AI-23-049, "Notice of Special Interest (NOSI): Using Targeted Degradation of Protein and non-Protein Targets for the Development of Novel Anti-Infectives," will be expired as of October 31, 2023**.** In place of NOT-AI-23-049, NIAID has issued NOT-AI-23-076, "Notice of Special Interest (NOSI): Using Targeted Degradation of Protein and non-Protein Targets for the Development of Novel Anti-Infectives;" this new NOSI retains the same aims and was expanded to include the development of anti-infective strategies against parasitic pathogens and/or their toxins. NOT-AI-23-076 This notice applies to due dates on or after January 5, 2024, and subsequent receipt dates through July 16, 2026**.**

**NOT-HL-23-116 Pulmonary Complications of Hematopoietic Stem Cell Transplantation (HCT)** The purpose of thi NOSI is to further elucidate mechanisms underlying the life-threatening pulmonary complications that ensue after hematopoietic stem cell transplantation (HCT) in *all age groups*. This reissue of NOT-HL-20-761 expands the scope of the science to include children and adults, autologous transplant recipients, innovative technologies including device development, and mechanistic clinical trials in children and adults. The NHLBI will only accept applications to PA-20-183 - Research Project Grant (Parent R01 Clinical Trial Required) that propose mechanistic studies which meet the NIH's definition of a clinical trial **and** that have the primary goal of understanding how an intervention works per guidance in NOT-HL-19-690. Applicants are ***strongly*** encouraged to consult the contact(s) listed below prior to submission to confirm that the proposed clinical trial application meets these requirements. This notice applies to due dates on or after February 5, 2024 and subsequent receipt dates through January 7, 2027.

**NOT-DE-23-007 Chronic Inflammation of the Oral Cavity - An Agent for Oral Mucosal Disease.** The National Institute of Dental and Craniofacial Research (NIDCR) is issuing this NOSI to encourage research studies that investigate the mechanisms of chronic inflammation of the oral cavity, including chronic oral manifestations of systemic diseases. Chronic inflammation of the oral mucosa can create or contribute to serious health conditions within and outside the oral cavity. This announcement encourages studies with a **mechanistic focus** on chronic inflammation as they relate to onset or progression of dental, oral and craniofacial diseases. Studies that propose microbial dysbiosis that result

as a consequence of disease are discouraged. Clinical observations and other descriptive studies without mechanistic analysis will be considered non-responsive. This notice applies to due dates on or after February 5, 202 4, and subsequent receipt dates through September 7, 2026.

## Notice of Funding Opportunity (NOFO)

**1. RFA-AI-23-061 Long-Acting Drug Delivery Systems for ART Optimization in Children Living with HIV-1 II (LADDS II) (R61/R33 Clinical Trial Not Allowed)**. The purpose of this NOFO is to accelerate the development of safe and effective long-acting drug delivery systems for improved, simplified treatment of HIV-1 in children. This NOFO invites applicants engaged in the development of existing long-acting platforms at early stages of development stages to perform specific preclinical activities that enable product optimization and accelerated translation to HIV-infected children. Collaborative research partnerships with industry are required.

**Due dates:** March 13, 2024. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** Applications budgets are not expected to exceed $850,000 in direct costs per year during the R61 Phase and $1,250,000 in direct costs per year during the R33 Phase. All F&A costs are excluded from this limit. Requested budgets should reflect the actual needs of the proposed project. Applicants may request up to two years of support for the R61 phase, and up to three years of support for the R33 phase. The maximum project period for an application submitted in response to this NOFO cannot exceed five years total.

**2. PAR-23-293 Ethical, Legal and Social Implications (ELSI) Research (R01 Clinical Trial Optional). This NOFO invites Research Project Grant (R01)** This NOFO invites 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. ***Plan for Enhancing Diverse Perspectives:*** The NIH recognizes that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogeneous teams. There are many benefits that flow from a diverse scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved populations participate in, and benefit from research, and enhancing public trust. Applicants are strongly encouraged to read the NOFO instructions carefully and view the available PEDP guidance material.

**Due dates:** February 20, 2024 through to November 18, 2026. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** Application budgets are not limited but need to reflect the actual needs of the proposed project. Budgets should include costs required to implement the proposed Data Management and Sharing Plan and the proposed Resource Sharing Plan. 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. Longer project periods should be well justified. Additional consideration for longer projects may be given to new or early-stage investigators or projects proposing significant stakeholder or community involvement. All applicants are strongly encouraged to discuss project length with Scientific/Research Staff prior to submission.

**3. PAR-23-294 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.

**Due dates:** February 20, 2024 through to November 18, 2026. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** 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. Budgets should include costs required to implement the proposed Data Management and Sharing Plan and the proposed Resource Sharing Plan. he scope of the proposed project should determine the project period. The maximum project period is 3 years.

**4.** PAR-23-295 Ethical, Legal and Social Implications (ELSI) Small Research Grant (R03 Clinical Trial Optional). This Notice of Funding Opportunity (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 and 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.

**Due dates: February 19, 2024 through to November 16, 2026.** Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** Application budgets are limited to no more than $50,000 in direct costs per year. Budgets should include costs required to implement the proposed Data Management and Sharing Plan and the proposed Resource Sharing Plan. The scope of the proposed project should determine the project period. The maximum project period is 2 years.

**5.** **PAR-24-043 Blueprint Neurotherapeutics Network (BPN): Small Molecule Drug Discovery and Development of Disorders of the Nervous System (UG3/UH3 Clinical Trial Optional).** The Blueprint Neurotherapeutics Network (BPN) invites applications from neuroscience investigators seeking support to advance their small molecule drug discovery and development projects into the clinic. Participants in the BPN are responsible for conducting all studies that involve disease- or target-specific assays, models, and other research tools and receive funding for all activities to be conducted in their own laboratories. In addition, applicants will collaborate with NIH-funded consultants and can augment their project with NIH contract research organizations (CROs) that specialize in medicinal chemistry, pharmacokinetics, toxicology, formulations development, chemical synthesis including under Good Manufacturing Practices (GMP), and Phase I clinical testing. Projects can enter either at the Discovery or the Development stage. In the Discovery phase the goal is to characterize and optimize promising hit compounds using medicinal chemistry to establish structure activity relationships (SAR) and structure property relationships (SPR) including in vitro and in vivo properties such as metabolism, selectivity, toxicity, etc. As projects enter or advance to the Development stage the goal is to advance a single development candidate through Investigational New Drug (IND)-enabling toxicology studies and phase I clinical testing. Projects can enter the program at the Development stage and progress in a shorter period to IND enabling toxicology studies and phase I clinical testing. BPN recipient Institutions retain their assignment of intellectual property (IP) rights and gain assignment of IP rights from the BPN contractors and consultants (and thereby control the patent prosecution and licensing negotiations) for drug candidates developed in this program.

**Due dates: February 09, 2024 through to August 18, 2026.** Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** Application budgets are not limited but need to reflect the actual needs of the proposed project. Applicants may seek up to one year of UG3 funding. The UH3 phase cannot exceed four years. While the total project period will not exceed 5 years, the actual duration of individual projects will depend on successful achievement of milestones and conditions as described in Milestones Section of the program overview.

**6.** **RFA-DA-25-021 Effect of HIV and Substance Use Comorbidity on the Placenta and Maternal Outcomes (R01 Clinical Trial Optional).** The purpose of this notice of funding opportunity (NOFO) is to solicit applications for research targeted at elucidating the effect of HIV and/or anti-retroviral therapy on the growth, development and functioning of the placenta in pregnant individuals with substance use/misuse, the impact of placental abnormalities on maternal outcomes, and the underlying mechanisms.

**Due dates: November 15, 2024** by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIDA intends to commit $2M in FY 2025 to fund 2-5 awards. The proposed budget must reflect the actual needs of the proposed project. Applicants are strongly encouraged to contact the Scientific/Research Contact listed in Section VII of this announcement prior to submission. The scope of the proposed project should determine the project period. The maximum project period is five years.

**7. RFA-DA-25-022 Advancing Technologies to Improve Delivery of Pharmacological, Gene Editing, and other Cargoes for HIV and SUD Mechanistic or Therapeutic Research (R01 Clinical Trial Optional).** The purpose of this notice of funding opportunity (NOFO) is to develop technologies to improve the delivery of pharmacological, gene editing, or other cargoes for HIV and substance use disorder (SUD) mechanistic or therapeutic research. This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP), which will be assessed as part of the scientific and technical peer review evaluation. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn. Applicants are strongly encouraged to read the NOFO instructions carefully and view the available PEDP guidance material.

**Due dates:** November 15, 2024. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIDA expects to fund four to six projects in FY 2025 totalling $2,000,000. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

**8. RFA-DA-25-058 Psychedelics Treatment Research in Substance Use Disorder (UG3/UH3 Clinical Trials Optional).** The purpose of this notice of funding opportunity (NOFO) is to support the development of classic psychedelics (e.g., psilocybin, LSD), empathogens (e.g., MDMA), dissociatives (e.g., ketamine and related compounds), and other hallucinogens (e.g., ibogaine and its analogues) (henceforth "psychedelics") as new treatment options for Substance Use Disorder (SUD). There is an urgent need to develop novel treatments for SUD in light of the escalating rates of substance use, addiction, and overdose. Psychedelics may offer a new potential therapeutic use in SUD. Applications may include the evaluation of an existing psychedelic, a new formulation, or a new psychedelic compound. The application can be at a preclinical and/or clinical phase of medication development. This NOFO utilizes the UG3/UH3 Phased Innovation Awards Cooperative Agreement grant mechanism that includes two phases. The applications responding to this funding opportunity should present a research plan that will cover both the UG3 and UH3 phases. In the 2-year UG3 phase, the project will have a set of milestones to be completed by the end of this period. Once the UG3 phase has been successfully completed, the project may transition to the UH3 phase and may be funded for up to three additional years. The ultimate goal is to advance the development of safe and effective treatments for SUDs with psychedelics in the FDA approval pathway. Investigators submitting to this NOFO must address both UG3 and UH3 phases.

**Due dates:** February 28, 2024. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIDA intends to commit $2,000,000 in FY 2025 to fund 3-5 awards. Application budgets are limited to $2M per year for direct costs. The scope of the proposed project should determine the project period. The maximum UG3 phase of the project duration is 2 years. The maximum UH3 phase of the project duration is 3 years.

**9. RFA-HD-25-008 Development of Novel Nonsteroidal Contraceptive Methods (R61/R33 - Clinical Trial Not Allowed).** The purpose of this notice of funding opportunity (NOFO) is to support and facilitate multidisciplinary research approaches for the development of novel nonsteroidal contraceptive products for men and women that act prior to fertilization using high molecular weight polymers, biologics, and devices. This NOFO aims to position innovative and validated methods for future clinical development.

**Due dates: March 29, 2024.** Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** The NICHD intends to commit a total of $960,000 in FY 2025 to fund up to two awards. For the R61 phase, direct costs may not exceed $300,000 per year. For the R33 phase, direct costs may not exceed $500,000 per year. The

scope of the proposed project should determine the project period. The maximum project period of the combined R61 and R33 phases is up to 4 years with 1 year for the R61 phase and up to 3 years for the R33 phase. Applications with a project period of less than 4 years are encouraged where feasible.

**10. RFA-MH-24-180 Bidirectional Influences Between Adolescent Social Media Use and Mental Health (R01 Clinical Trial Optional).** Adolescents have increasing access to and spend an increasing amount of time engaging in online social interactions and consuming content on social media platforms, yet there is limited knowledge of how online social behavior and experiences interact with adolescent mental illness and risk for psychopathology. The purpose of this Notice of Funding Opportunity (NOFO) is to encourage applications that focus on understanding bidirectional relationships between social media use and adolescent mental illness, psychiatric symptoms, and risk or resilience for psychopathology. This NOFO uses the R01 grant mechanism, whereas its companion NOFO, RFA-MH-24-181, seeks shorter, higher-risk R21 grant applications.

**Due dates:** March 01, 2024. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

**Budget:** NIMH intends to commit $5,000,000 total costs in FY 2024 to fund 5-6 awards across RFA-MH-24-180 and RFA-MH-24-181. 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.

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