NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support **14 Dec 2020 (#54)**

[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** or **www.sun.ac.za/RDSfunding** (current & archive).*

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

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Important Notices

- **NOT-OD-21-040: Required Use of Two-Factor Authentication Using Login.Gov for eRA's External Modules in 2021.** Login.gov is a shared service authentication provider managed by General Services Administration (GSA). With one login.gov account, users can sign into multiple government agency systems while taking advantage of login.gov's two-factor authentication capabilities that ensure the security of their personal information.
- **NOT-CA-21-021 Notice of Intent to Publish a Funding Opportunity Announcement: Cancer Prevention, Detection, Diagnosis, and Treatment Technologies for Global Health.** The purpose of this announcement is to alert the community that the National Cancer Institute (NCI) plans to publish a Funding Opportunity Announcement (FOA) to invite applications for Cancer Prevention, Detection, Diagnosis, and Treatment Technologies for Global Health (U01 activity code). This FOA supports the development of cancer-relevant technologies suitable for use in low- and middle-income countries (LMICs). Specifically, the FOA solicits applications for projects to adapt, apply, and validate existing or emerging technologies into a new generation of user-friendly, low-cost technologies for preventing, detecting, diagnosing, and/or treating cancers in people living in LMICs.

Upcoming Deadlines

- **Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa):** Research Hubs AIDS application due date: 8 February 2021
- **Strengthening Institutional Capacity to Conduct Global Cancer Research in Low- and Middle-Income Countries D43** 24 June 2021

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)

1. National Institute on Deafness and Other Communication Disorders (NIDCD) Low Risk Clinical Trials in Communication Disorders (R01 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-21-063** **Type: R01**

Application Due Date: Standard dates and Standard AIDS dates apply. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The NIDCD is committed to identifying effective interventions for the diagnosis, prevention, or treatment of communication disorders by supporting well-designed and well-executed clinical trials. This funding opportunity announcement (FOA) supports investigator initiated low risk clinical trials addressing the mission and research interests of NIDCD. Clinical trials must meet ALL the following criteria: meet the budget limits of this FOA, not require FDA oversight, are not intended to formally establish efficacy and have low risks to potentially cause physical or psychological harm. This FOA also supports low risk trials determined to be Basic Science Experimental Studies involving Humans (BESH). These studies fall within the NIH definition of a clinical trial and also meet the definition of basic research. It is advisable that only one clinical trial be proposed in each NIDCD Clinical Trials in Communication Disorders R01 application. High risk clinical trials not meeting all the criteria above are referred companion U01 FOA PAR-21-064, NIDCD Cooperative Agreement for Clinical Trials in Communication Disorders.

Budget: Application budgets should be less than $500,000 in direct costs in any year. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

2. Prevention and Intervention Approaches for Fetal Alcohol Spectrum Disorders (R34 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-21-097** **Type: R34**

Application Due Date: February 19, 2021, June 17, 2021, October 19, 2021, February 17, 2022, June, 17, 2022, October 18, 2022, February 17, 2023, June 19, 2023, October 17, 2023. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) for R34 planning grant applications focuses on prevention and intervention strategies for fetal alcohol spectrum disorders (FASD) throughout the lifespan. The intent of this FOA is to support research that advances (1) prevention approaches to reduce prenatal alcohol exposure and incidence of FASD and (2) interventions for FASD. It is expected that research conducted via this mechanism will consist of studies that are a pre-requisite for preparing and submitting subsequent applications for larger scale FASD prevention or intervention studies. Applicants interested in exploratory phased projects may consider FOA (PAR-21-098, the R61/R33 option).

Budget: The budget during the three-year project period may not exceed $450,000 direct cost, with no more than $225,000 direct cost requested in a single year. The project period is limited to 3 years.

3. Prevention and Intervention Approaches for Fetal Alcohol Spectrum Disorders (R61/R33 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-21-098** **Type: R61/R33**

Application Due Date: February 19, 2021, June 17, 2021, October 19, 2021, February 17, 2022, June, 17, 2022, October 18, 2022, February 17, 2023, June 19, 2023, October 17, 2023 Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) focuses on prevention and intervention strategies for fetal alcohol spectrum disorders (FASD) throughout the lifespan. The intent of this FOA is to support research that advances (1) prevention approaches to reduce prenatal alcohol exposure and the incidence of FASD and (2) interventions for FASD. These objectives will be accomplished with the Exploratory/Developmental Phased Award (R61/R33) mechanism, clinical trial optional. The R61 phase will support pilot studies or secondary data analysis for hypothesis development and feasibility, and research testing the hypotheses can be expanded in the R33 phase. The transition to the R33 phase will be determined by NIAAA program staff after evaluation of the achievement of specific milestones set for the R61 phase. Highest priority will be given to applications with clinical trials. Applicants interested in planning clinical trials or adding to current projects may also consider FOA (PAR-21-097, ***the R34 option***).

Budget: For the R61 phase, the combined budget for direct costs during the two-year project period may not exceed $350,000 with no more than $225,000 requested in a single year. For the R33 phase, the direct costs must not exceed $500,000 per year. The project period is limited to 2 years for the R61 phase and up to 3 years for the R33 phase. The total project period may not exceed 5 years.

4. Aging Effects on Osteoimmunology (R01 Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-AG-22-002** **Type: R01**

Application Due Date: June 15, 2021. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA), issued by the National Institute on Aging (NIA) of the National Institutes of Health, solicits grant applications that will examine the role of aging in the interactions between the immune systems and skeletal systems in animal models. Research projects that will determine the mechanisms involved in how both aging of the bone marrow niche and immunosenescence impact these interactions, leading to pathological conditions in bone homeostasis, are the focus of this FOA.

Budget: NIA intends to commit $3 million in FY 2022 to fund 5-6 awards. Application budgets are limited to $300,000 in direct costs per year. Budget requests must 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.

5. Physiologically-based pharmacokinetic (PBPK) models to aid the development of generic dermatological products (U01) Clinical Trials Optional

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-21-013** **Type: U01**

Application Due Date: February 15, 2021 by 11:59 PM Eastern Time.

Funding Opportunity Announcement: The purpose of this project is to develop enhanced mechanistic physiologically-based pharmacokinetic (PBPK) models that allow the description of absorption through the skin of active ingredients applied as dermatological drug products. The

developed models will be utilized to inform decisions on generic dermatological product development and to perform virtual bioequivalence assessments in support of regulatory decisions.
Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for ONE (1) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/CDER intends to fund up to $750,000, for fiscal year 2021 in support of this grant program. It is anticipated that up to three awards will be made, not to exceed $250,000 in total costs (direct plus indirect), per award. 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: $250,000; YR 02: $250,000. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

6. Development of Methods to Evaluate the Impact of Design Differences to the User Interface of Generic Drug-Device Combination Products in Comparison to their Reference Listed Drugs (U01) Clinical Trials Optional

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-21-014** **Type: U01**
Application Due Date: February 15, 2021 by 11:59 PM Eastern Time.
Funding Opportunity Announcement: The goal of this project is to develop methods for evaluating the impact of differences in the design of the user interface of generic drug-device combination products in comparison to the reference listed drug (RLD). Specifically, the project should (i) investigate methods that have the potential to support the categorization of differences in the design of the user interface (minor design differences or other design differences), and (ii) explore different approaches (using in vivo and/or in vitro methods) to assess other design differences as potential alternatives to comparative use human factors (CUHF) studies. The developed methods for evaluating the impact of differences in the design of the user interface will be used by all stakeholders engaged in the development of generic drug-device combination products including regulatory agencies, the pharmaceutical industry and academia. The outcomes of this project will help improve the understanding of the factors related to design differences of the user interface that may impact substitutability between generic and RLD drug-device combination products for intended end-user groups and, thereby, support the development of generic versions of these products that can enhance and stabilize patient access to medicines they need.
Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for TWO (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA/CDER intends to fund up to $600,000, for fiscal year 2021 in support of this research program. It is anticipated that up to 3 awards will be made, not to exceed $200,000 in total costs (direct plus indirect), per award. Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect), per award: YR 01: $200,000; YR 02: $200,000; YR 03: $100,000. The scope of the proposed project should determine the project period. The maximum project period is three (3) years.

7. Mood Disorders in People Living with HIV: Mechanisms and Pathways (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-MH-21-116** **Type: R01**
RFA-MH-21-117 **R21**
Application Due Date: March 10, 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 studies to better understand the underlying mechanisms and interplay of biological, psychosocial and structural factors contributing to mood disorders in people living with HIV. Applications testing a fully conceptualized and hypothesis-based solid premise founded with adequate preliminary data are appropriate for this FOA. Exploratory and high-risk research projects should consider applying to the companion R21 announcement RFA-MH-21-117. Basic and preclinical research in domestic and international settings are of interest. Multidisciplinary research teams and collaborative alliances are encouraged but not required.
Budget: NIMH intends to commit a total of $2,000,000 in FY 2021 to fund 3-5 awards in response to this FOA and the companion FOA. 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. **R21:** The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year. The maximum project period is 2 years.

8. New Chemistries for Un-drugged Targets through A Specialized Platform for Innovative Research Exploration (ASPIRE) Collaborative Research Program (UG3/UH3 Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-TR-21-001** **Type: UG3/UH3**
Application Due Date: July 8, 2021. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The purpose of the ASPIRE Collaborative Research Program is to facilitate translational and clinical research between NCATS intramural scientists and the extramural community to develop approaches that will enhance the ability to discover and develop new chemistries towards previously undrugged biological targets (i.e., biological targets with no known drugs to modulate their function) across many human diseases and conditions. NCATS intramural scientists have established an integrated NCATS ASPIRE platform consisting of physical and virtual modules for automated synthetic chemistry, artificial intelligence (AI) and machine learning (ML), engineering, informatics, and biological testing. The FOA will support intramural - extramural collaborations to develop additional physical modules that will enhance the platform's capabilities. The anticipated outcome includes identification, design, synthesis, and validation of new chemical entities as starting points for drug development of novel targets, and the expansion of chemical space available for drug screening.
Budget: NCATS intends to commit $4,000,000 in FY 2021 to fund 2 awards. Future year amounts will depend on annual appropriations. Application budgets are limited to $750,000 direct costs per year for the UG3 phase and $1,000,000 in direct costs per year for the UH3 phase. Application budgets need to reflect the actual needs of the proposed project. The project period is limited to 2 years for the UG3 phase and 4 years for the UH3 phase. The total project period is limited to a maximum of 5 years.

9. Virtual Approaches Towards New Chemistries for Un-drugged Targets through A Specialized Platform for Innovative Research Exploration (ASPIRE) Collaborative Research Program (U18 Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-TR-21-002** **Type: U18**

Application Due Date: July 8, 2021. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of the ASPIRE Collaborative Research Program is to facilitate translational and clinical research between NCATS intramural scientists and the extramural community to develop approaches that will enhance our ability to discover and develop new chemistries designed towards previously undrugged biological targets (i.e., biological targets with no known drugs to modulate their function) across many human diseases and conditions. NCATS intramural scientists have established an integrated platform consisting of physical and virtual modules for automated synthetic chemistry, artificial intelligence (AI) and machine learning (ML), engineering, informatics, and biological testing. This FOA will support intramural - extramural collaborations to develop virtual modules that will enhance the platform's capabilities (see companion FOA RFA-TR-21-001 for physical modules). The anticipated outcome includes identification, design, synthesis, and validation of new chemical entities as starting points for drug development of novel targets, and the expansion of chemical space available for drug screening.

Budget: NCATS intends to commit $2,000,000 in FY 2021 to fund 2 awards. Future year amounts will depend on annual appropriations. Application budgets are limited to $400,000 direct costs in any fiscal year and need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 2 years.