NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 23 Nov 2017 (#44)

[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:

- **Implementing a New Human Subject and Clinical Trial Information Form (Watch the short video) to improve transparency and trust in NIH funded clinical trials: Each study record requires a minimum number of requested data elements. This starts with leading the applicant through the four questions that determine whether the study is considered by NIH to be a clinical trial.**
- **Delayed onset is not the same as delayed start!**
- **Instructions to complete the Delayed Onset Study Justification attachment for your NIH application.**
- **Protection of Human Subjects attachment, explain the protections you anticipate for human subjects or else explain why protections cannot be described. Instructions for a refresher on required information for the protection of human subjects.**
- **Is the study exempt from Federal regulations?**
- **Infographic to assist you exemptions.**
- **Important Reminders for Appendix Sections and Post-submission Materials: If any other materials are included in the appendix, your application *will be withdrawn* and *not reviewed*.**
- **NIH will Make the Project Outcomes Section of all Interim and Final RPPRs Submitted on or After October 1, 2017 Available via the NIH RePORTER (NOT-OD-18-103)**

1. Pathogenesis of Age-Related HIV Neurodegeneration (Clinical Trial Not Allowed)

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

Application Due Date: February 9, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: NeuroHIV is at an inflection point, with an urgent need to understand the mechanisms that cause and modulate the CNS impairment in the era of antiretroviral therapies. This FOA will encourage basic and clinical research to study commonalities and differences in molecular and cellular mechanisms underpinning neurodegenerative diseases, particularly Alzheimer's disease, and neurological disorders associated with HIV infection and AIDS. In particular, it encourages research to explore the causal role of Alzheimer's disease and other related proteinopathies in HIV-associated neurocognitive disorders in older adults. The funding opportunity envisages cross-disciplinary, multi-PI, and integrative approaches. It will encourage development of both animal and human research to study whether, and how, different neuropathological processes interact with one another, as well as to understand how these interactions lead to neurodegeneration.

Budget: NIA intends to commit $5 million in FY 2018 to fund 6-8 awards. The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. Application budgets are limited to $500,000 in direct costs per year. The maximum project period is 5 years.

2. Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-700) **Type:** ***R01***

Application Due Date: February 14, 2018, June 15, 2018; October 15, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) seeks to support clinical trials to establish the effectiveness of interventions and to test hypotheses regarding moderators, mediators, and mechanisms of action of these interventions. This FOA supports clinical trials designed to test the therapeutic value of treatment and preventive interventions for which there is already evidence of efficacy, for use in community and practice settings. Applications might include research to evaluate the effectiveness or increase the clinical impact of pharmacologic, somatic, psychosocial (psychotherapeutic, behavioral), device-based, rehabilitative and combination interventions to prevent or treat mental illness. This FOA also supports clinical trials to test patient-, provider-, organizational-, or systems-level services interventions to improve access, continuity, quality, equity, and/or value of services. The intervention research covered under this announcement is explicitly focused on practice-relevant questions. This FOA supports trials that require participation of two or more collaborative sites for completion of the study. Accordingly, the collaborating studies share a specific protocol across the sites and are organized as such in order to increase sample size, accelerate recruitment, or increase sample diversity and representation. Each site has its own Program Director/Principal Investigator (PD/PI) and the program provides a mechanism for cross-site coordination, quality control, database management, statistical analysis, and reporting. Support for fully-powered effectiveness studies via a single R01 grant is provided through a separate FOA, RFA-MH-18-701 "Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Applications (R01)."

Budget: NIMH intends to commit $18 million in direct costs for FY 2018 to fund this FOA and the companion FOAs. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years; however, applicants are strongly encouraged to propose a project period of 3 or 4 years.

3. Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-701) **Type:** ***R01***

Application Due Date: February 14, 2018, June 15, 2018, October 15, 2018. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) seeks to support clinical trials to establish the effectiveness of interventions and to test hypotheses regarding moderators, mediators, and mechanisms of action of these interventions. This FOA supports clinical trials designed to test the therapeutic value of treatment and preventive interventions for which there is already evidence of efficacy, for use in community and practice settings. Applications might include research to evaluate the effectiveness or increase the clinical impact of pharmacologic, somatic, psychosocial (psychotherapeutic, behavioral), device-based, rehabilitative and combination interventions to prevent or treat mental illness. This FOA also supports clinical trials to test patient-, provider-, organizational-, or systems-level services interventions to improve access, continuity, quality, equity, and/or value of services. The intervention research covered under this announcement is explicitly focused on practice-relevant questions.
Applicants interested in submitting multi-site effectiveness trials (e.g., to answer primary effectiveness questions and key questions regarding moderators/mechanisms, to ensure geographic and demographic diversity) are directed to RFA-MH-18-700 "Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01)".

Budget: NIMH intends to commit $18 million in direct costs for FY 2018 to fund this FOA and the companion FOAs. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years; however, applicants are strongly encouraged to propose a project period of 3 or 4 years.

4. Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-702) **Type:** ***R61/R33***

Application Due Date: February 14, 2018, June 15, 2018; October 15, 2018 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 early stage testing of pharmacologic interventions with novel mechanisms of action, or device-based interventions, for the treatment of symptoms or domains of altered functions in individuals with mental illness (e.g., schizophrenia, depression, autism, obsessive compulsive disorder, anxiety, bipolar disorder). Early intervention studies are also encouraged where symptoms of a disorder have been identified in subjects (a prodromal phase), prior to full diagnostic criteria being met. Ultimately, this FOA is intended to support early stage testing of pharmacologic or device-based interventions using a protocol design where the presumed mechanism of action of the intervention is adequately tested, to provide meaningful information where target modulation yields a dose-dependent neurophysiological/clinical/behavioral effect. The R61/R33 FOAs are intended to support biphasic high risk applications. Support for a single phased award that does not need the developmental (R61) phase is available in the companion FOA, RFA-MH-18-703.

Budget: NIMH intends to commit $18 million in direct costs for FY 2018 to fund this FOA and the companion FOAs. 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 of the combined R61 and R33 phases is 5 years, with up to 2 years for the R61 phase and up to 3 years for the R33 phase. Applications with a project period less than 5 years are encouraged where feasible

5. Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Health Disorders (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-703) **Type:** ***R33***

Application Due Date: February 14, 2018, June 15, 2018; October 15, 2018 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 early stage testing of pharmacologic interventions with novel mechanisms of action or device-based interventions, for the treatment of symptoms or domains of altered functions in individuals with mental illness (e.g., schizophrenia, depression, autism, obsessive compulsive disorder, anxiety, bipolar disorder). Early intervention studies are also encouraged where symptoms of a disorder have been identified in subjects (a prodromal phase), prior to full diagnostic criteria being met. Ultimately, this FOA is intended to support early stage testing of pharmacologic or device-based interventions using a protocol design where the presumed mechanism of action of the intervention is adequately tested, to provide meaningful information where target modulation yields a dose-dependent neurophysiological/clinical/behavioral effect. Pediatric, adult and geriatric focused interventions are appropriate for this FOA. This R33 FOA supports single phased clinical trial awards. Applicants proposing high risk projects are encouraged to apply to the companion FOA, RFA-MH-18-702.

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 3 years.

6. Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-704) **Type:** ***R61/R33***

Application Due Date: February 14, 2018, June 15, 2018; October 15, 2018 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 efficient pilot testing of novel psychosocial therapeutic and preventive interventions for mental disorders in adults and children, using an experimental therapeutics approach. Under this FOA, trials must be designed so that results, whether positive or negative, will provide information of high scientific utility and will support "go/no-go" decisions about further development or testing of the intervention. This FOA supports the development and testing of innovative psychosocial intervention approaches where the target and/or the intervention strategy is novel. Targets might include, but are not limited to, potentially modifiable behavioral, cognitive, affective and/or interpersonal factors or processes, neural circuits or neural activity subserving specific behaviors or cognitive processes, and/or other neurobiological mechanisms associated with risk for, causation of, or maintenance of a mental disorder. Eligible psychosocial intervention strategies might include in-person or technology-assisted delivery, provided the target and/or the intervention strategy is novel. This FOA supports the development and testing of novel psychosocial interventions, as defined above, as monotherapies or as augmentations to standard treatment. Support will be provided for up to two years (R61 phase) for preliminary milestone-driven testing of the intervention's impact on a target (a process or mechanism associated with risk for, causation, or maintenance of a clinical condition), that is, its target engagement. Contingent on meeting "go/no-go" milestones in the R61 phase, up to 3 years of additional support (R33 phase) may be provided for studies to replicate target engagement and relate change in the intervention target/mechanism to clinical benefit. Ultimately, this R61/R33 FOA is intended to speed the translation of emerging basic science findings of mechanisms and processes underlying mental disorders into novel interventions that can be efficiently tested for their promise in restoring function and reducing symptoms for those living with mental disorders, or for preventing mental disorders among those at risk.

Budget: Application budgets for the R61 phase and the R33 phase 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 of the combined R61 and R33 phases is 5 years, with up to 2 years for the R61 phase and up to 3 years for the R33 phase. Applications with a project period less than 5 years are encouraged where feasible.

7. Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-705) **Type:** ***R33***

Application Due Date: February 14, 2018, June 15, 2018; October 15, 2018 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 efficient pilot testing of novel psychosocial therapeutic and preventive interventions for mental disorders in adults and children, using an experimental therapeutics approach. Under this FOA, trials must be designed so that results, whether positive or negative, will provide information of high scientific utility and will support "go/no-go" decisions about further development or testing of the intervention. This FOA supports the development and testing of innovative psychosocial intervention approaches where the target and/or the intervention strategy are novel. Targets might include, but are not limited to, potentially modifiable behavioral, cognitive, affective and/or interpersonal factors or processes, neural circuits or neural activity subserving specific behaviors or cognitive processes, and/or other neurobiological mechanisms associated with risk for, causation of, or maintenance of a mental disorder. Eligible psychosocial intervention strategies might include in-person or technology-assisted delivery, provided the target and/or the intervention strategy is novel. This FOA supports the development and testing of novel psychosocial interventions, as defined above, as monotherapies or as augmentations to standard treatment. Support will be provided for up to 3 years for studies to replicate previous target engagement findings, and relate change in the intervention target/mechanism to clinical benefit. Ultimately, this FOA is intended to speed the translation of emerging basic science findings of mechanisms and processes underlying mental disorders into novel interventions that can be efficiently tested for their promise in restoring function and reducing symptoms for those living with mental disorders, or for preventing mental disorders among those at risk.

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, which may not exceed 3 years.

8. Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-706) **Type:** ***R34***

Application Due Date: February 14, 2018, June 15, 2018; October 15, 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 pilot research consistent with NIMH's priorities for: 1) effectiveness research on preventive and therapeutic interventions with previously demonstrated efficacy, for use with broader target populations or for use in community practice settings, and 2) research on the development and preliminary testing of innovative services interventions. Applications should provide resources for evaluating the feasibility, tolerability, acceptability and safety of approaches to improve mental health/functional outcomes, to modify risk factors, or to improve service delivery, and for obtaining the preliminary data needed as a pre-requisite to a larger-scale intervention trial (e.g., comparative effectiveness study, practical trial) or large-scale services study. In this pilot phase of effectiveness research, NIMH places highest priority on approaches that can be justified in terms of their potential to substantially impact practice and public health and approaches that are empirically grounded. Adaptations or augmentations of efficacious interventions should only be undertaken if there is an empirical rationale for the adaptation target and for the corresponding mechanism by which the adapted intervention or augmentation is expected to substantially enhance outcomes. This FOA is intended to support pilot effectiveness trials that are designed to explicitly address whether the intervention engages the target(s)/mechanism(s) presumed to underlie the intervention effects.

Budget: 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.

9. Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders (Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (RFA-MH-18-707) **Type:** ***R01***

Application Due Date: February 14, 2018, June 15, 2018; October 15, 2018 Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to support confirmatory efficacy testing of non-pharmacological therapeutic and preventive interventions for mental disorders in adults and children through an experimental therapeutics approach. Under this FOA, trials must be designed so that results, whether positive or negative, will provide information of high scientific utility and will support "go/no-go" decisions about further development, effectiveness testing, or dissemination of the intervention. Interventions to be studied include, but are not limited to behavioral, cognitive, interpersonal, and device-based (both invasive/surgically implanted as well as noninvasive/transcranial) approaches, or a combination thereof. Interventions appropriate for efficacy testing must be based on a compelling scientific rationale, previous demonstration that the intervention engages and alters the hypothesized mechanism of action, a preliminary efficacy signal, and must address an unmet therapeutic need. Support will be provided for a trial of the intervention's efficacy that includes measurement of the hypothesized mechanism of action and the relationship between change in the mechanism and change in functional or clinical effects. Ultimately, this FOA is intended to support a sufficiently-powered efficacy trial to determine the intervention's potential for significant clinical benefit.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years; however, applicants are strongly encouraged to limit their proposed project period to 3 or 4 years.

10. Trophoblast Differentiation and Function (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-047) **Type:** ***R21***

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 applications from the scientific community to support outstanding research in the area of trophoblast differentiation and function in relation to fertility and pregnancy, including the role of the immune system. It is anticipated that fundamental knowledge gained by this research will act as a solid foundation to hasten treatments for a number of placental-based pregnancy disorders, such as implantation failure, frequent pregnancy loss, preeclampsia, fetal growth restriction, and preterm birth.

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. The scope of the proposed project should determine the project period. The maximum period is 2 years

11. Zika Virus (ZIKV) Complications (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-048) **Type:** ***R21***

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 provide support for research on Zika virus (ZIKV) and its complications.This FOA replaces PAR-16-106 which had used rolling application due dates to facilitate the rapid review and award of particularly urgent or time-sensitive projects. The last date for submitting an application to PAR-16-106 is January 13, 2017. ZIKV is a single-stranded RNA virus of the Flaviviridae family. It is transmitted to humans primarily through the bites of infected Aedes mosquitos, though both perinatal/in utero and sexual transmission have been reported. Initially discovered in 1947, it has been reported in the Americas since 2014, with a major outbreak in Brazil starting in 2015. Disease is seen in about 20% of infected people and is usually self-limited. However, an association between ZIKV infection in pregnant women and severe microcephaly in their babies has been very concerning. Additionally the virus has been found in blood, fueling growing concerns about the risk of transfusion-transmission with particular concern over severe outcomes in at risk transfusion recipient populations such as women who are pregnant.

Budget: 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. The scope of the project should determine the project period. The maximum period is 2 years.

12. Fertility Status as a Marker for Overall Health (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-049) **Type:** ***R21***

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

Funding Opportunity Announcement: The purpose of this funding opportunity announcement (FOA) is to support exploratory/developmental research that explores the premise that fertility status can be a marker for overall health. It is clear that chronic conditions such as cancer, diabetes, and obesity can impair fertility, however less is known about the extent to which fertility status can impact or act as a marker for overall health. Data suggest that infertility is not necessarily a unique disease of the reproductive axis, but is often physiologically or genetically linked with other diseases and conditions. Recent epidemiologic studies demonstrate links between fertility status in both males and females and various somatic diseases and disorders. Taken together, these data strongly suggest that fertility status can be a window into overall health. This FOA focuses on studies evaluating fertility as a marker for overall health and therefore applications that look at the effects of a disease or disorder on fertility are outside the scope of this program.

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. The scope of the proposed project should determine the project period. The maximum project period is 2 years.

13. Secondary Analyses in Obesity, Diabetes and Digestive and Kidney Diseases (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-052) **Type:** ***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 R21 applications that propose to conduct secondary analyses of existing data sets relevant to diabetes and selected endocrine and metabolic diseases including thyroid, parathyroid and Cushing's diseases and acromegaly; and genetic metabolic disease including cystic fibrosis, lysosomal storage diseases, and disorders of the urea cycle, amino acid metabolism and metal transport where the focus is on peripheral metabolism or organ function; obesity, liver diseases, alimentary GI tract diseases and nutrition; kidney, urologic, and hematologic diseases. The goal of this program is to facilitate research that explores innovative hypotheses through the use of existing data sets.

Budget: 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. Application budgets need to reflect the actual needs of the proposed project. The total project period may not exceed 2 years.

14. International Research Collaboration on Drug Abuse and Addiction Research (R03 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-065) **Type:** ***R03***
(PA-18-066) ***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 collaborative research applications on drug abuse and addiction that take advantage of special opportunities that exist outside the United States. Special opportunities include access to unusual talent, resources, populations, or environmental conditions in other countries that will speed scientific discovery. Projects should have relevance to the mission of NIDA and where feasible should address NIDA's international scientific priority areas (http://www.drugabuse.gov/international/research-priorities). While the priorities will change from year to year, in FY15 priority areas include: linkages between HIV/AIDS and drug abuse; prevention, initiation, and treatment of nicotine and tobacco use (especially among vulnerable populations such as children, adolescents, pregnant women, and those with co-morbid disorders); the neuroscience of marijuana and cannabinoids; and the effect of changes in laws and policies on marijuana and its impact. The NIH R03 activity code supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. **The R03 activity code** supports 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. **The R21 activity code** is intended to encourage exploratory and developmental research projects by providing support for the early and conceptual stages of these projects. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research. Projects of limited cost or scope that use widely accepted approaches and methods within well-established fields are better suited for the R03 small grant activity code.

Budget: **R03** - Budgets for direct costs of up to $50,000 per year for a maximum of $100,000 direct costs over a two-year period. **R21** - Direct costs are limited to $275,000 over an R21 two-year period, with no more than $200,000 indirect costs allowed in any single year. The maximum project period is 2 years.

15. Pilot Health Services and Economic Research on the Treatment of Drug, Alcohol, and Tobacco Abuse (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-068) **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 purpose of this Funding Opportunity Announcement (FOA) is to encourage pilot and preliminary research in preparation for larger-scale services research effectiveness trials. Relevant trials may test a wide range of approaches, including interventions, practices, and policies, designed to optimize access to, and the quality, effectiveness, affordability and utilization of drug, tobacco, or alcohol use disorder treatments and related services, as well as services for comorbid medical and mental disorder conditions. Relevant approaches may include both those that are novel, and those that are commonly used in practice but lack an evidence base. This FOA provides resources for assessing the feasibility, acceptability, and utility of these approaches.

Budget: Direct costs are limited to $450,000 over the 3-year 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 FOA may not exceed three years.

16. Pilot and Feasibility Studies in Preparation for Drug and Alcohol Abuse Prevention Trials (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-067) **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) for R34 applications seeks to support: (a) pilot and/or feasibility testing of innovative new, revised, or adapted prevention intervention approaches to prevent or delay the initiation and onset of drug and alcohol use, the progression to problem use or alcohol and other substance use disorder, reduce drinking and driving and deaths related to impaired driving and the drug- or alcohol-related acquisition or transmission of HIV infection and viral hepatitis among diverse populations and settings; and (b) pre-trial feasibility testing for prevention services and systems research. It is expected that research conducted via this R34 mechanism will consist of early stage efficacy, effectiveness or services research that will provide intervention pilot and/or feasibility data that is a pre-requisite for preparing and submitting subsequent applications for larger scale drug or alcohol abuse prevention and/or drug- or alcohol-related HIV prevention intervention studies. This R34 FOA does not support applications for which the sole focus is development of intervention protocols, manuals, or the standardization of protocols; rather, any development work must be imbedded within a pilot/feasibility study. Of particular interest are prevention interventions targeting the healthcare system.

Budget: Applicants may request direct costs of up to $450,000 for three years. Although variations from year to year are permissible, in no case may any year be more than $225,000 in direct costs, and total direct costs for the entire project period may not exceed $450,000. The maximum project period is 3 years.

17. Health Services and Economic Research on the Prevention and Treatment of Drug, Alcohol, and Tobacco Abuse (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-069) **Type:** ***R03***
(PA-18-070) ***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 R21 grant applications to conduct rigorous health services and economic research to maximize the delivery of efficient, high-quality drug, tobacco, and alcohol prevention, treatment, and recovery support services. Examples of such research include: (1) clinical quality improvement; (2) quality improvement in services organization and management; (3) implementation research; (4) economic and cost studies; and (5) development or improvement of research methodology, analytic approaches, and measurement instrumentation used in the study of drug, alcohol, and tobacco prevention, treatment, and recovery services.

Budget: R03 - Budgets for direct costs of up to $50,000 per year may be requested. The maximum project period is 2 years. 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. The total project period for an application submitted in response to this funding opportunity may not exceed two years.

18. Development and Testing of Novel Interventions to Improve HIV Prevention, Care, and Program Implementation (R34 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink:** (PA-18-071) **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 FOA provides resources to support (a) pilot or feasibility studies of new or adapted interventions to prevent HIV infection among populations where substance use may be a contributing factor; (b) pilot or feasibility studies of new or adapted interventions to improve the care of HIV infection among populations where substance use is prevalent, including interventions that integrate treatment for substance use disorders and HIV infection; or (c) pilot or feasibility studies to increase the scale, uptake, delivery, and/or quality of HIV prevention or care interventions with established evidence of efficacy. Both primary and secondary prevention will be supported. The full range of substance use will be considered including problematic episodic use and substance use disorders, as well as a full range of substances and modes of administration. The most important consideration is that substance use may affect transmission directly as in the case of injection or may affect transmission risk behavior. Domestic and overseas populations will be considered, with particular attention to populations with disproportionate burden of HIV infection and those where HIV infection and/or drug use are emergent

Budget: Direct costs are limited to $450,000 over a three-year period, with no more than $225,000 direct costs allowed in any single year. The maximum period is 3 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).