NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 12 Jul 2022 (#27)

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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** or **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 • 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-HD-22-026 Notice of Special Interest (NOSI): Advancing Research on Early Pregnancy Loss. Early Pregnancy loss (EPL), defined as a pregnancy loss occurring up to 20 weeks gestation, is a very common pregnancy complication, occurring in 12-15% of clinically recognized pregnancies, with increased prevalence associated with increasing maternal age. The use of highly sensitive hCG assays allows the detection of pregnancy earlier in gestation than the time of clinical recognition, and gives an even higher estimated loss of 50-70% of conceptions prior to the second trimester. To achieve a successful pregnancy, a series of strict embryonic and maternal conditions must be met, that include high quality embryos, favorable conditions for embryo implantation, receptive maternal endometrium and optimal uterine environment to sustain the conceptus to term. In addition, maternal immune tolerance and hormonal factors play a critical role. While approximately half of all cases of EPL appear to be due to embryonic aneuploidy, very little is known about the physiologic and pathophysiologic processes that underlie non-aneuploid EPL. As a result, there is also a lack of understanding for the underlying causes of recurrent pregnancy loss (RPL). This NOSI seeks to address these critical knowledge gaps by encouraging basic, translational and clinical studies on biological processes that may uncover potential etiologies of EPL and RPL. This includes research to understand implantation mechanistically and identify a range of key factors, involved in implantation and placentation that are important for early pregnancy establishment, including abnormalities that contribute to sporadic EPL and recurrent pregnancy loss. **Prohibition on Research Iinvolving Human Embryos.** The major gaps that this NOSI targets include, but are not limited to the following

- Discovering novel contributing factors that disturb embryo implantation, placenta development, endometrial receptivity and decidualization that lead to EPL, as well as the mechanisms that govern these processes
- Investigation into maternal- and paternal-derived factors in gametes that may be responsible for EPL
- Errors in epigenetic reprogramming in gametes and preimplantation embryo and early pregnancy loss
- Studies of immunological disorders (e.g., inflammatory cytokines, NK cell dysfunction) that contribute to EPL
- Uncovering male factor contribution and underlying mechanisms that lead to EPL

- Development of new model systems that allow mechanistic investigation
- Studies of nutrition factor contribution to EPL (e.g., over- or under- nutrition and vitamin/protein factors)
- Studies of dynamic communication between endometrium and embryo

Of Special Interest: Studies that explore immune system interactions between endometrium and placenta or embryo Model systems that allow mechanistic investigation of multi-component interactions – e.g., organoids and organs on a chip. Studies focused on the following topics will be given low priority unless there is a clear demonstration that they provide special advantages (diagnostics, risk prediction) over current approaches.

- Genomic abnormalities, such as aneuploidy, and genetic determinants
- Maternal Infections
- Uterine structure anomalies, such as adenomyosis, intrauterine adhesions and fibroid

This notice applies to due dates on or after September 8, 2022 and subsequent receipt dates through September 8, 2025

NOT-HL-22-035 Notice of NHLBI Participation in PAR-22-132 "Implementation Research to Reduce Noncommunicable Disease (NCD) Burden in Low-and Middle-Income Countries and Tribal Nations During Critical Life Stages and Key Transition Periods (R01 Clinical Trial Optional)". The purpose of this Notice is to inform potential applicants that the National Heart, Lung, and Blood Institute (NHLBI) is participating, effective immediately. NIH IC-Specific Priorities Potential applicants are strongly encouraged to contact NIH IC program staff. ***The National Heart, Lung, and Blood Institute encourages innovative implementation research that is within scope of NHLBI's Strategic Vision, and aligns with in-country national heart, lung, blood, and sleep (HLBS)-related non-communicable disease programs and policies for national population impact.***

NOT-MH-22-235 Notice of Information: High Priority Countries for the Center for Global Mental Health Research. In accordance with our mission, the Center for Global Mental Health Research (CGMHR) at the National Institute of Mental Health (NIMH) is issuing this notice to inform the extramural research community that the CGMHR will prioritize applications with foreign components where research will take place in low- and middle-income countries (LMICs). This prioritization will apply to investigator-initiated research applications. This notice applies to applications submitted on or after January 1, 2023.

NOT-MH-22-245 Notice of Information on High Priority Research Areas for Sex and Gender Influences on the Adolescent Brain and Mental Health of Girls and Young Women (Ages 12-24). The purpose of this Notice is to outline NIMH priorities for potential applications in the field of women's mental health research, specifically during the adolescent and young adult periods. The NIMH encourages research projects that examine biological, social, cultural, and behavioral contributions of sex and gender influences on mental illnesses (e.g., anxiety, depression, psychosis, schizophrenia, bipolar disorder, trauma-related disorders, eating disorders, etc.) autism spectrum disorder and suicide in adolescent girls and young women. Research is needed to identify biomarkers and behavioral indicators that predict risk trajectories of mental illness. Additionally, translational research is needed that applies recent basic research discoveries (e.g., brain-derived neurotrophic factor, gene-environment interactions) and identifies opportunities to advance clinical research and mental health services research. Prevention and intervention projects that consider the impact of biological as well as social, cultural, and gender-based target mechanisms on mental health outcomes are also encouraged. Investigators planning to submit an application are strongly encouraged to discuss their proposed research with the scientific contact listed in this notice well in advance of the application due date.

NOT-MH-22-265 Notice of Intent to Publish a Funding Opportunity Announcement for BRAIN Initiative: Engineering and optimization of molecular technologies for functional dissection of neural circuits (UM1 Clinical Trial Not Allowed). The National Institute of Mental Health (NIMH), along with the NIH Institutes and Centers participating in the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, intends to issue a Funding Opportunity Announcement (FOA) to support the creation of Centers for accelerated engineering and optimization of high-impact, molecular technologies to monitor and/or manipulate brain cell activity in experimental animals. The Centers will produce high-impact molecular probes such as, but not limited to, fluorescent protein indicators of neuronal state variables (e.g., intracellular calcium, membrane voltage, released neurotransmitters/neuromodulators, etc.), molecular integrators of neural activity, optogenetic, chemogenetic, sonogenetic, magnetogenetic actuators, and activity-dependent molecular switches. The Centers will be part of the BRAIN Initiative Armamentarium project, whose goal is to generate tools to specifically access, manipulate, and monitor brain cell types across multiple species. Technology optimization is sought for existing tools for brain cell monitoring or manipulation that are beyond the proof-of-concept stage and that can be delivered selectively as payloads to cell types using newly developed brain cell access reagents. This Notice is being provided to allow potential applicants sufficient time to develop the appropriate

collaborations for responsive projects. The FOA is expected to be published in December 2022 with an expected application due date in June 2023 and the earliest start date in April 2024. The FOA will use the UM1 activity code (cooperative agreement). Details of the planned FOA are provided in the notice.

NOT-OD-22-169 Notice of Intent to Publish a Funding Opportunity Announcement for Environmental influences on Child Health Outcomes (ECHO) Measurement Core (U24) Clinical Trial Not Allowed. The Environmental influences on Child Health Outcomes (ECHO) Program Office intends to publish a funding opportunity announcement (FOA) inviting applications for a Measurement Core to support a consortium of ECHO Cohort Study Sites to extend and expand the capacity of the ECHO Cohort to further investigate the roles of a broad range of early exposures from society to biology, including the preconception period, on ECHO's five key child health outcome areas—pre-, peri- and postnatal, upper and lower airways, obesity, neurodevelopment, and positive health—among diverse populations. The objectives of the intended Measurement Core will be to

- Develop and refine measures for the ECHO Cohort Protocol, including methods to implement the measures
- Assist all ECHO Cohort Study Sites, Cores, and Centers in implementing and evaluating the ECHO Cohort Protocol, which comprises standardized measures at specified study visits
- Lead strategic decision-making to incorporate new and revised measures to advance ECHO Cohort science while moderating participant and staff burden

This Notice is intended to allow applicants additional time to begin making arrangements to develop responsive applications. The NIH ECHO Program Office expects to publish the FOA in August 2022.This FOA will utilize the U24 activity code. Details of the planned FOA are provided in the notice.

NOT-OD-22-170 Notice of Intent to Publish a Funding Opportunity Announcement for Environmental influences on Child Health Outcomes (ECHO) Laboratory Core (U24) Clinical Trial Not Allowed. The Environmental influences on Child Health Outcomes (ECHO) Program Office intends to publish a funding opportunity announcement (FOA) inviting applications for a Laboratory Core to support a consortium of ECHO Cohort Study Sites to extend and expand the capacity of the ECHO Cohort to further investigate the roles of a broad range of early exposures from society to biology, including the preconception period, on ECHO's five key child health outcome areas—pre-, peri- and postnatal, upper and lower airways, obesity, neurodevelopment, and positive health—among diverse populations.
The objectives of the intended Laboratory Core will be to

1. Facilitate ECHO Cohort biospecimen collection and processing
2. Manage the ECHO Cohort Biorepository
3. Perform or facilitate a wide range of biospecimen assays to support ECHO Cohort analyses
4. Coordinate biospecimen information and assay results

This Notice is intended to allow applicants additional time to begin making arrangements to develop responsive applications. The NIH ECHO Program Office expects to publish the FOA in August 2022. This FOA will utilize the U24 activity code. Details of the planned FOA are provided in the notice.

NOT-OD-22-171 Notice of Intent to Publish a Funding Opportunity Announcement for Open Competition: Environmental influences on Child Health Outcomes (ECHO) Pregnancy Cohort Study Sites. Clinical Trial Not Allowed (UG3/UH3). The Environmental influences on Child Health Outcomes (ECHO) Program Office intends to publish a funding opportunity announcement (FOA) inviting applications for new ECHO Cohort Study Sites to extend and expand the capacity of the ECHO Cohort to further investigate the roles of a broad range of early exposures from society to biology, including the preconception period, on ECHO's five key child health outcome areas—pre-, peri- and postnatal, upper and lower airways, obesity, neurodevelopment, and positive health—among diverse populations.
The objectives of the intended Pregnancy Cohort Study Sites will be to

1. Lead collaborative ECHO Cohort science
2. Recruit new pregnant participants from diverse populations, their resulting offspring, and, if available, the conceiving partner
3. Develop and implement an ECHO Cohort preconception pilot study
4. Implement the ECHO Cohort Data and Biospecimen Collection Protocol using the ECHO Cohort consortium's central data capture system, e.g., REDCap Central

The FOA will not support site-specific analyses and science.
This Notice is intended to allow study teams other than existing ECHO UH3 Pediatric Cohort awardees or subrecipients during the current phase of the ECHO Cohort consortium (2016-2022) additional time to begin making arrangements to develop responsive applications. The NIH ECHO Program Office expects to publish the FOA in August 2022. This FOA will utilize the UG3/UH3activity code. Details of the planned FOA are provided in the notice.

NOT-OD-22-173 Notice of Intent to Publish a Funding Opportunity Announcement for Environmental influences on Child Health Outcomes (ECHO) Data Analysis Center (U24) Clinical Trial Not Allowed. The Environmental influences on Child Health Outcomes (ECHO) Program Office intends to publish a funding opportunity announcement (FOA) inviting applications for a Data Analysis Center to support a consortium of ECHO Cohort Study Sites to extend and expand the capacity of the ECHO Cohort to further investigate the roles of a broad range of early exposures from society to biology, including the preconception period, on ECHO's five key child health outcome areas—pre-, peri- and postnatal, upper and lower airways, obesity, neurodevelopment, and positive health—among diverse populations. The objectives of the intended Data Analysis Center will be to

- Lead, standardize, and integrate ECHO Cohort Protocol data capture, management, and storage through a central data system
- Provide analytic support and expertise to analysis proposals approved by the ECHO Cohort consortium
- Enrich research infrastructure and data science to facilitate broader sharing of ECHO Cohort data and resources with the scientific community

This Notice is intended to allow applicants additional time to begin making arrangements to develop responsive applications. The NIH ECHO Program Office expects to publish the FOA in August 2022. This FOA will utilize the U24 activity code. Details of the planned FOA are provided in the notice.

NOT-OD-22-174 Notice of Intent to Publish a Funding Opportunity Announcement for Limited Competition: Environmental influences on Child Health Outcomes (ECHO) Pregnancy and Pediatric Cohort Study Sites. Clinical Trial Not Allowed (UG3/UH3). The Environmental influences on Child Health Outcomes (ECHO) Program Office intends to publish a funding opportunity announcement (FOA) inviting applications to renew current ECHO Cohort Study Sites to extend and expand the capacity of the ECHO Cohort to further investigate the roles of a broad range of early exposures from society to biology, including the preconception period, on ECHO's five key child health outcome areas—pre-, peri- and postnatal, upper and lower airways, obesity, neurodevelopment, and positive health—among diverse populations. The objectives of the intended Pregnancy and Pediatric Cohort Study Sites will be to

- Lead collaborative ECHO Cohort science
- Follow up existing ECHO Cohort participants
- Recruit new pregnant participants from diverse populations, their resulting offspring, and, if available, the conceiving partner
- Develop and implement an ECHO Cohort preconception pilot study
- Implement the ECHO Cohort Data and Biospecimen Collection Protocol using the ECHO Cohort consortium's central data capture system, e.g., REDCap Central

The FOA will not support site-specific analyses and science.
This Notice is intended to allow existing ECHO UH3 Pediatric Cohort awardees or subrecipients that recruited pregnant participants during the current phase of the ECHO Cohort consortium (2016-2022) additional time to begin making arrangements to develop responsive applications. The NIH ECHO Program Office expects to publish the FOA in August 2022. This FOA will utilize the UG3/UH3 activity code. Details of the planned FOA are provided in the notice.

NOT-OD-22-175 Notice of Intent to Publish a Funding Opportunity Announcement for Limited Competition: Environmental influences on Child Health Outcomes (ECHO) Cohort Study Sites for Pediatric Follow Up. Clinical Trial Not Allowed (UG3/UH3). The Environmental influences on Child Health Outcomes (ECHO) Program Office intends to publish a funding opportunity announcement (FOA) inviting applications to renew current ECHO Cohort Study Sites to extend and expand the capacity of the ECHO Cohort to further investigate the roles of a broad range of early exposures from society to biology, including the preconception period, on ECHO's five key child health outcome areas—pre-, peri- and postnatal, upper and lower airways, obesity, neurodevelopment, and positive health—among diverse populations. The objectives of the intended Pediatric Cohort Study Sites will be to

- Lead collaborative ECHO Cohort science
- Follow up existing ECHO Cohort participants
- Implement the ECHO Cohort Data and Biospecimen Collection Protocol using the ECHO Cohort consortium's central data capture system, e.g., REDCap Central

The FOA will not support site-specific analyses and science. This Notice is intended to allow existing ECHO UH3 Pediatric Cohort awardees or subrecipients during the current phase of the ECHO Cohort consortium (2016-2022) additional time to begin making arrangements to develop responsive applications. The NIH ECHO Program Office expects to publish the FOA in August 2022. This FOA will utilize the UG3/UH3 activity code. Details of the planned FOA are provided in the notice.

Notice of Special Interest (NOSI)

NOT-AG-22-025 Notice of Special Interest: Alzheimer's-Focused Administrative Supplements for NIH Grants that are Not Focused on Alzheimer's Disease. The participating Institutes and Centers (ICs) are inviting applications to expand existing awards that are not currently focused on Alzheimer's disease and its related dementias (AD/ADRD)—frontotemporal dementia, Lewy body dementia, Vascular Contributions to Cognitive Impairment and Dementia (VCID), and multiple etiology dementias—to allow the research to develop such a focus. Active awards with project end dates in FY 2024 or later are eligible. The award may not be in a terminal no-cost extension or going into a no-cost extension in FY 2023. Please note that a few ICs limit no-cost extensions in the final non-competing year of an award. For that reason, it is important to contact staff at the IC supporting the award when planning the request. The participating Institutes and Centers (ICs) are inviting applications to expand existing awards that are not currently focused on Alzheimer's disease and its related dementias (AD/ADRD)—frontotemporal dementia, Lewy body dementia, Vascular Contributions to Cognitive Impairment and Dementia (VCID), and multiple etiology dementias—to allow the research to develop such a focus. Active awards with project end dates in FY 2024 or later are eligible. The award may not be in a terminal no-cost extension or going into a no-cost extension in FY 2023. Please note that a few ICs limit no-cost extensions in the final non-competing year of an award. For that reason, it is important to contact staff at the IC supporting the award when planning the request. Awards that currently focus on research on Alzheimer's disease or its related dementias are not eligible for this program. If an investigator is uncertain whether the project does carry an Alzheimer's focus as defined by NIH, then the investigator may contact the appropriate program officer who can check that status. (For example, the parent award may be focusing on cognitive change due to chemotherapy in cancer patients. Each IC will conduct administrative reviews of applications from their IC separately. NIA will make funds available to each of the participating ICs, provided that sufficient funds are available.

Criteria:

1. Is the work proposed within the scope of the active award?
2. Is the work proposed focused on Alzheimer's disease or its related dementias?
3. Is the work likely to stimulate additional activity leading to progress on any, or all, of these dementias?

Application Due Date is October 1, 2022 by 5:00 PM local time of applicant organization.

NOT-HL-22-030 Notice of Special Interest (NOSI): Studies of Cellular/Molecular Pathobiological Mechanisms of Lung Diseases Using Human 3-Dimensional Cellular Systems (R01). The purpose of this NOSI is to promote research characterizing the pathobiological processes and mechanisms that drive the onset and progression of lung diseases at a molecular/cellular level, providing a systems-level understanding by studying experimental systems with cellular heterogeneity and 3-D architecture. It is expected that projects supported by this NOSI will utilize ex vivo preparations (e.g., thin human lung slices) or 3-D multi-cellular in vitro systems (e.g., organoids) of human lung cells and will employ state-of-art multi-omics measures (e.g., spatial or single cell/nucleus omics) to better understand specific pathobiological processes in systems of interacting cell types. This notice applies to due dates on or after September 25, 2022 and subsequent receipt dates through September 7, 2025. Submit applications for this initiative using one of the following funding opportunity announcements (FOAs) or any reissues of these announcement through the expiration date of this notice.

- PA-20-185- NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- PA-20-183 - NIH Research Project Grant (Parent R01 Clinical Trial Required)

NHLBI will accept **only mechanistic studies** that meet the NIH definition of a clinical trial (see NOT-HL-19-690) in response to PA-20-183 - NIH Research Project Grant (Parent R01 Clinical Trial Required) and its reissues. For additional information, please see the *NHLBI Policy Regarding Submission of Clinical Trial Applications (*Notice NOT-HL-18-611) to identify the most appropriate FOA.

NOT-OD-22-167 Notice of Special Interest (NOSI): Research on Addressing Violence to Improve Health Outcomes. The purpose of this Notice is to highlight interest in addressing the role of violence in health outcomes and integrating violence-related screening and interventions into health care settings. This Notice is to encourage intervention research focused on addressing exposure to violence - including but not limited to child maltreatment, intimate partner violence/teen dating violence, elder mistreatment, peer violence/bullying, and community violence – to improve individual-level health processes and outcomes. Applicants must select the IC and associated FOA to use for submission of an application in response to this NOSI. The selection must align with the IC requirements listed in order to be considered responsive to that FOA. Non-responsive applications will be withdrawn from consideration for this initiative.

Funding Opportunity Announcements (FOA)

1. HEAL Initiative: Rapidly Assessing the Public Health Impact of Emerging Opioid Threats (UG1 - Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DA-23-045** **Type: UG1**

Application Due Date: February 02, 2023. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The goal of this funding opportunity announcement (FOA) is to seeks research to promote rapid development of analytical methods and tools to assess the prevalence of emerging illicit drugs and thereby understand their health impacts. By promoting research to develop peer-reviewed analytical and point of care assays for new drugs and metabolites, NIH intends that awardees can greatly reduce the cost of validated assay implementation and ensure the methods become standards at "sentinel" labs and clinical sites that employ them. Importantly, the initiative design builds in the flexibility to modify the target analytes over time to allow a rapid responses to changing opioid threat conditions

Budget: NIDA intends to commit $2.5Million in FY 2023 to fund 3-5 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

2. Impact of the Microbiome-Gut-Brain Axis on Alzheimer's Disease and Alzheimer's Disease-Related Dementias (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-22-211** **Type: R01**

Application Due Date: October 05, 2022. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) invites applications for basic and translational research on the impact of the microbiome on Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD). While there is growing evidence that the microbiome is an important factor that contributes to overall health and a variety of diseases and disorders, the role of the alimentary canaland other sources of endogenous microbiota in specific AD/ADRDs has not been adequately addressed. This FOA will support mechanistic research focused on a more rigorous in-depth examination of the potential interactions between the microbiome and genetic and non-genetic molecular targets that influence AD/ADRD. It is expected that these studies will address the clinical relevance of the microbiome on disease initiation, progression, or modification, and will lead ultimately to better therapeutic interventions.

Budget: NINDS and NIA intend to commit an estimated total of $3,750,000 per year to fund 5 awards. Application budgets are limited to $500,000 in direct costs per year and need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

3. Building in vivo Preclinical Assays of Circuit Engagement for Application in Therapeutic Development (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-22-170** **Type: R01**

Application Due Date: October 05, 2022 though to July 05, 2025. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The goal of this Funding Opportunity Announcement (FOA) is to identify, in animals, in vivo neurophysiological and behavioral measures for use as assays in the early screening phase of treatment development. This FOA will support efforts to optimize and evaluate measures of neurophysiological and behavioral processes that may serve as pharmacokinetic/pharmacodynamic (PK/PD) markers of neural processes of clinical interest based on available knowledge of the neurobiology of mental illnesses. The screening assays developed from this FOA are expected to build upon systems neurobiology and clinical neuroscience to enhance the scientific value of preclinical animal data contributing to a therapeutic development pipeline in which treatment candidates and therapeutic targets can be evaluated for their ability to impact neurobiological mechanisms of potential clinical relevance to mental illnesses. The objectives of this FOA will be accomplished by supporting basic neuroscience aimed at improving the efficiency and scientific value of the therapeutic development pipeline by advancing the discovery of in vivo physiological and behavioral measures reflecting circuit engagement as tools for early phase target validation and therapeutic screening for mental illness treatment development. The efforts supported by this initiative focus on measures in animals as a first step in generating translational assay measures that are adaptable across early therapeutic screens in animals to evaluation in humans. The FOA may be considered a prequel to build a suite of assays that are evaluated in future projects for coherence of assay performance between the preclinical species and healthy humans. In summary, this FOA will support efforts to improve the tool kit of assays available for early phase testing of novel therapeutic agents by incorporating measures proximal to neural systems that impact mental health.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. It is expected that budgets of $250,000 direct costs per year or less will be adequate for most projects proposing to optimize just one measure. The scope of the proposed project should determine the project period. The maximum period is 5 years.

4. Novel Assays to Address Translational Gaps in Treatment Development (UG3/UH3 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-22-169** **Type:**

Application Due Date: October 21, 2022 through to June 20, 2025. Apply by 5:00 PM local time of applicant organization.

Funding Opportunity Announcement: The goal of this initiative is to identify neurophysiological measures as potential assays for treatment development research. The Funding Opportunity Announcement (FOA) will support efforts to optimize and evaluate pharmacodynamic (PD) measures of neurophysiological processes that are disrupted within or across mental disorders in both healthy humans and in another species relevant to the therapeutic development pipeline. The initiative will support initial proof of concept studies aimed at identifying measures for potential development as preclinical assays for evaluating potential new drug and device therapies and their targets. Data may also reveal assay measures where performance is dissimilar between preclinical animal species and humans, thus establishing a firm basis for limiting speculative

extrapolations of preclinical animal findings to humans. The ultimate goal of this FOA is to improve the efficiency of the therapeutic development process by identifying congruent measures as well as inconsistencies between the preclinical screening pipeline and clinical evaluation of new treatment candidates. The objectives of the FOA will be accomplished by supporting partnerships among basic and translational neuroscientists who are committed to advancing the discovery of *in vivo* physiological measures as tools for target validation and therapeutic development. Groups will be tasked with developing and optimizing *in vivo* assays of brain processes in both animals and in healthy humans. Groups will evaluate assay performance across both species in response to pharmacologic manipulations. In this way, projects will reveal the potential of specific assays to translate from animals to humans, suggesting assays for further development as tools in the treatment development pipeline.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The UG3 period may be 1 to 3 years, the UH3 period may not exceed 3 years. The total duration of the UG3 and UH3 phases may not exceed 5 years.

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