



# NIH funding opportunities



Faculty of Medicine and Health Sciences: Research Development and Support

12 May 2021 (#12)

*[Click on blue [hyperlink](#) for further information]*

The NIH funding opportunities listed below are only a **selection** of pre-screened, currently open health funding opportunities for which **South African institutions are eligible to apply**. For a comprehensive selection of NIH funding opportunities, please visit [www.grants.nih.gov](http://www.grants.nih.gov) or [www.sun.ac.za/RDSfunding](http://www.sun.ac.za/RDSfunding) (current & archive).

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

Tygerberg Campus: [cdevries@sun.ac.za](mailto:cdevries@sun.ac.za) • Stellenbosch Campus [lizelk@sun.ac.za](mailto:lizelk@sun.ac.za)

## Important Notices

- [NOT-OD-21-107](#) **Publication of the Revised NIH Grants Policy Statement (Rev. April 2021) for Fiscal Year 2021.** The NIHGPS provides both up-to-date policy guidance that serves as NIH standard terms and conditions of award for all NIH grants and cooperative agreements, and extensive guidance to those who are interested in pursuing NIH grants.
- **New funding from [Cures Within Reach](#): ReGRoW:** Repurposing Grants for the Rest of the World - Funding for Underserved Researchers in LMICs will support grants of up to \$50,000 each for clinical repurposing trials led by an underserved researcher in any LMIC. Proposal deadline: August 6, 2021. [More information](#)
- [NIH FY 2020 By the Numbers: Extramural Investments in Research](#)
- [NOT-OD-21-110](#) **Implementation of Changes to the Biographical Sketch and Other Support Format Page**
  - [Updated Biographical Sketch and Other Support Format Pages Available Now and Required January 2022](#)
- [All Senior/Key Personnel Required to Have A Commons ID Listed on Applications for Due Dates on Or After January 25, 2022](#)
- [NOT-DA-21-049](#) **Notice of Information: Establishment of a Standard THC Unit to be used in Research** Cannabis is a plant containing more than 500 chemicals, and more than 100 cannabinoids. Delta-9-Tetrahydrocannabinol (THC) is the main cannabinoid responsible for the psychotropic and addictive properties of cannabis. Inconsistency in the measurement and reporting of THC exposure has been a major limitation in studies of cannabis use.
- [NOT-OD-21-120](#) **Notice of Technical Assistance Webinar for NOT-OD-21-087, Developing and Testing Multilevel Physical Activity Interventions to Improve Health and Well-Being NOSI.** A technical assistance webinar will be held on Tuesday, June 8, 2021, from 10:00 – 11:30 a.m. (Eastern Time) for all prospective applicants. Registration required.
- **The NIH Office of Intramural Training and Education (OITE) hosts a monthly seminar series, the [Mental Health and Well-being of Biomedical Researchers](#).** Sessions are free and open to NIH trainees, PIs and staff (intramural and extramural), as well as trainees, PIs and staff from universities and research institutions. Registration is required. Videos of past sessions are available on the [NIH OITE YouTube channel](#).

## Notices of Special Interest (NOSI)

**[NOT-AA-21-028](#) Public Policy Effects on Alcohol-, Cannabis-, Tobacco-, and Other Drug-Related Behaviors and Outcomes.** This announcement encourages applications to conduct research on the effects of public policies on health-related behaviors and outcomes associated with alcohol, cannabis, tobacco, prescription drugs, and other substances. The purpose of the Notice is to advance understanding of how public policy may serve as a tool for improving public health and welfare through its effects on behaviors and outcomes pertaining to alcohol and other drugs. This Notice is intended to support innovative research to examine policy effects that have the potential to lead to meaningful changes in public health. This notice applies to due dates on or after June 5, 2021 and subsequent receipt dates through September 8, 2024. Submit applications for this initiative using one of the following funding opportunity announcements (FOAs) or any reissues of these announcement through the expiration date of this notice.

- [PA-20-185](#) - NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- [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)

**[NOT-CA-21-057](#) Biology of Lung and Head and Neck Preneoplasia** This NOSI seeks applications investigating mechanistic and biological aspects of preneoplasia leading to invasive lung and head and neck (HN) cancers. Despite having better molecular understanding of lung and HN cancers and improved therapies for affected patients, these tumors remain a major health problem in the United States (US) and globally. Applications that are responsive to the NOSI include those focused on any areas related to:

- The mechanisms and biology of early and preinvasive stages of lung or HN carcinogenesis;
- Immune regulation of premalignancy at these anatomic sites; and/or
- Identification of potential targets or strategies for early intervention to intercept lung or HN oncogenesis.

Submit applications for this initiative using one of the following funding opportunity announcements (FOAs)

- [PA-20-185](#) - NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- [PA-20-195](#) - NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)

**[NOT-CA-21-074](#) Early-life Factors and Cancer Development Later in Life.** The purpose of this NOSI is to stimulate research focused on the roles of early-life factors (maternal-paternal, in utero, birth and infancy, puberty, adolescence, and young adult years) in cancer development later in life. Applications that will be considered nonresponsive to this NOSI will include:

- Studies that establish new cohorts.
- Studies that fund infrastructure for follow-up visits of an existing cohort.

Submit applications for this initiative using one of the following funding opportunity announcements

- [PA-20-185](#) - NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- [PAR-21-190](#) - Modular R01s in Cancer Control and Population Sciences (R01 Clinical Trial Optional)
- [PAR-19-277](#) - Exploratory Grants in Cancer Epidemiology (R21 Clinical Trial Optional)
- [PA-20-195](#) - NIH Exploratory/Development Research Grant Program (Parent R21 Clinical Trial Not Allowed)
- [PAR-20-052](#) - NCI Small Grants Program for Cancer Research for Years 2020, 2021, and 2022 (NCI Omnibus R03 Clinical Trial Optional)

**[NOT-HD-21-025](#) Reproductive Health, Pregnancy, and Parenting among Women with Disabilities.** The purpose of this Notice of Special Interest (NOSI) is to encourage and support research studies in women with disabilities (WWD) in any of three interconnected areas of high priority to NICHD:

- Gynecologic care and preconception health for women and adolescent girls with disabilities
- Pregnancy in WWD
- Postpartum and parenting needs of WWD

It is not expected or required that all areas will be addressed in one application. This notice applies to due dates on or after June 5, 2021 and subsequent receipt dates through May 31, 2024. Submit applications for this initiative using one of the following funding opportunity announcements

- [PA-20-185](#) – NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- [PA-20-183](#) – NIH Research Project Grant (Parent R01 Clinical Trial Required)
- [PA-20-200](#) – NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)

- [PA-21-221](#) – NICHD Small Research Grant Program (R03 Clinical Trial Required)
- [PA-21-231](#) – NICHD Small Research Grant Program (R03 Basic Experimental Studies with Humans Required)

**NOT-HD-21-026 Research on the Impact of the Covid 19 Pandemic and Risks for Abuse and Injury Among Vulnerable Children and Youth.** Treating injured and traumatized children and efforts to implement preventive interventions have become increasingly challenging in the context of the current pandemic. Children are notably at greater risk of injury, morbidity and mortality due to the social isolation, economic stressors, and other challenges related to policies and practices designed to mitigate the spread of the coronavirus. Given the limitations of traditional contexts for identifying and reporting abuse due to these mitigation strategies, research on treatment and care in diverse (e.g. primary, emergency and acute care) settings is essential to identify effective ways of screening, diagnosing and assessing trends in abuse and abuse related injuries in this current context. This notice applies to due dates on or after June 5, 2019 and subsequent receipt dates through May 31, 2024. Submit applications for this initiative using one of the following funding opportunity announcements

- [PA-20-185](#) – NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- [PA-20-183](#) – NIH Research Project Grant (Parent R01 Clinical Trial Required)
- [PA-20-200](#) – NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
- [PA-21-221](#) – NICHD Small Research Grant Program (R03 Clinical Trial Required)
- [PA-21-231](#) – NICHD Small Research Grant Program (R03 Basic Experimental Studies with Humans Required)
- [PA-20-195](#) – NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)
- [PA-21-194](#) – NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)
- [PA-21-196](#) – NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

**NOT-DA-21-012 Women and Sex/Gender Differences in Drug and Alcohol Abuse/Dependence** The purpose of this Notice is to inform potential applicants of the National Institute on Drug Abuse (NIDA) special interest in grant applications to conduct rigorous basic, translational and/or clinical research to: (1) advance identification of sex and/or gender differences in risk for substance use disorders or the response or medical consequences of alcohol or substance misuse to uncover the mechanisms of those differences, and to conduct translational research on those differences, and (2) advance research specific to women or highly relevant to women. Both preclinical and clinical studies are sought across all areas of drug and alcohol research. This notice applies to due dates on or after June 5, 2021 and subsequent receipt dates through September 8, 2024. Submit applications for this initiative using one of the following funding opportunity announcements:

- [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 (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)
- [PA-20-146](#) - NIDA Small Research Grant Program (R03 Clinical Trial Required)

## 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-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)

## Funding Opportunity Announcements (FOA)

### 1. NeuroNEXT Clinical Trials (U01 Clinical Trial Optional)

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

**Hyperlink:** [PAR-21-223](#)

**Type:** U01

**Application Due Date:** June 05, 2021, October 05, 2021, February 05, 2022, June 05, 2022 October 05, 2022. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** This FOA encourages applications for exploratory clinical trials of investigational agents (drugs, biologics, surgical therapies or devices) that may contribute to the justification for and provide the data required for designing a future trial, for biomarker validation studies, or for proof of mechanism clinical studies. Diseases chosen for study should be based on the NINDS' strategic plan and clinical research interests ([www.ninds.nih.gov/funding/areas/index.htm](http://www.ninds.nih.gov/funding/areas/index.htm)). Successful applicants will be given access to the NeuroNEXT infrastructure. Following peer review, NINDS will prioritize and order trials that are given access to the NeuroNEXT infrastructure. The NeuroNEXT Clinical Coordinating Center (CCC) will work with the successful applicant to efficiently implement the proposed study. The NeuroNEXT Data Coordinating Center (DCC) will provide statistical and data management support. The NeuroNEXT clinical sites will provide recruitment/retention support as well as on-site implementation of the clinical protocol. Applicants do not need to be part of the existing NeuroNEXT infrastructure.

**Budget:** Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum request cannot exceed 5 years but the actual funded project period is dependent on reaching specific milestones as described in this FOA.

### 2. Screening and Functional Validation of Human Birth Defects Genomic Variants (R01 Clinical Trial Not Allowed)

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

**Hyperlink:** [PAR-21-229](#)

**Type:** R01

**Application Due Date:** June 05, 2021, February 05, 2022, June 05, 2022, February 05, 2023. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** Rapid advances in genotyping and next generation sequencing technologies have led to the identification of genetic variants that are associated with a wide variety of congenital defects including structural birth defects (SBDs), intellectual developmental disabilities (IDDs) and inborn errors of metabolism (IEMs). Large quantities of genomic data collected from pediatric birth defects cohorts are available to the research community through several databases such as the Database of Genotypes and Phenotypes (dbGaP), the Gabriella Miller Kids First Data Resource Portal, the European Genome-Phenome Archive and Clinical Genome Resource (ClinGen). The purpose of this initiative is to promote the screening, functional validation and characterization of birth defects-associated genetic variants identified through public facing databases and individual efforts using in-silico tools, appropriate animal models, in vitro systems or multi-pronged approaches. This initiative addresses a challenging gap between identifying sequence variations of potential interest and recognizing which of those variations have functional effects on the phenotype of interest.

**Budget:** Application budgets are limited to \$499,999 direct costs per year and need to reflect the actual needs of the proposed projects. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

### 3. National Institute of Neurological Disorders and Stroke (NINDS) Exploratory Clinical Trials (U01 - Clinical Trial Required)

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

**Hyperlink:** [PAR-21-236](#)

**Type:** U01

**Application Due Date:** June 05, 2021, October 05, 2021, February 05, 2022. **AIDS dates:** September 07, 2021, January 07, 2022, May 07, 2022. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** The purpose of this Funding Opportunity Announcement (FOA) is to encourage grant applications for investigator-initiated exploratory clinical trials to the National Institute of Neurological Disorders and Stroke (NINDS). The trials must address questions within the mission and research interests of the NINDS and may evaluate drugs, biologics, and devices, as well as surgical, behavioral and rehabilitation therapies. Information about the mission and research interests of the NINDS can be found at the NINDS website (<https://www.ninds.nih.gov/>). Examples of appropriate studies include, but are not limited to, those designed to:

- Evaluate and optimize the dose, formulation, safety, tolerability or pharmacokinetics of an intervention in healthy volunteers or the target population.
- Evaluate whether an intervention produces sufficient evidence of short-term activity (e.g., biomarker activity, target engagement, dose-response trends, pharmacodynamic response) in a human "proof of concept" trial.
- Select or rank the best of two or more potential interventions or dosing regimens to be evaluated in a subsequent trial, based on tolerability, biological activity, or preliminary clinical efficacy (e.g., futility trials).
- For devices: Establish proof-of-principle and optimize techniques, operation, and usability of a device; inform the final device design decisions; and estimate the magnitude of treatment effect.

**Budget:** Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum request cannot exceed 5 years.

### 4. Integrated Pathogen Reduction Technologies for whole blood and blood components for transfusion (R01) Clinical Trials Not Allowed

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

**Hyperlink:** [RFA-FD-21-032](#)

**Type:** R01

**Application Due Date:** July 6, 2021 by 11:59 PM Eastern Time.

**Funding Opportunity Announcement:** Center for Biologics Evaluation and Research (CBER), FDA seeks to support the development of innovative pathogen reduction technologies for whole blood and blood components to prevent transfusion-transmitted infectious diseases.

**Budget:** Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect): YR 01: \$4,000,000 and YR 02: \$4,000,000

#### 5. Human Milk as a Biological System (R01 Clinical Trial Optional)

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

**Hyperlink:** [RFA-HD-22-020](#)

**Type:** R01

**Application Due Date:** November 29, 2021. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** This Funding Opportunity Announcement (FOA) invites grant applications that address priority gaps in our understanding of human milk as a biological system and that expand our understanding of the myriad factors influencing the composition and function of human milk using a systems biology approach.

**Budget:** NICHD intends to commit \$2,000,000 in FY 2022 to fund 1-8 awards. Application budgets are limited to \$499,999 in direct costs per year (exclusive of subcontracts F&A) 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 5 years.

#### 6. National Institute of Mental Health (NIMH) Research Education Mentoring Program for HIV/AIDS Researchers (R25 Clinical Trial Not Allowed)

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

**Hyperlink:** [PAR-21-228](#)

**Type:** R21

**Application Due Date:** September 7, 2021; September 7, 2022; September 7, 2023. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** Consistent with the NIH global health research mission, NIMH is committed to developing clinical research expertise and sustainable research infrastructure both outside and within the United States. Although this research education opportunity is primarily for US programs, NIMH also encourages U.S.-based **applications with Low- and Middle-Income Country (LMIC) sites**. Inter-institutional collaborations could be useful when US institutions with foreign sites are involved and should build upon the pairing of mentors from different locations for an integrated approach. **SA institutions can not directly apply.**

The NIH Research Education Program (R25) supports research education activities in the mission areas of the NIH. The overarching goal of this R25 program is to support educational activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs.

To accomplish the stated over-arching goal, this FOA will support creative educational activities with a primary focus on:

- **Research Experiences**
- **Mentoring Activities**

Both research experiences and mentoring activities are required. These Research Education Mentoring Programs are expected to enhance the professional development of the mentees and foster career trajectories towards independent research to reduce the incidence of HIV worldwide and to decrease the burden of living with HIV. The terms participant and mentee are used throughout this FOA to refer to individuals who are enrolled in the research education program.

**Budget:** Application budgets may not exceed \$200,000 in direct costs annually and are expected to reflect the actual needs of the proposed project. The total project period for an application may not exceed five years.

#### 7. Hubs of Interdisciplinary Research and Training in Global Environmental and Occupational Health (GEOHealth) – Research (Collaborative U01 Clinical Trial Optional)

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

**Hyperlink:** [RFA-TW-21-001](#)

**Type:** U01

**Application Due Date:** July 08, 2021. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** This Funding Opportunity Announcement (FOA) solicits applications for research projects in linked Hubs of Interdisciplinary Research and Training in Global Environmental and Occupational Health (GEOHealth). The overall objective of the GEOHealth program is to support the development of institutions in Low- or Middle-Income Countries (LMICs) that will serve as regional hubs for collaborative research, data management, research training, curricula and outreach material development, and policy support around high priority local, national, and regional environmental and occupational health threats. These hubs are expected to conduct the research and training needed to identify and design mitigation strategies for the adverse consequences of environmental exposures and inform relevant policy development in LMICs. The global network of hubs will serve as a platform for coordinated research and research training. GEOHealth Hubs are expected to provide leadership in environmental and occupational health research and in training a new generation of environmental and occupational health experts.

**Budget:** FIC and partner components intend to commit an estimated total of \$4.2 million for FY2022 for the combined linked (U01 and U2R) awards, corresponding to approximately seven linked hub awards. The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. The application budget should be developed in close coordination with the linked U2R research training application ([RFA-TW-21-002](#)) because the combined budget for both linked applications cannot exceed \$600,000 in total costs per year (including 8% F&A), and at least 50% of the combined budget must be in the LMIC's U01 application. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

#### 8. Systems Approach to Understand Mechanisms of Heterogeneous Response to Influenza (R01 Clinical Trial Not Allowed)

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

**Hyperlink:** [RFA-AI-21-017](#)

**Type:** R01

**Application Due Date:** September 08, 2021. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** The purpose of this Funding Opportunity Announcement (FOA) is to support the identification of mechanisms behind heterogeneous responses in the population to influenza infection and/or vaccination through development and application of computational tools.

**Budget:** NIAID intends to commit \$4.0 million in FY 2022 to fund 4-6 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

### 9. BRAIN Initiative: Development and Validation of Novel Tools to Probe Cell-Specific and Circuit-Specific Processes in the Brain (R01 Clinical Trial Not Allowed)

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

**Hyperlink:** [RFA-MH-21-175](#)

**Type:** R01

**Application Due Date:** October 08, 2021, October 07, 2022, October 06, 2023. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** The purpose of this Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative is to encourage research that will develop and validate novel tools to facilitate the detailed analysis of complex circuits and provide insights into cellular interactions that underlie brain function. The new tools and technologies should inform and/or exploit cell-type and/or circuit-level specificity. Plans for validating the utility of the tool/technology will be an essential feature of a successful application. The development of new genetic and non-genetic tools for delivering genes, proteins and chemicals to cells of interest or approaches that are expected to target specific cell types and/or circuits in the nervous system with greater precision and sensitivity than currently established methods are encouraged. Tools that can be used in a number of species/model organisms rather than those restricted to a single species are highly desired. Applications that provide approaches that break through existing technical barriers to substantially improve current capabilities are highly encouraged.

**Budget:** Issuing IC and partner components intend to commit an estimated total of \$8 million to fund 6-9 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 3 years.

### 10. Translational Neural Devices (UG3/UH3 - Clinical Trial Optional)

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

**Hyperlink:** [RFA-NS-21-021](#)

**Type:** UG3/UH3

**Application Due Date:** July 01, 2021, October 20, 2021; February 18, 2022; June 20, 2022; October 18, 2022. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** The purpose of this Funding Opportunity Announcement (FOA) is to encourage investigators to pursue translational activities and small clinical studies to advance the development of therapeutic, and diagnostic devices for disorders that affect the nervous or neuromuscular systems. Activities supported in this program include implementation of clinical prototype devices, non-clinical safety and efficacy testing, design verification and validation activities, obtaining an Investigational Device Exemption (IDE) for a Significant Risk (SR) study or Institutional Review Board (IRB) approval for a Non-Significant Risk (NSR) study, as well as a subsequent small clinical study. The clinical study is expected to provide information about the device function or final design that cannot be practically obtained through additional non-clinical assessments (e.g., bench top or animal studies) due to the novelty of the device or its intended use. This FOA is a milestone-driven cooperative agreement program and will involve participation of NIH program staff in negotiating the final project plan before award and monitoring of research progress.

**Budget:** NINDS intends to commit \$4,000,000 to support 3-5 awards per fiscal year. Application budgets are not limited but need to reflect the actual needs of the proposed project. Applicants should rarely exceed \$1,000,000 direct costs per year for the UG3 phase and \$1,500,000 direct costs per year for the UH3 phase. The proposed project period for the UG3 phase must not exceed 4 years. The proposed project period for the UH3 phase must not exceed 4 years. The total duration of the UG3 and UH3 may not exceed 5 years.

### 11. Eunice Kennedy Shriver National Institute of Child Health and Human Development NICHD Small Research Grant Program

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

**Hyperlink:** [PA-21-221](#)

**Type:** R03

**Application Due Date:** June 16, 2021, October 16, 2021; February 16, 2022; June 16, 2022 **AIDS dates:** September 07, 2021, January 07, 2022, May 07, 2022; September 07, 2022. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** The NICHD Small Research Grant Program (R03 Clinical Trial Required) supports clinical trials that fall within the NICHD mission. The R03 activity code supports small research projects that can be carried out in a short period of time with limited resources. The R03 program may be used for different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology.

**Budget:** Application budgets are limited to \$50,000 in direct costs per year. The maximum project period is two years.

### 12. Pilot Effectiveness Trials of Interventions for Preschoolers with ADHD (R34 Clinical Trial Required)

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

**Hyperlink:** [RFA-MH-21-230](#)

**Type:** R34

**Application Due Date:** July 01, 2021; March 01, 2022. Apply by 5:00 PM local time of applicant organization

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) seeks applications for pilot projects to evaluate the preliminary effectiveness of interventions targeting preschool attention deficit hyperactivity disorder (ADHD) symptoms and impairments. An emphasis is placed on studies that take a theory-driven, empirical approach to developing and testing interventions intended to impact current ADHD symptoms and impairments and/or prevent or forestall the emergence of co-occurring disorders or additional ADHD-related impairments. In this pilot phase of effectiveness research, the trial should be designed to evaluate the feasibility, tolerability, acceptability, safety, and potential effectiveness of the approach, to address whether the intervention engages the target mechanisms presumed to underlie the intervention effects, and to obtain preliminary data needed to inform a larger, more definitive test of the intervention.

**Budget:** NIMH intends to commit a total of \$1.25M in FY 2022 and FY 2023 to fund up to 5 awards depending on the submission of a sufficient number of meritorious applications. Direct costs are limited to \$450,000 over the R34 project period, with no more than \$225,000 in direct costs allowed in any single year. The total project period for an application submitted in response to this funding opportunity may not exceed three years.

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