

# **NIH** funding opportunities



Faculty of Medicine and Health Sciences: Research Development and Support

17 Jan 2022 (#2)

[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 <a href="www.grants.nih.gov">www.grants.nih.gov</a> or <a href="www.grants.nih.gov">www.sun.ac.za/RDSfunding</a> (current & archive).

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

Tygerberg Campus: cdevries@sun.ac.za • Stellenbosch Campus lizelk@sun.ac.za

#### **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)

#### **Important Notices**

- NOT-OD-22-050 Publication of the Revised NIH Grants Policy Statement (Rev. December 2021) for Fiscal Year 2022. The NIHGPS provides both up-to-date policy guidance that serves as NIH standard terms and conditions of award for all NIH grants and cooperative agreements, and extensive guidance to those who are interested in pursuing NIH grants. The requirements set out in the NIHGPS are aligned with 2 CFR Part 200, as implemented for HHS at 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. Also refer to NIHs implementation of the federal-wide Research Terms and Conditions (RTCs), available <a href="here">here</a>. Documents summarizing significant changes implemented with each revision, are available <a href="here">here</a>.
- NOT-CA-22-026 Notice of Intent to Publish a Funding Opportunity Announcement for Systematic Testing of Radionuclides in Preclinical Experiments (STRIPE) (R01 Clinical Trial Not Allowed). This Notice is to inform the research community that the National Cancer Institute intends to issue a Funding Opportunity Announcement (FOA) to solicit applications for the Systematic Testing of Radionuclides in Preclinical Experiments (STRIPE) program. The STRIPE program seeks to support pre-clinical research projects utilizing state-of-the-art cancer biology methods and model systems that study how radiopharmaceutical therapy (RPT) agents affect the biology of normal tissue, tumor cells and the tumor microenvironment. Ideally, proposed aims will be designed to test hypotheses on how RPT dynamically impacts cancer biology processes, which can serve as the pre-clinical basis for developing new targeting strategies and approaches. Studies supported by this PAR will ultimately inform the rationale and design of new RPT-based clinical trials. This Notice is being provided to allow potential applicants sufficient time to develop a responsive proposal. The STRIPE program FOAs will utilize the R01 activity code for pre-clinical research. Applications seeking support for clinical trials will not be allowed. The FOAs are expected

to be published in February 2022 with an expected application due date in June 2022. **Related Notice NOT-CA-22-027** - STRIPE R21 Clinical Trial Not Allowed.

- NOT-EB-21-023 Notice of Intent to Publish a Funding Opportunity Announcement for Bioengineering Partnership with Industry (BPI) (U01 Clinical Trial Optional). The National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Cancer Institute (NCI), National Eye Institute (NEI), National Institute on Aging (NIA), and National Institute of Environmental Health Sciences (NIEHS) intend to reissue a modified version of the Bioengineering Research Partnership FOAs Bioengineering Research Partnerships (U01 Clinical Trial Not Allowed) and Bioengineering Research Partnerships (U01 Clinical Trial Required) with new FOAs entitled, Bioengineering Partnership with Industry (BPI), whose goal is to drive the development and speed the adoption of promising tools and technologies that can address important biomedical problems for which insufficient or no solutions exist. The use of engineering principles is encouraged to establish these tools and technologies as robust, well-characterized solutions that fulfill an unmet need. Applications must include at least one academic and one industrial organization. The purpose of the BPI FOA will be to encourage applications to: 1) establish a robust engineering solution to a problem in biomedical research or the practice of medicine; 2) develop a strategic alliance of multi-disciplinary partners based on a well-defined leadership plan; and 3) realize a specific endpoint within 5-10 years based on a detailed plan with a timeline and quantitative milestones. This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects. The FOA is expected to be published in February 2022 with an expected application due date in May 2022. Related Notice: NOT-EB-21-**024**: BPI U01 Clinical Trial Not Allowed.
- NOT-NS-22-063 Notice of Intent to Publish a Funding Opportunity Announcement for HEAL Initiative: Human Pain-associated Genes & Cells Data Coordination and Integration Center (U24 Clinical Trial Not Allowed). The National Institutes of Health (NIH) intends to promote a new initiative by publishing a Funding Opportunity Announcement (FOA) to solicit applications for a Data Coordination and Integration Center that will curate, harmonize, and integrate comprehensive -omics and cellular function datasets for the discovery and functional evaluation of human pain-associated genes and cells. This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and develop responsive projects. The FOA is expected to be published in February 2022. First Estimated Application Due Date: 5 April 2022.
- NOT-NS-22-065 Notice of Intent to Publish a Funding Opportunity Announcement for HEAL Initiative: Discovery and Functional Evaluation of Human Pain-associated Genes & Cells (U19 Clinical Trial Not Allowed). The National Institutes of Health (NIH) intends to promote a new initiative by publishing a Funding Opportunity Announcement (FOA) to solicit applications for multidisciplinary, team-based research efforts for the discovery and functional evaluation of human pain-associated genes and cells. This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations among neurobiologists, pain biologists, human pain scientists and/or physicians, and scientists from statistics, physics, mathematics, engineering, and computer and information sciences. It will also allow potential applicants sufficient time to develop responsive projects. The FOA is expected to be published in February 2022. First Estimated Application Due Date: 5 April 2022.
- NOT-MH-22-105 Notice of NIMH Intent to Issue Funding Opportunity Announcements and Notice of Special Interest for COVID-19 and Mental Health Research. The National Institute of Mental Health (NIMH) is issuing this Notice to provide potential applicants additional time to develop responsive applications to upcoming initiatives that encourage research addressing the quickly evolving data related to mental health in the COVID-19 pandemic. Funding Opportunity Announcements are expected to be published in early March and we will accept applications for FY22 funding. In addition, a Notice of Special Interest is expected to be published in January 2022 and applications will be accepted through 2024. If sufficient funds are available, the goal is to begin awarding grants in August 2022. This Notice encourages investigators to acquire and review pilot data to support accelerated research project grants to address the ongoing challenges that SARS-CoV-2 and the secondary impacts of the COVID-19 pandemic pose to mental health. Research areas supported under this program include basic, translational, and services and intervention research to provide an evidence base to understand how mental illness contributes to COVID-19 risk and mortality, how incident mental illness develops with COVID-19, and the development of scalable interventions to meet the public mental health needs of the pandemic among those who survive infection from the SARS-CoV-2 virus and broader populations impacted by stress, disruptions,

and loss of lives in the pandemic. Research addressing the intersection of COVID-19, mental health, and HIV treatment and prevention are also relevant. Given the disproportionate impact of the pandemic on populations who experience health disparities as well as preexisting mental health disparities, NIMH is particularly interested in projects that focus on those populations most in need. Proposed research should reflect the highest impact and feature rigorous methods including sufficient power, and consideration of urgent public health needs.

## **Notices of Special Interest**

- NOT-AG-21-033 Notice of Special Interest: Health Disparities and Alzheimer's Disease. The need to diversify Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD) research cohorts and improve methods and tools for conducting health disparities research related to AD/ADRD has been emphasized by the National Alzheimer's Project Act; the Alzheimer's Research Summits (2012, 2015, and 2021); the National Research Summit on Care, Services, and Supports for Persons with Dementia and their Caregivers (2017 and 2020); and the Alzheimer's Disease-Related Dementia Summits (2013, 2016, and 2019). To achieve such diversity, projects are needed that will increase enrollment of underrepresented populations, expand the use of existing cohorts, and create robust estimates of AD/ADRD in diverse populations. Improvements are also needed in research tools, research methods, and design and recruitment practices. The National Institute on Aging (NIA) is committed to diverse representation in all research studies, including clinical trials. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-034 Notice of Special Interest (NOSI): Genetic Underpinnings of Endosomal Trafficking as a Pathological Hub in Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD). Despite the intensive efforts that have been made in understanding amyloid and other pathological processes in AD, current approved interventions for AD have shown only modest effects in modifying clinical symptoms; none have been efficacious for slowing disease progression as demonstrated through clinical outcome measures. The goals of this Notice of Special Interest (NOSI) are to encourage basic and translational research focused on the molecular, cellular, and physiological processes associated with the endosomal compartment in AD and Alzheimer's disease-related dementias (ADRD). Studies funded under this topic will support research into AD/ADRD pathogenesis related to enhancing our understanding of how the genetic underpinnings of endosomal trafficking in AD/ADRD may act as a hub in the pathophysiological changes associated with the disease. Applications proposing clinical trials on this topic would not be considered a high priority. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AR-22-012 Notice of Special Interest: Promoting Research on COVID-19 and Rheumatic, Musculoskeletal and Skin Diseases. The purpose of this Notice is to announce to potential applicants to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) an interest in research on the impact of COVID-19 as related to diseases and conditions within the NIAMS mission. Patients with many underlying diseases and conditions are at increased risk of acquiring and having adverse outcomes from SARS-CoV-2 infection. Furthermore, persistent symptoms (post-acute sequelae), including fatigue, muscle pain, weakness or wasting, joint pain, skin rash, arthritis, and biobehavioral changes, are being reported among COVID-19 survivors, even among individuals who initially experience a mild acute illness. In line with overall NIH efforts, NIAMS would like to promote basic, translational, pre-clinical and clinical observational research focused on COVID-19 infection and its intersection with rheumatic, musculoskeletal, and skin diseases and conditions. This notice applies to due dates on or after February 5, 2022 and subsequent receipt dates through January 7, 2023.
- NOT-HD-21-053 Notice of Special Interest (NOSI): Advancing Innovative Non-invasive Physiologic Monitoring To Improve Fetal Assessment. The purpose of this Notice of Special Interest (NOSI) is to stimulate adaptation of non-invasive monitoring technologies for use in fetal assessment. The aim of the initiative is to improve accuracy in fetal assessment, leading to improved clinical decision making and, ultimately, improved maternal and fetal outcomes. Research encouraged and supported by this NOSI should focus on direct assessment of fetal status through non-invasive measurement of fetal blood pH, oxygenation, or other direct measures. The objectives of

this NOSI are to advance the accuracy and useability of fetal assessment technology, ultimately resulting in improved maternal and neonatal outcomes and an enhanced birth experience. This initiative also seeks to build on the growing and advancing field of non-invasive physiologic monitoring and sensor technology. This notice applies to due dates on or after February 5, 2022 and subsequent receipt dates through May 8, 2024.

- NOT-NS-22-050 Notice of Special Interest (NOSI) in National Institute of Neurological Disorders and Stroke (NINDS) mission relevant Pain Research. New and innovative advances are needed in nearly every area of pain research. This NOSI is specific for pain conditions within NINDS' mission, which includes but is not limited to cellular and molecular pain research, neuropathic pain not associated with cancer treatments or diabetes, pain due to damage to nerves or other parts of the nervous system, and pain associated with neurological disorders such as Parkinson's disease. Please reach out to the research contacts listed in the NOSI to confirm the NINDS mission relevance of your project prior to submission. This notice applies to due dates on or after January 25, 2022 and subsequent receipt dates through May 8, 2022.
- NOT-NS-22-051 Notice of Special Interest (NOSI) in Migraine and Headache Research. This Notice of Special Interest (NOSI) is issued by the National Institute of Neurological Disorders and Stroke (NINDS) to outline NINDS priorities for applications in the field of headache and migraine research in Fiscal Year 2022. Studies of other primary headache such as nummular headache, hypnic headache and new daily persistent headache (NDPH) are also responsive to this NOSI. This notice applies to due dates on or after February 5, 2022 and subsequent receipt dates through May 8, 2022
- NOT-AG-21-036 Notice of Special Interest (NOSI): Novel Approaches to Diagnosing and Studying Clinical Alzheimer's Disease and Related Dementias. The goal of this NOSI is to encourage the development of novel approaches to characterizing, diagnosing, and predicting outcomes in AD and ADRD. Both clinical and preclinical studies may be supported by this NOSI. Applications proposing clinical trials on this topic would not be considered a high priority. his notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-038 Notice of Special Interest (NOSI): In vivo Synaptic Function in Alzheimer's Disease and Related Dementias. This Notice of Special Interest (NOSI) has two aims:
  - o To study *in vivo* synaptic structure and function in Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD), and
  - o To advance the development of methods to study synapses, *in vivo*, in humans.

Preclinical or animal studies could be appropriate for either of this topic's aims. This topic is appropriate for R21 applications that already have preliminary data. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.

- NOT-AG-21-040 Notice of Special Interest (NOSI): Selective Cell and Network Vulnerability in Aging and Alzheimer's Disease. The goal of this Notice of Special Interest (NOSI) is to stimulate research to define and characterize neural cell populations (e.g., neurons and glia), neural activity and circuits, structural and functional networks, and brain regions that are vulnerable (or resistant) in brain aging and AD and the mechanisms underlying such selective vulnerability. Genetic and molecular signatures of different types of neurons and glial cells across the adult lifespan, in AD compared to other dementias of aging, and in different stages of AD will implicate cell processes and pathways mediating selective vulnerability in AD. Defining cell types by physiological measures such as electrophysiology and connectivity and manipulating neural activity in circuits and networks will provide a functional index of selective vulnerability. Applicants are encouraged to use new approaches to generate sophisticated data on molecular signatures of brain cells and on structure and function of brain circuits and networks. Understanding the mechanisms underlying selective vulnerability from cells to networks in AD is critical to fully define the disease process and to develop effective therapies. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-041 Notice of Special Interest (NOSI): Capturing Complexity in the Molecular and Cellular Mechanisms Involved in the Etiology of Alzheimer's Disease. The goal of this NOSI is to support innovative

research focused on understanding the molecular and cellular mechanisms underlying the heterogeneity and multifactorial nature of AD, with the potential to create new, or to challenge existing, scientific paradigms. This NOSI encourages individual and/or collaborative research projects that propose innovative approaches to understanding the complex biology of AD to fill critical knowledge gaps or to examine critical areas of AD biology that have not been adequately addressed in the past. Applicants are encouraged to use or develop state-of-the-art research and analytical tools and to integrate the use of human data and biosamples with cell-based and animal models. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.

- NOT-AG-21-042 Notice of Special Interest (NOSI): Deciphering the Glycosylation Code of Alzheimer's Disease. Glycosylation and complex carbohydrates have been reported to play many critical roles in the early pathogenesis and progression of AD, but the potential of these molecules to serve as biomarkers and targets of disease intervention remains largely unexplored. several recently developed technologies now allow one to systematically monitor the change of protein glycosylation and glycans in various biological fluids from a large number of individuals. Therefore, the goal of this Notice of Special Interest (NOSI) is to invite research projects using state-of-the-art methods of protein carbohydrate analyses to understand the potential impact of glycosylation on the etiology of AD and biomarker discovery. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-044 Notice of Special Interest (NOSI): Sensory and Motor System Changes as Predictors of Preclinical Alzheimer's Disease. The purpose of this Notice of Special Interest (NOSI) is to encourage applications that propose either basic, clinical, or a combination of basic and clinical studies that investigate how functional changes in the sensory and/or motor systems impact the development and progression of Alzheimer's disease. This NOSI encourages applications investigating how functional changes in sensory systems (e.g., olfactory, visual, auditory, somatosensory, gustatory) and/or motor systems impact the development and progression of AD. Applications proposing to distinguish the sensory and/or motor changes associated with early AD from those associated with normal aging are also highly encouraged. Studies may include older adults and/or animal models and may employ a variety of approaches—including cellular, molecular, imaging, physiological, and genetic—to address this need. For clinical studies, leveraging of existing longitudinal cohorts already collecting sensory and/or motor assessments is highly encouraged. Studies proposing to establish new cohorts must present a strong justification for why this is needed. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024
- NOT-AG-21-045 Notice of Special Interest (NOSI): Opportunities for Research in Epidemiology of Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD) and Cognitive Resilience. This Notice of Special Interest (NOSI) encourages investigator-initiated research on all aspects of cognitive epidemiology relevant to AD/ADRD and cognitive resilience, but identifies specific areas that build on current efforts supported by NIA as well as gaps and opportunities identified in the 2018 and 2021 Alzheimer's Disease Research Summits. The following areas are of particular interest to the NIA:
  - o Augmenting existing longitudinal cohort studies
  - Enabling precision medicine for AD/ADRD through deep phenotyping
  - o Enhancing the power of multiethnic cohort studies.
  - o Exploring of trends in the risk of AD/ADRD and their explanation via putative risk and protective factors.
  - Collecting and sequencing DNA samples from well-characterized cases and controls.
  - Electronic archiving of cohort studies and linkage to administrative data
  - Harmonizing complex data sets relevant to AD/ADRD
  - Harmonizing dementia assessment, additional data collection, and analysis to enhance cross-national comparisons.

Note that applications proposing exploratory or developmental projects for which there are insufficient preliminary data as well as certain focused secondary analysis projects should consider applying to PAR-22-094 (R21), whereas projects that already have sufficient preliminary data or a very strong and well-developed

scientific premise should apply to <u>PAR-22-093</u> (R01). This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.

- NOT-AG-21-046 Notice of Special Interest (NOSI): Dementia Care Research: Programs and services for persons with dementia. This Notice of Special Interest (NOSI) highlights priority areas of dementia care research other than intervention development. Applications focused solely on unpaid dementia care partners/caregivers may cite NOT-AG-21-047, and applications focused on the paid dementia care workforce may cite NOT-AG-21-049 in the Agency Routing Identifier field (box 4B). PLEASE NOTE: Applications proposing clinical trials will not be considered a high priority for this NOSI. Studies proposing dementia care intervention research are encouraged to explore whether PAR-21-307 Dementia Care and Caregiver Support intervention Research (R01- Clinical Trial Required) or PAR-21-308 Pragmatic Trials for Dementia Care and Caregiver Support (R61/R33 – Clinical Trial Required) would be more appropriate. This NOSI invites applications on high-priority Alzheimer's disease (AD) and AD-related dementias (ADRD) care research areas as set forth by the National Institute on Aging's Division of Behavioral and Social Research. The NOSI is based on expert discussions from the NIH 2020 Dementia Care Summit, the NASEM Decadal Survey of Behavioral and Social Science Research on AD/ADRD, and is aligned with AD/ADRD research implementation milestones. Applications considered high priority should propose research involving secondary data analysis, new data collection and data linkages, and/or measurement development, with an emphasis on variables relevant to persons living with dementia (person-centered perspective), paid care providers, communities, and systems providing care. Applications that solely document descriptive trends without addressing potential mechanisms or explanations will not be considered a high priority, nor will applications that focus solely on caregivers or care partners without considering outcomes for PLWD. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-047 Notice of Special Interest (NOSI): Behavioral and Social Science Priority Areas in Dementia Care Partner/Caregiver Research. This Notice of Special Interest (NOSI) highlights priority areas of dementia care partner/caregiver research other than intervention development. Applications focused on care of persons living with dementia and the systems that provide care may cite NOT-AG-21-046. Applications focused on the paid dementia care workforce may cite NOT-AG-21-049. PLEASE NOTE: Applications proposing clinical trials will not be considered a high priority for this NOSI. Studies that focus on AD/ADRD behavioral intervention research are encouraged to explore whether PAR-21-307, Dementia Care and Caregiver Support intervention Research (R01 Clinical Trial Required) or PAR-21-308, Pragmatic Trials for Dementia Care and Caregiver Support (R61/R33 Clinical Trial Required) would be more appropriate. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-048 Notice of Special Interest (NOSI): Digital Technology for Early Detection and Monitoring of Alzheimer's Disease and Related Dementias. This Notice of Special Interest (NOSI) encourages research on the use of digital technology for early detection and monitoring of cognitive and functional decline in persons with Alzheimer's disease (AD) and AD-related dementias (ADRD). The goal of this NOSI is to facilitate research on the use of digital signals and data as digital phenotyping that may flag or signal early changes within individuals at risk of AD/ADRD before cognitive symptoms are evidenced by current cognitive assessment and/or brain imaging biomarkers. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-049 Notice of Special Interest (NOSI): Dementia Care Workforce for Those Living with Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD). This Notice of Special Interest (NOSI) is intended to promote behavioral and social research on the dementia care workforce and the impact of workforce factors on outcomes for persons living with Alzheimer's disease or Alzheimer's disease-related dementia (AD/ADRD) and their families. Applications focused on care of persons living with dementia and the systems that provide care may cite NOT-AG-21-046, and applications focused solely on unpaid dementia care partners/caregivers may cite NOT-AG-21-047 Studies proposing dementia care intervention research are encouraged to explore whether PAR-21-307 Dementia Care and Caregiver Support intervention Research (R01 Clinical Trial Required) or PAR-21-308 Pragmatic Trials for Dementia Care and Caregiver Support (R61/R33 –

Clinical Trial Required) would be more appropriate. This NOSI is based on expert discussions from the NIH 2018 AD Summit, 2020 Dementia Care and Caregiving Summit, 2019 ADRD Research Summit, and NIA workshops, including Gaps in the Dementia Care Workforce: Research Update and Data Needs (2019). This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.

- NOT-AG-21-050 Notice of Special Interest (NOSI): Sex and Gender Differences in Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD). This NOSI promotes multidisciplinary research to clarify sex and gender differences in the risk, development, progression, diagnosis, and clinical presentation of Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD). Studies that examine sex and gender differences in outcomes (e.g., clinical, functional, well-being) among people living with AD/ADRD as well as AD/ADRD caregiving-related outcomes are also relevant. Broad areas of interest include biological (e.g., hormonal, genetic, metabolic, comorbidity-related), neuroscientific (e.g., neural systems and functions), behavioral (e.g., physical activity, substance use, social engagement), social (e.g., history of maltreatment or adversity, parenthood, marital status, educational attainment, socioeconomic and employment status), psychological (e.g., depression, cognitive functioning, socio-emotional functioning and self-regulation, stress reactivity, personality), healthcare profession (e.g., provider knowledge and attitudes about dementia) and healthcare system-level (e.g., access to care) factors and processes that separately, or together, may drive observed differences by sex and gender and/or may operate differently by sex and gender. Studies that account for methodological and measurement issues that may drive sex and gender differences are also of interest. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-052 Notice of Special Interest (NOSI): Human Cell Biology of Alzheimer's Disease Genetic Variants. Genome-wide association studies (GWAS) and the Alzheimer's Disease Sequencing Project (ADSP) have identified many genetic variants that contribute to the risk of late-onset AD. Determining the function of identified variants, as well as other cellular factors or pathways, that directly contribute to AD is challenginge. Moreover, many AD risk loci are in non-coding intragenic or regulatory regions of the genome, making their role in disease etiology unclear. This suggests that AD risk variants may impact DNA regulatory events, such as epigenetic and chromatin states and transcriptional activity. Direct and targeted approaches are required to identify the cell biological consequences of AD risk genomic variants and other risk or disease-modifying factors or processes to confirm their role in AD. The goal of this Notice of Special Interest (NOSI) is to encourage research that assesses the function of AD genetic variants and other age- and disease-modifying factors contributing to AD using human cell reprogramming (e.g., iPSCs and iNeurons) and genomic editing approaches. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-AG-21-053 Notice of Special Interest (NOSI): Role of Age-Associated Metabolic Changes in Alzheimer's Disease. This Notice of Special Interest (NOSI) is aimed at improving our understanding of how age-associated metabolic changes in peripheral tissues or in the brain affect the onset and/or progression of Alzheimer's disease (AD). The goal of this NOSI is to encourage research projects focused on the impact of changes in metabolism that occur with aging and their possible role in AD onset, pathogenesis, and progression. National Institute on Aging (NIA) views this topic as highly interdisciplinary and encourages researchers who have expertise in metabolic regulation and aging to collaborate with AD researchers in order to identify critical links between metabolic modulation and AD pathogenesis and/or progression. This notice applies to due dates on or after March 11, 2022 and subsequent receipt dates through November 13, 2024.
- NOT-CA-22-029 Notice of Special Interest (NOSI): Disparities Affecting Healthcare Utilization and Health Outcomes Among Childhood Cancer Survivors. The purpose of this Notice is to highlight the interest of the National Cancer Institute (NCI) Division of Cancer Control and Population Sciences (DCCPS) in receiving applications to understand and address the full spectrum of factors that contribute to disparities in survivorship care, healthcare utilization, and health outcomes among childhood cancer survivors. Studies that focus on factors that extend beyond the individual (e.g., survivor, caregiver, clinician) to include an examination or intervention that involves healthcare teams, healthcare system, community, payer, and/or policy-level factors that contribute

to disparities in health outcomes and result in inequitable survivorship care are strongly encouraged. Of specific interest are studies of factors operating at two or more of the following levels: individual, healthcare teams, healthcare system, community, payer, and policy. Investigators are encouraged to discuss their application with the scientific/research contacts listed in this Notice prior to submission. This notice applies to due dates on or after *March 7*, 2022, and subsequent receipt dates through *October 9*, 2024.

- NOT-HG-22-011 Notice of Special Interest: Development and Implementation of Clinical Informatics Tools to Enhance Patients' Use of Genomic Information. The National Human Genome Research Institute (NHGRI) is issuing a Notice of Special Interest (NOSI) to encourage applications to develop and implement patient-facing genomic-based clinical informatics tools that facilitate or enhance patient-provider electronic communication, patient tracking and registry functions, patient self-management and support, provider electronic prescribing, test tracking, referral tracking, and health care decision-making. Applications should describe how approaches will mitigate bias, health disparities, and other factors that threaten the meaningful, equitable, and beneficial use of genomics in patient care. These factors may be tied to the availability, accessibility, quality, use and/or interpretation of data and clinical algorithms, information systems, and health care providers and services. Applications should also describe how they will involve and integrate feedback from future users. This notice applies to due dates on or after February 10, 2022 and subsequent receipt dates through September 24, 2025.
- NOT-NS-22-052 Notice of Special Interest (NOSI): BRAIN Initiative: Translation of Groundbreaking Technologies from Early-stage Development through Early Clinical Study via Blueprint MedTech. This Notice of Special Interest (NOSI) encourages the translation of the novel neurotechnologies, funded through the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative and overseen by the NIH Blueprint MedTech program. Academic and Small Business Concerns (SBCs) are encouraged to submit grant applications that propose non-clinical validation for subsequent clinical feasibility studies. Applications supporting the development and translation of groundbreaking neurotechnologies that fit within the mission of the BRAIN Initiative are encouraged. This NOSI is intended to alert applicants that there is a need to help transition BRAIN Initiative-relevant technologies from early device development to first-in-human studies. Projects that fit the following categories can be submitted through the Blueprint MedTech Program. Applicants are strongly encouraged to consult Program Staff regarding the appropriateness of the planned application to the BRAIN Initiative's mission, scientific areas of interest, and programmatic priorities. This notice applies to due dates on or after February 18, 2022, and subsequent receipt dates through June 20, 2024.

# **Funding Opportunity Announcements (FOA)**

### 1. Lipids in Brain Aging and Alzheimer's Disease (AD) and its Related Dementias (ADRD) (R01 Clinical Trial Not Allowed)

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

Hyperlink: <u>RFA-AG-23-009</u> Type: R

**Application Due Date: June 14, 2022.** Apply by 5:00 PM local time of applicant organization **Funding Opportunity Appouncement**: he goal of this Funding Opportunity Appouncement.

Funding Opportunity Announcement: he goal of this Funding Opportunity Announcement (FOA) is to support research addressing critical knowledge gaps in our understanding of how lipids contribute to vulnerability and resilience to brain aging and Alzheimer's disease (AD) and its related dementias (ADRD), including research addressing how: 1) lipid droplets affect brain aging and AD, including whether their accumulation is pathological or protective; (2) the periphery interacts with lipids in the aging brain, including whether these could be targets for future biomarkers; (3) APOE and lipid-mediated signaling influence brain aging and AD/ADRD progression; and (4) myelin lipids and their signaling contribute to brain aging and AD/ADRD.

**Budget**: NIA intends to commit \$6,400,000 in FY 2023 to fund 8 to 10 awards. Application budgets are limited to \$500,000 in annual direct costs. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

#### 2. Host Immunity and Novel Immunization Strategies for Clostridioides difficile Infection (CDI) (U19 Clinical Trial Not Allowed)

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

Hyperlink: RFA-AI-22-001

Type: U19

**Application Due Date:** May 20, 2022. 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 formation of Cooperative Research Centers (CRCs) to pursue vaccine development through multidisciplinary investigations into the host immune response to *Clostridioides difficile* infection (CDI). To this end, it will be critical to advance knowledge of immunity against CDI by leveraging clinical

samples, identifying new protective antigens, and employing novel vaccine and adjuvant platforms. Information stemming from this research initiative will serve as a guide to develop the next generation of *C. difficile* vaccines to be tested in appropriately devised model systems.

**Budget**: NIAID intends to commit \$3.875 M in FY 2023 to fund 2-3 awards. Application budgets are limited, not to exceed \$1.0 M in direct costs. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

#### 3. U.S. and Low- and Middle-Income Country (LMIC) HIV-Associated Malignancy Research Centers (U54 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date Hyperlink: RFA-CA-22-011 Type: U54

Application Due Date: March 30, 2022. Apply by 5:00 PM local time of applicant organization

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to support research on human immunodeficiency virus (HIV)-associated cancers in low- and middle-income countries (LMICs) through the formation of collaborative partnerships between investigators in United States (U.S.) and investigators in LMICs. The FOA solicits applications for Specialized Center Cooperative Agreements (U54) for research on HIV-associated cancers from research institutions in the U.S. and LMICs. These partnerships are referred to as HIV-Associated Malignancy Research Centers (HAMRCs). Each proposed U54 HAMRC should be based upon partnerships involving at least one U.S. institution and institutions from at least two or more LMICs. Each HAMRC application is required to propose between two and three research projects that address questions in one scientific theme (e.g., viral-associated cancers) that is relevant to HIV-associated malignancies in LMICs or the U.S. The proposed projects may range, as appropriate, from basic research to translational efforts as well as to population and implementation studies. Mechanistic clinical studies that meet NIH's definition of a clinical trial will be allowed. In addition, the proposed U54 HAMRC must include an Administrative Core and a Developmental Core. Each U54 HAMRC will conduct research projects in countries with a significant burden of HIV-associated cancers (e.g., Kaposi sarcoma, cervical cancer, ocular surface squamous neoplasia, lymphoma, and hepatocellular carcinoma). The proposed research projects should focus on increasing our knowledge on risks, pathobiology, and treatment of HIV-associated cancers. These projects are expected to be relevant to specific needs of a given LMIC region and support the development of strategies for prevention, care and/or management of HIV-associated cancers. This initiative will also foster the development of junior investigators from the U.S. and LMICs interested in conducting research on HIV-associated cancers. Each application in response to this FOA must be based on collaborations between researchers working at U.S. institution(s) and researchers working at LMIC institutions. LMICs are countries of per capita income as defined using the World Bank classification system (according to Gross National Income (GNI) per capita as "low-income," "lower-middle-income," and "upper-middle-income" (http://data.worldbank.org/about/countryclassifications/country-and-lending-groups).

**Budget:** The NIH intends to commit \$3,600,000 in FY 2022 to fund 3-4 awards. he number of awards is contingent upon 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 \$800,000 per year in direct costs. Applicants may request project periods of up to 5 years.

# 4. Elucidating the heterogeneity of impaired awareness of hypoglycemia in Type 1 Diabetes (T1D) Clinical Centers (U01 Clinical Trial

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

Application Due Date: March 31, 2022. Apply by 5:00 PM local time of applicant organization

Hyperlink: RFA-DK-21-020 Type: U01

Funding Opportunity Announcement: The purpose of this FOA is to establish a clinical consortium to determine the factors that contribute to the heterogeneity in the restoration of impaired awareness of hypoglycemia (IAH) and improved counter-regulatory responses in adult individuals with Type 1 Diabetes (T1D). Individuals with IAH are often excluded from clinical trials and this omission contributes greatly to a lack of knowledge regarding the clinical characteristics which determine or predict an individual's ability to restore hypoglycemic awareness. New technologies such as continuous glucose monitors (CGM) and closed loop systems (i.e. artificial pancreas) have been shown to reduce hypoglycemic events. However, despite a reduction in hypoglycemic events, restoration of hypoglycemia awareness does not occur in all individuals and the effects on improving the counter-regulatory responses are not known. The goals of the clinical consortium will be to 1) determine if the most up-to-date management strategies using diabetes technology to optimize HbA1c while minimizing hypoglycemia can restore awareness of hypoglycemia and improve counter-regulatory responses in individuals with T1D and IAH; 2) identify the magnitude and duration of time in range (TIR), time spent in hypoglycemia or other CGM metrics that are associated with restoration of awareness of hypoglycemia; and 3) determine the association of current or newly developed self-reported measures of IAH with counter-regulatory responses to elucidate the heterogeneity in restoration of hypoglycemia awareness. It is expected that state of the art metabolic assessments such as hypoglycemic, hyperinsulinemic clamps for the measurement of counter-regulatory responses will be utilized to determine restoration of awareness and validate self-report assessments.

**Budget:** NIDDK intends to commit \$4.72 million in FY 2022 to support this consortium in grant year 1. Future year amounts will depend on appropriations. It is anticipated that awards will be made to 10 Clinical Centers under this FOA and to one Biostatistics Research Center under the companion FOA, RFA-DK-21-036. Application budgets need to reflect the actual needs of the proposed project. Application awards are limited to \$250,000 Direct Costs in grant year 1; \$500,000 Direct Costs in grant year 2; \$600,000 Direct Costs in grant year 3, \$600,000 Direct Costs in grant year 4 and \$500,000 in Direct costs in grant year 5. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

#### 5. Advancing communication strategies to support future HIV vaccine use (R01 Clinical Trial Optional)

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

Hyperlink: <u>RFA-MH-22-170</u> Type: R01

**Application Due Date:** May 10, 2022 Apply by 5:00 PM local time of applicant organization

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) invites applications for Research Project Grants (R01) that will advance novel health communication research designed to inform and support acceptance and uptake of future vaccines that protect against HIV. Research should focus on understanding key drivers for HIV vaccine communication success, communication strategies for engagement of communities placed at greatest risk for acquiring HIV, and/or mitigating the impact and reach of HIV vaccine misinformation.

Research applications may leverage HIV vaccine analogs (e.g., COVID-19, HPV, HBV vaccines), so long as they have a primary focus on populations placed at risk for HIV, and/or healthcare settings and providers involved in HIV prevention delivery. This FOA uses the R01 grant mechanism, while RFA-MH-22-171 uses the R21 mechanism. Applications with preliminary data and/or those including longitudinal analysis, advanced modeling, or large-scale clinical trials should consider using the R01 mechanism. Applicants proposing to conduct exploratory, novel studies that break new ground, extend previous discoveries in new directions or result in novel techniques, models or applications should consider the R21 mechanism.

**Budget:** NIMH intends to commit an estimated total of \$2,000,000 in FY 2023 to fund 3-5 awards in response to this FOA and the companion (RFA-MH-22-171). NIDA intends to commit an estimated total of \$1,000,000 in FY 2023 to fund 2-3 awards in response to this FOA and the companion (RFA-MH-22-171). 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.

#### 6. HEAL Initiative: Discovery and Validation of Novel Targets for Safe and Effective Pain Treatment (R01 Clinical Trial Not Allowed)

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

Hyperlink: RFA-NS-22-034 Type: R01

Application Due Date: March 02, 2022 to December 06, 2024. Apply by 5:00 PM local time of applicant organization

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to promote the discovery and validation of novel therapeutic targets to facilitate the development of pain therapeutics. Specifically, the focus of this FOA is on the basic science discovery of targets in the peripheral nervous system, central nervous system, immune system or other tissues in the body that can be used to develop treatments that have minimal side effects and little to no abuse/addiction liability. Research supported by this FOA must include rigorous validation studies to demonstrate the robustness of the target as a pain treatment target. This will lower the risk of adopting the target in translational projects to develop small molecules, biologics, natural substances, or devices that interact with this target for new pain treatments. Translational research to develop new medical devices is not the focus of this FOA. Basic science studies of pain and related systems in the body are responsive to this FOA and are encouraged in the context of novel pain therapeutic target discovery. This FOA is not specific for any one or group of pain conditions. Projects to identify novel targets for acute pain, chronic pain, migraine, other headache disorders, osteoarthritis, diabetic neuropathy, chemotherapy-induced neuropathy, sickle-cell pain, post stroke pain, orofacial pain, etc. will be considered. Projects to identify novel targets in specific populations such as women, children, older adults or other underrepresented groups will also be responsive to this FOA.

**Budget**: Issuing IC and partner components intend to issue 8-10 awards in 2022. Awards issued under this FOA are part of funds set aside to support the HEAL (Helping to End Addiction Long-term) initiative. Application budgets are not limited but need to reflect the actual needs of the proposed project. Total project duration of no more than 5 years.

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