



# NIH funding opportunities



Faculty of Medicine and Health Sciences: Research Development and Support

8 Mar 2021 (#05)

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

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

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

## Notices of Special Interest (NOSI)

- **[NOT-MD-21-014](#) Notice of Special Interest (NOSI): Multi-Level HIV Prevention Interventions for Individuals at the Highest Risk of HIV Infection.** The objective of the Ending the HIV Epidemic: A Plan for America is to reduce new HIV infections in the United States by 75% in five years and by 90% by 2030 (<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>). This will be accomplished by implementing proven strategies to prevent new HIV infections – including use of PrEP by high-risk HIV-negative individuals and achieving an undetectable viral load through antiretroviral therapy (ART) among individuals living with HIV – in geographic hotspots with disproportionate numbers of new HIV infections. New infections disproportionately occur in young men who have sex with men (MSM) from racial/ethnic minority populations, particularly African Americans and Latinos. However, the subpopulations at the highest risk of acquiring HIV may vary across geographic hotspots, and the challenges in engaging these high-risk populations may also vary depending on local or state HIV-related resources, laws and policies, and social norms and cultural factors.
- **[NOT-MD-21-015](#) Notice of Special Interest (NOSI): Promoting Viral Suppression among Individuals from Health Disparity Populations Engaged in HIV Care.** The objective of the Ending the HIV Epidemic: A Plan for America is to reduce new HIV infections in the United States by 75 percent in five years and by 90 percent by 2030 (<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>). This will be accomplished by implementing proven strategies to prevent new HIV infections--including use of pre-exposure prophylaxis (PrEP) by high risk HIV negative individuals and achieving an undetectable viral load through antiretroviral therapy (ART) among people living with HIV (PLWH)--in geographic hotspots with disproportionate numbers of new HIV infections. PLWH who are virally suppressed cannot transmit HIV, but according to the CDC, PLWH engaged in HIV care but not virally suppressed account for 20% of new HIV transmissions.
- **[NOT-MH-21-090](#) Notice of Special Interest (NOSI) in Reducing Suicide Risk in Young People in Low- and Middle-Income Countries and Low-Resource Settings.** The National Institute of Mental Health is issuing this Notice of Special Interest (NOSI) to highlight interest in developing and implementing prevention strategies to reduce suicide risk (suicide ideation and behavior, including acts of self-harm/suicide) and promote resilience among young people, age 10-24 years, in low-and middle-income countries (LMICs)and low-resources settings. NIMH welcomes applicants from LMICs and strongly encourages applicants from the United States or upper middle-income countries to partner with sites in LMICs. LMICs and low-resource settings present several challenges to delivering mental health care that should be taken into account and addressed in the proposed research plan, including participation of in-country suicide experts, trained and specialized mental health workers, mental health stigma among care providers, task sharing approaches and challenges, high staff turn-over, strategies to improve quality of care, delivery system challenges, lack of government investment for mental health, cost-effective and /or budgetary impact to delivery of evidence-based interventions, and inadequate protection services and human rights for young people and others. It is strongly recommended that applicants review the [NIMH Center for Global Mental Health website](#) and consult with a Program Officer before application submission. Applicants should also consult [NOT-MH-19-027](#) for NIMH policies on oversight and monitoring of clinical research.

- [NOT-MH-21-105](#) **Notice of Special Interest: Advancing Health Communication Research on HIV Prevention, Treatment and Cure.** The National Institute of Mental Health is issuing this Notice to highlight interest in research applications to optimize health communication strategies that advance HIV prevention, treatment and cure. Health communication science has made pivotal contributions to HIV prevention and treatment efforts. Early media campaigns that promoted condom use and HIV testing proved to be positive influences on knowledge, attitudes and social norms. Increased use of client-centered communication in HIV treatment settings, contributed to greater antiretroviral therapy (ART) adherence and retention in care. Communication strategies that leveraged strengths-based messages about resilience, empowerment and “living with HIV”, helped dispel harmful stereotypes and stigmatizing messages that connoted HIV with a death sentence. A better understanding of how various communication channels influence HIV behavior change at the individual, interpersonal and community levels, as well as how effective health communication is deployed at each stage of the HIV care continuum, continue to be critical scientific competencies for advancing HIV prevention, treatment and cure efforts across the lifespan.

## Parent Announcements

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

- [PA-20-185](#) NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- [PA-20-184](#) Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)
- [PA-20-183](#) Research Project Grant (Parent R01 Clinical Trial Required)
- [PA-20-200](#) NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
- [PA-20-195](#) NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)
- [PA-20-194](#) NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)
- [PA-20-196](#) NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

## Funding Opportunity Announcements (FOA)

### 1. Basic Research to Inform Vaccine and Therapeutic Development for Non-Polio Human Enteroviruses (NPEV) (R01 Clinical Trial Not Allowed)

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

**Hyperlink:** [RFA-AI-21-006](#)

**Type:** R01

**Application Due Date:** July 13, 2021. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** The purpose of this funding opportunity announcement is to solicit applications to expand basic research on non-polio enteroviruses (NPEV) that will inform the development of pan-enterovirus vaccines and broad-spectrum antivirals against enteroviruses A, B, C, and D.

**Budget:** NIAID intends to commit \$6 million in FY 2022 to fund 8 - 13 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. A maximum project period of 5 years is allowed.

### 2. Tropical Medicine Research Centers (U01 Clinical Trial Not Allowed)

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

**Hyperlink:** [RFA-AI-21-004](#)

**Type:** U01

**Application Due Date:** June 18, 2021. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** This funding opportunity announcement (FOA) solicits research applications focused on the etiology, epidemiology, pathogenesis, clinical manifestations, diagnosis, prevention, treatment and control of select Neglected Tropical Diseases (NTDs) in endemic areas. The Tropical Medicine Research Centers (TMRCs) are intended to advance NIAID’s global research effort by targeting research endeavors to: develop novel diagnostic, prevention and therapeutic strategies adapted for the unique needs of low and middle-income countries (LMICs), as classified by the World Bank; create and sustain in-country research capacity; stimulate scientific collaboration and global partnerships; provide opportunities for junior and early-stage investigators to conduct research on NTDs; and facilitate sample sharing to support translational research to develop or evaluate new drugs, diagnostics, vaccines, therapeutics, and/or vector control strategies.

**Budget:** NIAID intends to commit \$3,800,000 in FY 2022 to fund four to six awards. Application budgets should not exceed \$500,000 per year in direct costs. It is required that at least 65% of the annual direct costs should be committed for field work and related research activities at the endemic sites. Awards are contingent upon the availability of funds and submission of a sufficient number of meritorious applications. The scope of the proposed project should determine the project period. The maximum period is 5 years.

### 3. Tropical Medicine Research Centers Coordinating Center (U01 Clinical Trial Not Allowed)

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

**Hyperlink:** [RFA-AI-21-005](#)

**Type:** U01

**Application Due Date:** June 18, 2021. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** This Funding Opportunity Announcement (FOA) solicits applications for a Tropical Medicine Research Centers Coordinating Center (TMRC CC) for the Tropical Medicine Research Centers (TMRC). The TMRC CC will oversee and coordinate efforts across the TMRCs related to data management, data and specimen sharing, scientific collaboration, creation and maintenance of a virtual sample repository, organizing annual meetings, managing an Opportunity Fund to support research by junior and early-stage investigators, and liaising with United States Government (USG) counterparts and other stakeholders.

**Budget:** NIAID intends to commit \$700,000 in FY 2022 to fund one award and includes a minimum of \$200,000 direct costs annually beginning in the second year to support an Opportunity Fund. For this funding opportunity, budgets totaling up to \$500,000 in direct costs per year may be requested. Beginning in year 2, a minimum of \$200,000 of that \$500,000 direct costs per year will be designated for the Opportunity Fund. Application budgets should reflect the actual needs of the proposed project. The project period is 5 years.

### 4. Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01 Clinical Trial Required)

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

**Hyperlink:** [PAR-21-129](#)

**Type:** R01

**Application Due Date:** June 15, 2021, October 15, 2021, February 15, 2022, June 15, 2022. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) solicits clinical trial applications through a series of Funding Opportunity Announcements (FOAs) that cover the intervention development pipeline, from first-in-human, early testing of new interventions, confirmatory efficacy trials, through to effectiveness trials. This 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 (e.g., 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, [PAR-21-130](#), "Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01)." This FOA is designed for applicants seeking funding for multi-site collaborative clinical trials to establish the effectiveness of interventions. Applicants pursuing other [stages of the clinical trial pipeline](#) should consider one of the companion FOAs listed above.

**Budget:** NIMH intends to commit a total of \$27 million FY 2022 to fund this FOA and the companion FOAs listed in [Part 1. Overview Information](#). 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 consider efficiencies and projects of shorter duration, as feasible.

### 5. Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01 Clinical Trial Required)

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

**Hyperlink:** [PAR-21-130](#)

**Type:** R01

**Application Due Date:** June 15, 2021, October 15, 2021, February 15, 2022, June 15, 2022. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) solicits clinical trial applications through a series of Funding Opportunity Announcements (FOAs) that cover the intervention development pipeline, from first-in-human, early testing of new interventions, confirmatory efficacy trials, through to effectiveness trials. This 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 (e.g., 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 uses the R01 grant mechanism to support trials that are adequately powered and of sufficient scope to test effectiveness and examine mediators and moderators of response. Support for multi-site trials that require participation of two or more collaborative sites for completion of the study (e.g., in order to increase sample size, accelerate recruitment, or increase sample diversity and representation) is provided through a separate FOA, [PAR-21-129](#), "Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01)." This FOA is designed for applicants seeking funding for single-site clinical trials to establish the effectiveness of interventions. Applicants pursuing other [stages of the clinical trial pipeline](#) should consider one of the companion FOAs listed above.

**Budget:** NIMH intends to commit a total of \$27 million FY 2022 to fund this FOA and the companion FOAs listed in [Part 1. Overview Information](#). 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 consider efficiencies and projects of shorter duration, as feasible.

### 6. Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions (R34 Clinical Trial Required)

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

**Hyperlink:** [PAR-21-131](#)

**Type:** R34

**Application Due Date:** June 15, 2021, October 15, 2021, February 15, 2022, June 15, 2022. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) solicits clinical trial applications through a series of Funding Opportunity Announcements (FOAs) that cover the intervention development pipeline, from first-in-human, early testing of new interventions, confirmatory efficacy trials, through to effectiveness trials. The purpose of this 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.

Consistent with the NIMH experimental therapeutics approach, this FOA is intended to support pilot studies of intervention effectiveness or service delivery approaches that explicitly address whether the intervention engages the target(s)/mechanism(s) presumed to underlie the intervention effects (i.e., the mechanism(s) that accounts for changes in clinical/functional outcomes, changes in provider behavior, improved access or continuity of services, etc.). In this pilot effectiveness phase of research, NIMH places highest priority on intervention and service delivery approaches that can be justified in terms of their potential to substantially impact practice and public health. This FOA supports pilot studies and provides resources for evaluating the feasibility, tolerability, acceptability and safety and preliminary effectiveness 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 effectiveness trial (e.g., comparative effectiveness study, pragmatic trial). Support for fully-powered effectiveness studies is provided through separate FOAs that utilize the R01 mechanism for single-site effectiveness trials ([PAR-21-130](#); "Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01).") and collaborative R01 mechanism for multi-site effectiveness trials ([PAR-21-129](#); "Clinical Trials to Test the Effectiveness of Treatment, Prevention, and Services Interventions (Collaborative R01 Clinical Trial Required)"). Applicants pursuing other [stages of the clinical trial pipeline](#) should consider one of the companion FOAs listed above. **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.

#### 7. Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders (R01 Clinical Trial Required)

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

**Hyperlink:** [PAR-21-132](#)

**Type:** R01

**Application Due Date:** June 15, 2021, October 15, 2021, February 15, 2022, June 15, 2022. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) solicits clinical trial applications through a series of Funding Opportunity Announcements (FOAs) that cover the intervention development pipeline, from first-in-human, early testing of new interventions, confirmatory efficacy trials, through to effectiveness trials. The purpose of this 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. Applicants pursuing other [stages of the clinical trial pipeline](#) should consider one of the companion FOAs listed above.

**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 consider efficiencies and projects of shorter duration, as feasible.

#### 8. Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R33 Clinical Trial Required)

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

**Hyperlink:** [PAR-21-134](#)

**Type:** R33

**Application Due Date:** June 15, 2021, October 15, 2021, February 15, 2022, June 15, 2022. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) solicits clinical trial applications through a series of Funding Opportunity Announcements (FOAs) that cover the intervention development pipeline, from first-in-human, early testing of new interventions, confirmatory efficacy trials, through to effectiveness trials. The purpose of this FOA is to encourage pilot research developing and testing innovative psychosocial intervention approaches in which the target and/or intervention strategy is novel. Consistent with NIMH's experimental therapeutics approach, this FOA is intended to speed the translation of emergent research on mechanisms and processes underlying mental disorders into promising novel psychosocial preventative or therapeutic interventions. Targets may 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. Novel psychosocial intervention strategies might include in-person or technology-assisted delivery, provided the target and/or the intervention strategy is novel. They may also be standalone interventions or augmentations of efficacious interventions for which there is an empirical rationale by which the augmentation (and corresponding target) is expected to substantially enhance outcomes. Support will be provided for up to 3 years for studies to replicate previous target engagement findings, and to relate change in the intervention target/mechanism to clinical benefit. Ultimately, 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 and/or testing of the intervention. This FOA is designed for applicants seeking to fund pilot stages of research. Applicants pursuing other stages of the clinical trial pipeline should consider one of the companion FOAs listed above.

**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.

#### 9. Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R61/R33 Clinical Trial Required)

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

**Hyperlink:** [PAR-21-135](#)

**Type:** R61/R33

**Application Due Date:** June 15, 2021, October 15, 2021, February 15, 2022, June 15, 2022. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) solicits clinical trial applications through a series of Funding Opportunity Announcements (FOAs) that cover the intervention development pipeline, from first-in-human, early testing of new interventions, confirmatory efficacy trials, through to effectiveness trials. The purpose of this FOA is to encourage pilot research developing and testing innovative psychosocial intervention approaches in which the target and/or intervention strategy is novel. Consistent with NIMH's experimental therapeutics approach, this FOA is intended to speed the translation of emergent research on mechanisms and processes underlying mental disorders into promising novel psychosocial preventative or therapeutic interventions. Targets may 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. Novel psychosocial interventions may be standalone interventions

or augmentations to efficacious interventions for which there is an empirical rationale by which the augmentation (and corresponding target) is expected to substantially enhance outcomes. Support will be provided for up to two years (R61 phase) for preliminary milestone-driven testing of a novel intervention's impact on a target process or mechanism associated mental disorder risk, causation, or maintenance (target engagement). Up to 3 years of additional support (R33 phase) will be provided for studies with findings that meet the "go/no-go" milestones embedded in the R61 phase. The R33 phase is intended to support the replication of target engagement and to test whether engaging the intervention target/mechanism mediates changes in clinical outcomes. Ultimately, 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 and/or testing of the intervention. Applicants pursuing other [stages of the clinical trial pipeline](#) should consider one of the companion FOAs listed above.

**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 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.

#### 10. Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders (R33- Clinical Trial Required)

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

**Hyperlink:** [PAR-21-136](#)

**Type:** R33

**Application Due Date:** June 15, 2021, October 15, 2021, February 15, 2022, June 15, 2022. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** National Institute of Mental Health (NIMH) solicits clinical trial applications through a series of Funding Opportunity Announcements (FOAs) that cover the intervention development pipeline, from first-in human, early testing of new interventions, confirmatory efficacy trials, through to effectiveness trials. The purpose of this 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 well-controlled, 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, [PAR-21-137](#) or [PAR-21-133](#).

**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.

#### 11. Triadic Interactions in Clinical Encounters Involving People with Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD), Clinicians, and Care Partners (R01 Clinical Trial Optional)

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

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

**Type:** R01

**Application Due Date:** June 23, 2021. Apply by 5:00 PM local time of applicant organization.

**Funding Opportunity Announcement:** This Funding Opportunity Announcement (FOA) invites applications focused on triadic interactions and interpersonal processes between individuals with Alzheimer's disease or Alzheimer's disease-related dementias (AD/ADRD), clinicians, and care partners. NIA seeks to increase our understanding of the impact of such interactions on patient health and well-being outcomes. The goal of this initiative is to identify targets for the development of behavioral interventions to optimize interactions in clinical settings and help build and preserve strong and supportive caregiving relationships throughout all stages of AD/ADRD and across the continuum of care. To these ends, this FOA solicits basic research and Stage I behavioral intervention development clinical trials in two high-priority areas: (1) triadic communication and interpersonal relationships between patients, clinicians, and care partners; and (2) the clinical significance of dyadic processes in caregiving relationships between patients and care partners in the context of patient-caregiver-clinician encounters.

**Budget:** NIA intends to commit \$1.87 million in FY 2022 to fund three to four awards. Budgets up to \$500,000 in direct costs per year may be requested. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

#### 12. Data Standards for Tobacco Research and Scientific Review Program (U24) Clinical Trial Not Allowed

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

**Hyperlink:** [RFA-FD-22-002](#)

**Type:** U24

**Application Due Date:** June 1, 2021, by 11:59 PM Eastern Time.

**Funding Opportunity Announcement:** The FDA Center for Tobacco Products is encouraging applications for projects to expedite development of data standards and terminologies to facilitate tobacco research, scientific review, harm reduction, and information exchange. The primary objective is to facilitate the development of non-proprietary, consensus-based, standards for use in studies of tobacco products. Projects may focus on solutions to general data standards development and implementation challenges and/or on specific concepts, domains or areas where standardization is needed.

**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 contingent upon annual appropriations, availability of funding and satisfactory awardee performance. FDA /Center for Tobacco Products intends to commit up to \$750,000 in FY 2022 to fund 2-3 awards. Application budgets need to reflect the actual needs of the proposed project, and should not exceed the following in total costs (direct and indirect): \$250,000 per year. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

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