

NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 16 Jan 2023 (#03)

Confirm your intent to apply ASAP, but not later than **60 days** before the submission date. Tygerberg Campus: <u>cdevries@sun.ac.za</u> • Stellenbosch Campus <u>lizelk@sun.ac.za</u>

To prepare an application can take 4-18 months, depending on many factors:

- 1. Mechanism for which you will apply e.g. U54, R01, D43, K43
- 2. Requirement of preliminary data
- 3. Time to assemble the research team
- 4. Time available to work on the grant, taking into consideration other responsibilities
- 5. Time for internal review

Important Notices

<u>Gearing Up for Transition to FORMS-H Application Forms</u>: As <u>announced</u> over the summer, NIH requires the use of updated application forms (FORMS-H) for due dates **on or after January 25, 2023**. The <u>How to Apply – Application</u> <u>Guide</u> was updated on October 25 with FORMS-H application form instructions to prepare for the transition. Also see **Guide Notice** <u>NOT-OD-23-012</u>. All form changes are listed in <u>High-level Grant Application Form Change Summary</u>: <u>FORMS-H</u>.

- A key change in FORMS-H is support for the implementation of the 2023 <u>NIH Data Management and Sharing</u> <u>Policy</u>. NIH expects applicants to submit a plan for how they will manage and share their data and allows applicants to include certain costs associated with data management and sharing in their budget.
 - Writing a Data Management & Sharing Plan. Learn what NIH expects Data Management & Sharing plans to address.
 - **Budgeting for Data Management & Sharing.** Find out what data sharing related costs may be requested in an application for funding.
 - o Sample DMS Plans to get you started

Data Management and Sharing Policy does apply to all research and career development grants but not apply to training grants. Make sure you do **not** include hypertext (e.g., hyperlinks and URLs) in the DMS Plan attachment. The <u>hyperlink policy</u> applies to DMS Plans as well, and NIH may withdraw your application from consideration if you include them. Don't risk it!

<u>NOT-TW-23-001</u> Notice of Information to Expire the PAR-21-311, Global Brain and Nervous System Disorders Research Across the Lifespan (R01 Clinical Trials Optional). Current Expiration Date: December 12, 2023. New Expiration Date: January 10, 2023. Applicants with research interests relevant to this topic and within FIC's mission areas are encouraged to submit an application through <u>PAR-22-097</u>, Global Brain and Nervous System Disorders Research Across the Lifespan (R01 Clinical Trials Optional), whose next application due date is November 15, 2023.

<u>NOT-TW-23-002</u> Notice of Information to Expire PAR-21-319, Global Brain and Nervous System Disorders Research Across the Lifespan (R21 Clinical Trials Optional). Current Expiration Date: December 12, 2023. New Expiration Date: January 10, 2023. Applicants with research interests relevant to this topic and within FIC's mission areas are encouraged to submit an application through <u>PAR-22-098</u>, Global Brain and Nervous System Disorders Research Across the Lifespan (R21 Clinical Trials Optional), whose next application due date is November 15, 2023.

NOT-DA-23-014 Notice of Intent to Publish a Funding Opportunity Announcement for Exploratory Clinical Neuroscience Research on Substance Use Disorders (R61/R33 Clinical Trial Optional). The National Institute on Drug Abuse intends to re-issue the Funding Opportunity Announcement (FOA) <u>PAR-19-282</u>, "Exploratory Clinical Neuroscience Research on Substance Use Disorders (R61/R33 Clinical Trial Optional)". This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects. First Estimated Application Due Date: November 05, 2023. Support will be provided for up to 5 years, which will include initial support of up to 2 years of the R61 phase, followed by up to 3 years of support for the R33 phase, upon successfully meeting R61 milestones. Preliminary data will not be required; however, applicants may include preliminary data if they are available.

Notices of Special Interest (NOSI)

<u>NOT-CA-23-030</u> Adaptive Biomaterials for Cancer Biology. The purpose of this Notice of Special Interest (NOSI) is to promote research focused on the development, adaptation, or integration of innovative biomaterials for cancer biology. The applications of these new materials are expected to enable new insights into basic cancer research. This notice applies to due dates on or after February 5, 2023, and subsequent receipt dates through May 7, 2025.

NOT-CA-23-036 Administrative Supplement to Support Global Cancer Stigma Research. NOSI informs current awardees that the National Cancer Institute (NCI) is providing an opportunity for supplemental funding to support exploratory research studies to expand the current understanding of cancer stigma (as defined below), assess its impact on cancer control and prevention, and develop stigma-reduction interventions to improve cancer outcomes in low- and middle-income countries (LMICs). *Effective immediately, this NOSI replaces <u>NOT-CA-23-025</u>, Notice of Special Interest (NOSI): Administrative Supplement to Support Global Cancer Stigma Research. The goals of these administrative supplements focused on global cancer stigma research are to: 1) elucidate the etiology and perpetuation of cancer stigma; 2) measure the impact of cancer stigma on physical and mental well-being and associated health behaviors of patients; 3) identify mechanisms and pathways by which stigma is a barrier to cancer prevention, treatment, palliation, and survivorship; and 4) develop interventions to reduce cancer stigma and improve cancer outcomes. Permitted for 1 year of support only; the earliest anticipated start date is September 1, 2023. The budget should not exceed \$125,000 in direct costs for the entire allowable 1-year project period of the application/award.*

NOT-DA-22-048 Targeting the Endocannabinoid System for Brain Health and Acute and Chronic Diseases. NOSI encourages studies of the endocannabinoid system (ECS) and its roles in brain health and acute and chronic disease, substance use, and substance use disorder (SUD). The desired outcomes of research will be a mechanistic understanding of how cannabinoids and manipulation of the ECS can elicit both therapeutic and deleterious effects as well as the role of cannabinoids and ECS in symptom management. This notice applies to due dates on or after February 5, 2023 and subsequent receipt dates through January 8, 2026.

<u>NOT-HL-22-039</u> Administrative Supplements to Support Programs for Inclusion and Diversity Among Individuals Engaged in Health-Related Research (PRIDE) Small Research Projects. This Notice invites applications for administrative supplements to <u>existing</u> PRIDE Summer Institute (SI) programs to support program mentees in carrying out Small Research Projects (SRPs). Briefly, mentees in an active cohort will be eligible to be supported by their host PRIDE SI to conduct SRPs during or immediately following their first SI. These pilot studies are intended to be conducted over 9-12 months in the interim between the first and second SIs with guidance from SI and institutional mentors. Updates on projects are expected to be provided at the mid-year SI meetings, the consortium-wide PRIDE Annual Meetings, and/or during the mentee's second SI.

Funding Opportunity Announcements (FOA)

1. Formative and Pilot Intervention Research to Optimize HIV Prevention and Care Continuum Outcomes (R34 Clinical Trial Optional)

 Letter of Intent: 30 days prior to the application due date
 Hyperlink: PAR-23-060

Type: R34

Application Due Date: May 09, 2023 through to January 09, 2026. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Funding Opportunity Announcement: The NIMH invites applications for Research Project Grants (R34) that propose formative research, intervention development, and pilot-testing of interventions; formative implementation research to inform adaptation of evidence-based interventions; or development or selection of implementation strategies. Primary scientific areas of focus include the feasibility, acceptability, and safety of novel or adapted interventions that target HIV prevention or treatment, or implementation outcomes using implementation science approaches. For the purposes of this FOA, "intervention" is defined to include behavioral, social, or structural approaches, as well as combination biomedical and behavioral, social, or structural approaches that improve HIV prevention or treatment outcomes. Applications should be aligned with NIMH Division of AIDS Research (DAR) priorities. Applicants are encouraged to read current Notice of Special Interest (NOSIs) from NIMH Division of AIDS Research (DAR) for further information about the Division's research priorities (NIMH DAR; <u>https://www.nimh.nih.gov/about/organization/dar/aids-related-funding-opportunity-announcements-foas</u>), and the NIH Strategic Plan for HIV and HIV-Related Research by NIH Office of AIDS Research (NIH OAR; <u>https://www.oar.nih.gov/hiv-policy-and-research/strategic-plan</u>). This FOA, PAR-23-060, uses the R34 grant mechanism to provide support for the initial development and pilot testing of a clinical trial or

formative implementation research. Applications with preliminary data and/or those including longitudinal analysis, advanced modeling, or large-scale clinical trials or implementation science approaches should consider using the companion R01 mechanism, <u>PAR-23-062</u>. 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 (<u>PAR-23-061</u>).

Budget: Direct costs are limited to \$225,000 per year and \$450,000 over the 3-year project period. The total project period for an application submitted in response to this funding opportunity may not exceed three years.

2. Innovations to Optimize HIV Prevention and Care Continuum Outcomes (R21 Clinical Trial Optional)

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

Hyperlink: <u>PAR-23-061</u>

Type: R21

Application Due Date: May 09, 2023 through to January 09, 2026. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Budget: The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year. The total project period may not exceed 2 years.

3. Innovations to Optimize HIV Prevention and Care Continuum Outcomes (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due dateHyperlink: PAR-23-062Type: R01Application Due Date: May 09, 2023 through January 09, 2026. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Funding Opportunity Announcement: The NIMH invites applications for Research Project Grants (R01) that propose to advance innovative research to optimize HIV prevention, treatment, and care. Applications may include formative basic behavioral and social science to better understand a step or steps in the HIV prevention or care continuum, large-scale intervention efficacy or effectiveness trials, implementation science studies, or data science approaches to optimize HIV prevention, treatment, and care. Applicants are encouraged to read current Notice of Special Interest (NOSIs) from NIMH Division of AIDS Research (DAR) for further information about the Division's research priorities (NIMH DAR; https://www.nimh.nih.gov/about/organization/dar/aids-related-funding-opportunity-announcements-foas), and the NIH Strategic Plan for HIV and HIV-Related Research by NIH Office of AIDS Research (NIH OAR; https://www.oar.nih.gov/hiv-policy-and-research/strategic-plan). This FOA, PAR-23-062, uses the R01 grant mechanism for applications with preliminary data or those including longitudinal analysis, advanced modeling, large-scale clinical trials or implementation science studies. Applicants proposing to conduct exploratory, povel studies that break

modeling, large-scale clinical trials or implementation science studies. 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 (<u>PAR-23-061</u>). Applicants proposing the initial development and pilot testing of a clinical trial or formative implementation research should consider using the R34 mechanism (<u>PAR-23-060</u>).

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

4.	In-Depth Phenotyping and Research Using IMPC-Generated Knockout Mouse Strains Exhibiting Embryonic or Perinatal Lethality	or
	Subviability (R01 Clinical Trial Not Allowed)	

Letter of Intent: 30 days prior to the application due date Hyperlink: PAR-23-074 Type: R01 Application Due Date: June 05, 2023 through to October 05, 2025. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage applications to phenotype and/or perform research on embryonic lethal knockout (KO) mouse strains being generated through the International Mouse Phenotyping Consortium (IMPC) of which the NIH Knockout Mouse Phenotyping Program (KOMP2) is a member. The mission of IMPC is to generate a comprehensive catalogue of mammalian gene function that will provide the foundation for functional analyses of human genetic variation. The current (July 19, 2022) IMPC data release includes phenotypic data for 8260 knockout genes. Overall, the IMPC hopes to generate a null mutant and undertake broad-based phenotyping for every gene in the mouse genome. About 30% of these strains are expected to be either embryonic or perinatal lethal, or subviable. However, a large portion of homozygous lethal mutations are expected to have viable heterozygous phenotypes. The scientific community has the unique opportunity to leverage these mouse strains while they are being created and bred as part of the IMPC adult mouse phenotyping effort to perform additional in-depth phenotyping and research.

Budget. Budgets with direct costs of up to \$499,999 per year may be requested. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

5. Integrative Research to Understand the Impact of Sex Differences on the Molecular Determinants of AD Risk and Responsiveness to Treatment (U01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date Hyperlink: PAR-23-082 Type: U01 Application Due Date: February 21, 2023 through February 21, 2025. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) invites applications that apply a cross-disciplinary and team science approach to gain a comprehensive mechanistic understanding of the impact of sex differences on the molecular trajectories of brain aging on the phenotypes of risk and resilience to Alzheimer's disease (AD) and AD-related dementias (ADRD), and on the molecular determinants underlying responsiveness to pharmacologic and non-pharmacologic interventions.

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

6. Investigator Initiated Extended Clinical Trial (R01 Clinical Trial Required)

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

Hyperlink: PAR-23-084 Type: R01 Application Due Date: May 15, 2023 through to January 13, 2026. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) invites applications for implementation of investigatorinitiated clinical trials requiring an extended project period of 6 or 7 years. The trials can be any phase, must be hypothesis-driven, and related to the research mission of the participating IC. Consultation with IC staff is strongly encouraged prior to the submission of the clinical trial implementation application. This FOA is not intended for support of clinical trials that do not require an extended project period of 6 or 7 years. 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 of 6 or 7 years.

7. 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-23-087 Type: UG3/UH3 Application Due Date: February 21, 2023 through to June 20, 2025 Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

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.

8. Utilizing Invasive Recording and Stimulating Opportunities in Humans to Advance Neural Circuitry Understanding of Mental Health Disorders (R21 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due dateHyperlink: PAR-23-101Type: R21Application Due Date: February 16, 2023 through to June 16, 2024. Applications are due by 5:00 PM local time of applicant organization.Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage applications to pursue invasive neural recording studies focused on mental health-relevant questions. Invasive neural recordings provide an unparalleled window into the human brain to explore the neural circuitry and neural dynamics underlying complex moods, emotions, cognitive functions, and behaviors with high spatial and temporal resolution. Additionally, the ability to stimulate, via the same electrodes, allows for direct causal tests by modulating network dynamics. This FOA aims to target a gap in the scientific knowledge of neural circuit function related to mental health disorders. Researchers should target specific questions suited to invasive recording modalities that have high translational potential. Development of new therapies is outside the scope of this FOA, though development of novel tools/methods to enable relevant mental health studies is encouraged. This FOA uses the R21 grant mechanism, encouraging shorter, higher-risk applications, whereas its companion funding opportunity, <u>PAR-23-093</u>, seeks R01 grant applications.

Budget. The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year. The maximum project period is 2 years.

9. Mood and Psychosis Symptoms during the Menopause Transition (R21 Clinical Trial Optional)

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

Type: R21

Application Due Date: February 16, 2023 through to October 16, 2024. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Hyperlink: PAR-23-102

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage applications that will advance mechanistic and translational research on the onset and worsening of mood and psychotic disorders during the menopausal transition (or perimenopause). In particular, NIMH seeks research that will advance understanding of the underlying neurobiological and behavioral mechanisms of mood disruption and psychosis during the menopausal transition and that will identify novel targets for future mental health interventions or prevention efforts. This FOA uses the R21 mechanism, while the companion FOA (<u>PAR-23-097</u>) uses the R01 grant mechanism. Investigators proposing high risk/high reward projects, projects that lack preliminary data, or studies that utilize existing data may wish to apply using the R21 mechanism, while applicants with preliminary data who seek longer-term funding may wish to apply using the R01 mechanism. **Budget**. The combined budget for direct costs for the two year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year.

10. Innovative Pilot Mental Health Services Research Not Involving Clinical Trials (R34 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due dateHyperlink: PAR-23-105Type: R34Application Due Date: February 16, 2023 through to February 16, 2025. Applications are due by 5:00 PM local time of applicant organization.Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage innovative pilot research that will inform and support the delivery of high-quality, continuously improving mental health services to benefit the greatest number of individuals with, or at risk for developing, a mental illness. This announcement invites applications for non-clinical trial pilot projects that address NIMH strategic priorities to strengthen the public health impact of NIMH-supported research as described in <u>Goal 4 of the NIMH Strategic Plan</u>. Proposed research should seek to:

- 1. Identify mutable factors that impact access, continuity, utilization, quality, value, and outcomes, including disparities in outcomes, or scalability of mental health services, which may serve as targets in future service delivery intervention development;
- 2. Develop and test new research tools, technologies, measures, or methods and statistical approaches to study these issues;
- 3. Test the feasibility of integrating and analyzing large data sets to understand factors affecting mental health services outcomes using advanced computational and predictive analytic approaches;
- 4. Wherever possible, leverage existing infrastructure and partnerships to accomplish these goals.

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 one year. The total project period for an application submitted in response to this funding opportunity may not exceed three years.

11. Pediatric Heart Network Clinical Research Centers (UM1 Clinical Trial Optional)

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

Hyperlink: <u>RFA-HL-24-001</u> Type: UM1

Application Due Date: May 12, 2023. Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. Funding Opportunity Announcement: The purpose of this FOA is to invite applications to participate as a Clinical Research Center (CRC) in the Pediatric Heart Network (https://www.pediatricheartnetwork.org/). CRCs will be expected to support and conduct research to improve the

health and quality of life for children and adults with congenital heart disease and children with acquired heart disease through multi-center collaborative clinical research. Collaboration among the CRCs, the Data Coordinating Center (DCC; see companion FOA <u>RFA-HL-24-002</u>, <u>U24</u> Resource-Related Research Project (Cooperative Agreements), and other stakeholders is expected to facilitate multi-center evaluation of medical, interventional and surgical therapies; support development of novel treatment techniques and methodologies; identify and attempt

to address equity gaps in outcomes; provide a training platform for fellows, junior faculty, and nurses; and promote dissemination and implementation of study results to improve the scientific basis for the care of affected individuals.

Budget: NHLBI intends to commit total costs up to \$4,050,000 in Fiscal Year 2024 to fund up to nine new awards. Application budgets are limited to \$281,250 direct costs per year in Fiscal Years 2024 through 2030. The scope of the proposed project should determine the project period. The maximum project period is 7 years.

12. Using Just-in-Time Adaptive Interventions to Optimize Established Adolescent Mental Health Treatments (R61/R33 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due dateHyperlink: RFA-MH-23-170Type: R61/R33Application Due Date: February 22, 2023 Applications are due by 5:00 PM local time of applicant organization. Applicants are encouraged to
apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.Funding Opportunity Announcement: NIMH seeks applications for pilot research to develop and test just-in-time adaptive intervention (JITAI)
augmentations to enhance the effectiveness and clinical potency of established adolescent mental health treatments. An emphasis is placed on
studies that are informed by developmental science and grounded in an empirical model of behavior change. Support will be provided for up
to two years (R61 phase) for milestone-driven testing, refinement, and/or validation of the intervention's impact on empirically supported,
measurable target mechanisms and the possibility (contingent on meeting the R61 milestones) of up to 3 additional years of support (R33 phase)
to replicate the target engagement findings in a larger sample and examine the relationship between the target mechanisms and clinical
outcomes.

Budget: NIMH intends to commit \$2.0 million in FY 2023 to fund up to 5 awards. 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.

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