NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 12 Dec 2017 (#46)

[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.*

Confirm your intent to apply ASAP, but not later than 30 days before the submission date.

***Contact: RGMO Pre-Awards** cdevries@sun.ac.za*

Important Notices:

- **A number of recent applications to NIH have been disqualified for being in violation of the new NIH appendix policy.**
- **NIH urges grantees to publish only in credible journals**
- **Fogarty and its NIH partners plan to provide more than $5 million over five years to support twelve additional early-career researchers each year, through the Emerging Global Leader Award. Fogarty's Emerging Global Leader Award helps provide protected time for research activities for early-career research scientists at LMIC institutions. Two applicants from Stellenbosch University were successful in 2017:**
  - **Dr. Angela Dramowski: Developing a care bundle for neonatal sepsis prevention in low-resource settings**
  - **Dr. Amy Slogrove: The effect of hypertensive disorders in pregnancy and HIV-infection on maternal, birth and infant outcomes in South Africa**
- **Notice of Intent to Revise the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects (NOT-OD-18-008)**
- **Revision: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (NOT-OD-18-014)**
- **Reminder: Policy on Funding Opportunity Announcements (FOA) for Clinical Trials Takes Effect January 25, 2018 (NOT-OD-18-106)**
- **NIH Enforcement of Closeout Policies (NOT-OD-18-107)**
- **Revision: The NIH Announces New Review Criteria for Career Development Award Applications Involving Clinical Trials (NOT-OD-18-109)**
- **Notice of Intent to Publish a Funding Opportunity Announcement for Genetics of Tolerance (R01- Clinical Trial Not Allowed) (NOT-AA-17-016)**

1. Centers of Excellence for Translational Research (CETR) (Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-AI-17-042) **Type:** ***U19***

Application Due Date: March 30, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) solicits applications from single institutions or consortia of institutions to participate in the Centers for Excellence in Translational Research (CETR) program. The purpose of this program is to support multidisciplinary translational research centers focused on generating, validating and advancing medical countermeasures to select NIAID Emerging Infectious Diseases/Pathogens.

Budget: NIAID intends to commit $64 million in FY 2019 to fund 8-10 awards. Application budgets are limited to $5 million for FY2019 direct costs and need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum period is 5 years.

2. Strengthening the HIV Pre-Exposure Prophylaxis (PrEP) Care Continuum through Behavioral, Social, and Implementation Science (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-271) **Type:** ***R21***
(PA-18-281) ***R01***

Application Due Date: Standard dates and Standard AIDS dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages behavioral, social, and implementation science research designed to (a) identify gaps in the HIV pre-exposure prophylaxis (PrEP) care continuum and associated determinants; (b) develop and test interventions to strengthen PrEP delivery, use, and outcomes; and (c) reduce racial/ethnic and age-related disparities in PrEP uptake and use. High risk/high payoff projects that lack preliminary data are appropriate for the R21 mechanism, while applicants with preliminary data who propose longitudinal analyses and/or large scale projects may consider the R01 mechanism.
Budget: 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. R01 - 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.

3. Targeted basic behavioral and social science and intervention development for HIV prevention and care (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-272) **Type:** ***R21***
(PA-18-273) ***R01***

Application Due Date: Standard dates and Standard AIDS dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages innovative, targeted basic behavioral and social science and intervention development research to reduce incident HIV infections and improve the health of those living with HIV. This FOA encourages research designed to (a) conduct basic behavioral and social science research that is needed to advance the development of HIV prevention and care interventions, (b) translate and operationalize the findings from these basic studies to develop interventions and assess their acceptability and feasibility and (c) conduct tests of the efficacy of HIV prevention and care interventions. High risk/high payoff projects that lack preliminary data or utilize existing data may be most appropriate for the R21 mechanism, while applicants with preliminary data and/or include longitudinal analysis may wish to apply using the R01 mechanism.
Budget: 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. R01 - 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.

4. Innovations in Mechanisms and Interventions to Address Mental Health in HIV Prevention and Care Continuum (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-275) **Type:** ***R21***
(PA-18-274) ***R01***

Application Due Date: Standard dates and Standard AIDS dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages applications focused on 1) advancing understanding of mechanisms by which mental health affects HIV prevention and treatment in order to identify modifiable intervention targets; and 2) developing and pilot testing expanded interventions to improve both mental health and HIV outcomes along the entire HIV care continuum (from HIV testing to viral suppression). High risk/high payoff projects that lack preliminary data or utilize existing data may be most appropriate for the R21 mechanism, while applicants with preliminary data and/or include longitudinal analysis may wish to apply using the R01 mechanism
Budget: 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. R01 -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.

5. Formative and Pilot Intervention Research for Prevention and Treatment of HIV/AIDS (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-276) **Type:** ***R34***
Application Due Date: Standard dates and Standard AIDS dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages formative research, intervention development, and pilot-testing of interventions. Primary scientific areas of focus include the feasibility, tolerability, acceptability and safety of novel or adapted interventions that target HIV prevention or treatment. For the purposes of this FOA, "intervention" is defined to include behavioral, social, or structural approaches, as well as combination biomedical and behavioral, social, or structural approaches that prevent acquisition and transmission of HIV infection, or improve clinical outcomes for persons who are HIV infected, or both.
Budget: Direct costs are limited to $450,000 over the entire project period, with no more than $225,000 in direct costs in any single year. The total project period for an application submitted in response to this funding opportunity may not exceed three (3) years.

6. Innovations in HIV Testing, Adherence, and Retention to Optimize HIV Care Continuum Outcomes (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-277) **Type:** ***R21***
(PA-18-278) ***R01***

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

Funding Opportunity Announcement: The health and preventive benefits of treatment for HIV/AIDS, regardless of CD4 count, are now unequivocal. In the United States and globally, ambitious goals have been targeted for HIV testing, adherence, and retention in care, to optimize HIV clinical outcomes and preventive benefit. Additional tools are needed to inform the gaps and strategies that are unique to particular populations, cities, regions, and countries. Applications appropriate for this FOA could include formative basic behavioral and social science to better understand a step in the care continuum and/or multiple steps in the HIV care continuum, and initial development and pilot tests of innovative approaches for intervention. High risk/high payoff projects that lack preliminary data or utilize existing data may be most appropriate for the R21 mechanism, while applicants with preliminary data and/or including longitudinal analysis may wish to apply using the R01 mechanism.

Budget: 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. R01-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.

7. Targeted Implementation Science to Achieve 90/90/90 Goals for HIV/AIDS Prevention and Treatment (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-279) **Type:** ***R01***
(PA-18-280) ***R21***

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

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages implementation research projects designed in partnership with global and domestic service providers, to target the particular needs in the selected community, to achieve the 90/90/90 HIV prevention and treatment targets identified by HIV/AIDS global leadership. The targets for HIV testing are that 90% of all persons living with HIV know their status, for treatment initiation that 90% of those diagnosed receive timely and effective antiretroviral treatment (ART), and for optimal treatment and preventive benefit that 90% of those on treatment achieve sustained viral suppression. High risk/high payoff projects that lack preliminary data or utilize existing data may be most appropriate for the R21 mechanism, while applicants with preliminary data and/or include longitudinal analysis may wish to apply using the R01 mechanism.

Budget: R01-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 may not exceed $275,000. No more than $200,000 may be requested in any single year.

8. Epidemiology and Prevention in Alcohol Research (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-390) **Type:** ***R01***
(PA-18-391) ***R21***
(PA-18-413) ***R03***

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

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages the submission of investigator-initiated research grant applications to support research investigating the epidemiology of alcohol use, alcohol-related harms, and alcohol use disorders and the prevention of underage drinking, alcohol-related harms, and alcohol use disorders.

Budget: R01 - Application budgets are not limited but need to reflect the actual needs of the proposed project. 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. R03-Application budgets are limited to $50,000 in direct costs per year. The total project period may not exceed two years.

9. National Institute of Biomedical Imaging and Bioengineering (NIBIB) Research Project Grant (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-418) **Type:** ***R01***

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

Funding Opportunity Announcement: The NIH Research Project Grant supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s). This NIBIB Funding Opportunity Announcement requires that at least 1 clinical trial be proposed. The proposed project must be related to the programmatic interests of the NIBIB. For this Funding Opportunity Announcement, NIBIB will only support R01 applications proposing early-stage clinical trials through Phase I, first-in-human, safety, feasibility or other small clinical trials that inform early-stage technology development. NIBIB will not support applications proposing Phase II, III, IV or pivotal clinical trials or trials in which the primary outcome is efficacy, effectiveness or a post-market concern.

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.

10. Tobacco Use and HIV in Low and Middle Income Countries (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-022) **Type:** ***R21***
(PAR-18-023) ***R01***

Application Due Date: April 4, 2019; November 1, 2019; April 4, 2020; November 1, 2020; April 4, 2021, November 1, 2021 Aids Dates: May 7, 2019; January 7, 2020; May 7, 2020; January 7, 2021; May 7, 2021, January 7, 2022Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The purpose of this funding opportunity announcement (FOA) is to encourage exploratory/developmental research focused on tobacco use and human immunodeficiency virus (HIV) infection in low and middle income countries (LMICs). In particular, applications are encouraged that focus on the development and evaluation of tobacco cessation interventions tailored to HIV positive populations, including those with co-morbidities such as tuberculosis (TB), in low-resource settings in LMICs. This FOA provides funding for research planning, intervention delivery, and follow-up activities.
Budget: 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. R01 - 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.

11. Predicting Behavioral Responses to Population-Level Cancer Control Strategies (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-024) **Type:** ***R21***
Application Due Date: April 11, 2018; October 10, 2018; April 11, 2019. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The goal of this funding opportunity announcement (FOA) is to facilitate research to identify individual influences on the effectiveness of population-level strategies that target cancer-related behaviors. We seek to encourage collaborations among scientists with expertise in health policy research and implementation, as well as investigators in scientific disciplines that have not traditionally conducted cancer or policy research, such as: psychological science (e.g., social, developmental); affective and cognitive neuroscience; judgment and decision-making; consumer behavior and marketing; organizational behavior; sociology, cultural anthropology; behavioral economics; linguistics; and political science.
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.

12. Building Evidence: Effective Palliative/End of Life Care Interventions (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-173) **Type:** ***R01***
Application Due Date: June 11, 2018; October 8, 2018; June 10, 2019.Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This funding opportunity announcement (FOA) seeks to stimulate research that tests optimal end-of-life and palliative care (EOLPC) interventions/models of care that are based on individual- and family-centered outcomes. The testing of EOLPC interventions and models of care are urgently needed that address racial, ethnic and/or cultural diversity in children and adults for those with serious, advanced illness. Trials are needed to test efficacy and effectiveness of these interventions and/or models of care.
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.

13. Multidisciplinary Studies of HIV/AIDS and Aging (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-189) **Type:** ***R01***
(PAR-18-190) ***R21***

Application Due Date: Standard dates and Standard AIDS dates Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: This FOA encourages applications at the intersection of HIV and aging by addressing two overarching objectives: 1) to improve understanding of biological, clinical, and socio-behavioral aspects of aging through the lens of HIV infection and its treatment; and 2) to improve approaches for testing, prevention, and treatment of HIV infection, and management of HIV-related comorbidities, co-infections, and complications in different populations and cultural settings by applying our current understanding of aging science. Applications appropriate to this FOA should be consistent with the scientific priorities outlined by the NIH Office of AIDS Research (OAR) as described in NOT-OD-15-137.
Budget: R01 - Application budgets are not limited but need to reflect the actual needs of the proposed project. 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.

14. Translational Research in Pediatric and Obstetric Pharmacology and Therapeutics

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-214) **Type:** ***R21***
(PAR-18-215) ***R01***

Application Due Date: April 4, 2018; August 7, 2018; November 7, 2018; April 4, 2019; August 7, 2019; November 7, 2019; April 3, 2020. Apply by 5:00 PM local time of applicant organization.
Funding Opportunity Announcement: The purpose of this funding opportunity announcement (FOA) is to encourage applications for translational and clinical research as well as clinical trials that will advance our knowledge about the underlying mechanisms of drug action, response, and safety in children at various developmental stages, and in women during pregnancy and lactation. The overall goals of the FOA are to improve the safety and effectiveness of current drugs for pediatric or obstetric patients, and to enhance the development of new drugs or a safer usage of the existing drugs for tailored therapies to meet emerging clinical needs for these special populations.
Budget: R21- 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. R01- Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is five years.

15. Evaluating the National Institute on Drug Abuse (NIDA) Standardized Research E-Cigarette in Risk Reduction and Related Studies (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-220) **Type:** ***U01***

Application Due Date: April 24, 2018; April 24, 2019. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to accelerate research evaluating electronic cigarettes (e-cigarettes, electronic nicotine delivery systems, ENDS) as a potential means of reducing the risks associated with combustible tobacco use. This goal will be achieved by funding clinical studies that use the newly-developed NIDA Standard Research E-cigarette (SREC) to examine potential risks and benefits associated with e-cigarette use in current tobacco smokers. Ultimately, this FOA aims to evaluate whether e-cigarettes can reduce the risks associated with combustible tobacco use and to establish the NIDA SREC as a standard to which other e-cigarettes can be compared. Studies submitted to this FOA should examine the effects of the SREC on multiple behavioral and health biomarkers in current tobacco smokers and may include examination of whether e-cigarettes can reduce the negative health impacts of conventional tobacco use, and / or examine their effects on craving and dependence. Funding will be contingent upon the FDA Center for Tobacco Products (CTP) determination that the studies fall under their regulatory jurisdiction. Furthermore, funding will require that CTP accepts the use of the NIDA SREC as an Investigational Tobacco Product (ITP) in the proposed study, or determines that an ITP is not required. Studies funded by this FOA are expected to rapidly increase understanding of whether e-cigarettes reduce the risks associated with tobacco use. Additionally, these studies may provide significant data to inform e-cigarette public health policy decision-making.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 2 years.

16. Fast-Track Development of Medications to Treat Cannabis Use Disorders (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-221) **Type:** ***UG3/UH3***

Application Due Date: May 7, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to accelerate the discovery and development of medications to treat Cannabis Use Disorders (CUDs) using the UG3/UH3 mechanism. The objective is to advance medications toward the ultimate goal of obtaining FDA approval. Advances in understanding the cannabinoid systems and the effects of marijuana on the brain, coupled with the availability of both novel and marketed medications that may be efficacious to treat these disorders, offer unprecedented opportunities to develop safe and effective pharmacotherapies for CUDs. The compounds to be evaluated can be small molecules or biologics. They can be tested in pre-clinical models and/or for the clinical manifestations of CUDs or their consequences such as withdrawal, craving, or cannabis use relapse. Applications may focus on the development of new chemical entities, new formulations of marketed medications available for other indications, or combinations of medications that hold promise for the treatment of CUDs. The UG3/UH3 Phase Innovation Awards Cooperative Agreement 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. Through this FOA, NIDA seeks to fast-track the discovery and development of pharmacotherapies for CUDs and to advance them in the FDA's drug development approval pipeline.

Budget: NIDA intends to commit $3,000,000 in FY16 to fund 3 awards. Application budgets are limited to $1,000,000 direct costs and need to reflect the actual needs of the proposed project. The project period is limited to 2 years for the UG3 phase and 3 years for the UH3 phase.

17. Mobile Health: Technology and Outcomes in Low and Middle Income Countries (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-242) **Type:** ***R21***

Application Due Date: August 31, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage exploratory/developmental research applications that propose to conduct research to develop or adapt innovative mobile health (mHealth) technology specifically suited for low and middle income countries (LMICs) and determine the health-related outcomes associated with implementation of the technology. Of highest interest are innovative, well-designed multidisciplinary projects that aim to generate generalizable knowledge for the field. The overall goal of the FOA is to contribute to the evidence base for the use of mobile technology to improve clinical outcomes and public health while building research capacity in LMICs and establishing research networks in this area. Applicants are required to propose partnerships between at least one U.S. institution and one LMIC institution and the proposed research plan should strengthen the mHealth research capabilities at the LMIC institution.

Budget: Applicants may request up to $125,000 direct costs per year. The total project period may not exceed 2 years.

18. Quantitative Imaging Tools and Methods for Cancer Therapy Response Assessment (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-248) **Type:** ***UG3/UH3***

Application Due Date: May 9, 2018; September 12, 2018; January 9, 2019; May 9, 2019; September 12, 2019; January 9, 2020. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages research project applications under the cooperative agreement (UG3/UH3) mechanism to address the development, optimization and validation of quantitative imaging (QI) software tools and methods for prediction and/or measurement of response to cancer therapies or for planning and validating radiation therapy treatment strategies in clinical trials. The scientific scope of this FOA includes:

- Development and optimization of QI tools and/or methods for treatment planning, predicting or measuring response to therapy as open source tools that will translate into clinical trial decision support;

- Validation of the optimized tools in clinical settings to demonstrate their value for decision support in ongoing single-site or multi-site clinical trials.

A phased approach that emphasizes each of these activities must be proposed. Investigators must apply for both the UG3 and UH3 phases together in the single application. The UG3 effort is to be used for the development and optimization of QI tools and methods chosen for study by the investigating team, while the UH3 phase is for the validation of the tools/methods developed in the UG3 phase. The UG3 phase can be no more than 2 years in duration, and the total project cannot exceed 5 years. At completion, UG3 projects will be reviewed by program staff. Those that have met their milestones may be administratively considered by NCI program staff for transition to the UH3 validation phase.

Budget: UG3/UH3 – Application budgets need to reflect the actual needs of the proposed project but must not exceed $300,000 in direct costs for each year of the UG3 phase and $500,000 (direct costs) for each year of the UH3 phase. The proposed project period for the initial development phase (UG3) award may not exceed 2 years. The total UG3/UH3 period of performance may not to exceed 5 years. U01

19. Quantitative Imaging Tools and Methods for Cancer Response Assessment (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-249) **Type:** ***U01***

Application Due Date: May 9, 2018; September 12, 2018; January 9, 2019; May 9, 2019; September 12, 2019; January 9, 2020. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This purpose of this Funding Opportunity Announcement (FOA) is to provide a mechanism of support to research organizations interested in clinically translating already optimized quantitative imaging software tools capable of measuring or predicting the response of cancer to clinical therapies, or in translating imaging tools for planning and validating radiation therapy treatment strategies in clinical trials. The quantitative tools must have been developed and optimized during a performance period in the Quantitative Imaging Network (QIN) or under other separate funding. The proposed research effort should be an extension of the research that successfully completed the tasks of developing and optimizing the chosen software tools or data collection methods intended to facilitate clinical decision making during clinical trials. This FOA is intended to support the efforts of validating those tools in prospective multisite clinical trials in order to test tool performance and to demonstrate that the tool can be integrated into clinical workflow with a minimum of disruption.

Budget: The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. Application budgets need to reflect the actual needs of the proposed project but must not exceed $500,000 (direct costs) for each proposed year. The maximum project period is 5 years.

20. Improving Smoking Cessation in Socioeconomically Disadvantaged Populations via Scalable Interventions (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-250) **Type:** ***R21***
(PAR-18-251) ***R01***

Application Due Date: June 13, 2018; October 11, 2018, June 13, 2019 Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to provide support for innovative and promising intervention research designed to improve smoking cessation outcomes among socioeconomically disadvantaged populations. Specifically, this FOA is intended to stimulate research efforts aimed at the development of smoking cessation interventions that: 1) are targeted to socioeconomically disadvantaged populations, and 2) could be made scalable for broad population impact. Applicants may propose projects that develop and test novel cessation interventions with the potential to be scaled up, as well as projects that focus on enhancing the effectiveness, quality, accessibility, utilization, and cost-effectiveness of currently scaled smoking cessation interventions. The R21 provides funding for up to 2 years for protocol development and early phase, pilot, or exploratory projects. The R01 provides funding for up to 5 years for research planning, intervention delivery, and follow-up activities.

Budget: R21 - Direct costs are limited to $275,000 over an R21 two-year period, with no more than $200,000 in direct costs allowed in any single year. R01 - Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

21. Image-guided Drug Delivery (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-252) **Type:** ***R01***

Application Due Date: June 21, 2018; November 22, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) will support innovative research projects that are focused on image-guided drug delivery (IGDD), including real-time image guidance, monitoring, quantitative in vivo characterizations and validation of delivery and response. It will support research in development of integrated imaging-based systems for delivery of drugs or biologics in cancer and other diseases, quantitative imaging assays of drug delivery, and early intervention.

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

22. Increased Knowledge and Innovative Strategies to Reduce HIV Incidence-iKnow Projects (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-254) **Type:** ***R01***

Application Due Date: May 8, 2018 Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to promote innovative research that addresses one or both of the following objectives:

- Devise optimal strategies to improve the identification of persons unaware of their HIV-1 infection and successfully link them to HIV testing, treatment, and prevention interventions.

- Develop and examine the feasibility and acceptability of novel integrated interventions of biomedical and behavioral strategies that substantially reduce the likelihood of onward HIV transmission in these populations.

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 period is 5 years.

23. Feasibility Clinical Trials of Mind and Body Interventions for NCCIH High Priority Research Topics (Clinical Trials Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-417) **Type:** ***R34***

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

Funding Opportunity Announcement: The goal of this funding opportunity is to support early phase clinical trials of mind and body approaches for conditions that have been identified by NCCIH as high priority research topics. This funding opportunity is intended to support feasibility clinical trials, which will provide data that are critical for the planning and design of a subsequent controlled cohort study, clinical efficacy or effectiveness study, or a pragmatic trial. The data collected should be used to fill gaps in scientific knowledge necessary to develop a competitive full-scale clinical trial, including, but not limited to the following: adapting an intervention to a specific population; refining the intervention to determine the most appropriate frequency or duration; determining feasibility of recruitment, retention and data collection procedures; examining acceptability of the intervention and control conditions. This FOA will not support randomized clinical trials to test or determine efficacy or effectiveness. Applications that propose solely to write a protocol or manual of operations or to develop infrastructure for a clinical trial are not appropriate for this announcement. The subsequent larger trial should have the potential to make a significant impact on public health.

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

24. National Institute of Neurological Disorders and Stroke (NINDS) Exploratory Clinical Trials (Clinical Trials Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-420) **Type:** ***U01***

Application Due Date: Standard dates and Standard AIDS dates 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/).

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

25. National Institute of Neurological Disorders and Stroke (NINDS) Efficacy Clinical Trials - Clinical Trial Required

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PAR-18-422) **Type:** ***U01***

Application Due Date: Standard dates and Standard AIDS dates 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 efficacy 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/).

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

Brief definitions of some NIH grant mechanisms: ***comprehensive list of extramural grant and cooperative agreement activity codes***

R01 – NIH Research Project Grant Program: most common NIH program; to support a discrete, specified, circumscribed research project; generally 3-5 years; budget may be specified, but generally <$500,000 p.a. (direct costs).

R21 – NIH Exploratory/Developmental Research Grant: encourages new, exploratory and developmental research projects (could be used for pilot or feasibility studies); up to 2 years; budget total generally <$275,000 (direct costs).

R03 – NIH Small Grant Program: limited funding for short period to support e.g. pilot / feasibility study, collection of preliminary data, secondary analysis of existing data, small-contained research projects, development of new research technology, etc.; normally for "new investigators"; not renewable; up to 2 years; budget generally <$50,000 (direct costs).