NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 03 Jan 2023 (#01)

Important Notices

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

NOT-MH-23-150 Notice of Intent to Publish a Funding Opportunity Announcement for Suicide Prevention Across the Life Span in Low- and Middle-Income Countries (R34 Clinical Trial Optional). The National Institute of Mental Health intends to publish a Funding Opportunity Announcement (FOA) to solicit applications to encourage formative research and pilot testing of culturally appropriate innovative preventive, therapeutic, and service interventions to reduce the risk of suicide and suicide ideation and behavior (SIB), and/or non-suicidal self-injury (NSSI) and promote resilience for people across the life span in Low- and Middle-Income Countries (LMICs). During the development and testing of interventions, attention to implementation factors is strongly encouraged. This could include formative work to measure and understand the feasibility, acceptability, adoption, fidelity, and costs of interventions to reduce the risk of suicide and SIB and/or NSSI and promote resilience for people across the life span in LMICs. 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 March 2023 with an expected application due date in June 2023. This FOA will utilize the R34 activity code. Clinical trials will be optional. NIMH intends to commit $3,000,000 in FY 2024. Direct costs are limited to $225,000 per year and $450,000 over the 3-year project period.

NOT-OD-23-045 Publication of the Revised NIH Grants Policy Statement (Rev. December 2022) for Fiscal Year 2023. 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. This update incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated December 2021. The current version of the NIHGPS, in both HTML and PDF formats, as well as previous versions of the NIHGPS and documents summarizing significant changes implemented with each revision, are available on the NIH Grants Policy website.

NOT-OD-23-047 Updates to the Non-Discrimination Legal Requirements for NIH Recipients. NIH complies with all federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and applicable conscience protections. Effective immediately, NIH is updating and implementing HHS language on the Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance. All Notices of Funding Opportunity (NOFOs) (i.e. Funding Opportunity Announcements) and Notices of Award (NoAs) will include the updated non-discrimination language.

Notices of Special Interest (NOSI)

NOT-OD-23-032 Administrative Supplement for Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grant Awards. This is the reissuance of Notice of Special Interest (NOSI): Administrative Supplement for Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grant Awards (NOT-OD-20-055). The overarching goal of this program is to enhance the retention of investigators facing critical life events who are transitioning to the first renewal of their first independent research project grant award or to a second new NIH research project grant award. Retention at the first renewal or continuous NIH research project grant support is crucial for sustaining both the ongoing research NIH has made an investment in and for retaining diverse talent in the biomedical research workforce. This program supports "at-risk" investigators as identified in the NIH Next Generation Researchers Initiative (see https://grants.nih.gov/ngri.htm). This retention program seeks to maintain the productivity of current first-time recipients of eligible independent NIH research project grant awards who are dealing with a critical life event(s), such that they can remain competitive for the first renewal of their award or for a second research project grant award. For retention supplements to support the transition from K award to independence, see the companion NOSI (NOT-OD-23-031).

NOT-MH-23-120 Notice of Special Interest (NOSI): The Neural Mechanisms of Multi-Dimensional Emotional and Social. NIMH is issuing this Notice of Special Interest (NOSI) to outline priorities for research that incorporates a multi-dimensional perspective into studies of the neural mechanisms underlying emotional and/or social representations. The ability to integrate a broad array of emotional and social information is impaired in many mental disorders, yet the neural mechanisms underlying these processes are not well understood. This NOSI encourages studies in humans and animals investigating how diverse multi-dimensional emotional and/or social cues are represented across brain circuits that are important for mental health relevant cognitive, social, and affective behavioral functions. The term "multi-dimensional" refers to the consideration of multiple modalities (e.g., social, emotional, visual, and auditory), the effects of complex contexts and development, and/or dynamic processes that unfold over a variety of temporal scales. Applicants are strongly encouraged to consult with the Scientific/Research contacts Early contact will provide an opportunity to clarify NIMH priorities and guidelines as well as to discuss specific components of the application subject to peer review. Submit applications for this initiative using one of the funding opportunity announcements listed in the NOSI or any reissues of these announcement through the expiration date of this notice. This notice applies to due dates on or after January 25, 2023 and subsequent receipt dates through January 8, 2025.

NOT-GM-23-015 Optimization of Data Storage and Utilization for the Sequence Read Archive (SRA). The purpose of this Notice of Special Interest (NOSI) is to inform the scientific community of the interest of NIGMS, NLM, and ODSS in supporting efficiency optimization and cost reduction for Sequence Read Archive (SRA) data storage and utilization. The SRA, hosted by the National Center for Biotechnology Information (NCBI) at NLM, contains a broad collection of raw DNA and RNA sequence data and alignment information that continues to grow exponentially. SRA supports several scientific use cases, such as replication of a published study, data analysis to identify genetic variation, metagenomic profiling, expression analysis, and pathogen identification. Committed to store, preserve, and make the SRA available to the community, NIH recognizes the need to reduce the cost of SRA data storage and identify solutions for efficient SRA data storage, retrieval, and analysis. This NOSI encourages grant applications focused on efficiency optimization and cost reduction for SRA data storage and utilization. NIH is particularly interested in identifying efficient solutions for SRA data compression and representation while still meeting the needs of a range of use cases, including but not limited to:

- Assessment of current SRA data formats and proposed future refinements and utilization costs for scientific use cases
- Development of novel SRA data compression formats, methods, data representation strategies, and utility assessment for different use cases

- Development of tools that utilize current SRA compressed data formats to enable their use by or integration with existing bioinformatics tools
- Development of compressed and/or lower-cost SRA data formats to meet the needs of a range of use cases

This NOSI applies to due dates on or after January 17, 2023 and subsequent application due dates through December 19, 2025. Submit applications for this NOSI using one of the listed FOAs or any subsequent reissues through the expiration date of this Notice.

NOT-NS-23-038 Efficacy Trials of Epidural Stimulation for Spinal Cord Injury. The mission of National Institute of Neurological Disorders and Stroke (NINDS) is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all people. Spinal Cord Injury (SCI) can occur following an acute or long-term insult to the spinal cord, resulting in devastating neurological loss and concomitant systemic dysfunction with no current ameliorative treatment or cure. This Notice of Special Interest is to advise the research community of NINDS interest in clinical trials to study epidural stimulation in spinal cord injury that meet the requirements of PAR-21-237 NINDS Efficacy Clinical Trials (UG3/UH3 Clinical Trial Required) Funding Opportunity Announcement. This notice applies to the February 9 ,2023 receipt date and subsequent due dates through October 10, 2023. Submit applications for this initiative using PAR-21-237 - NINDS Efficacy Clinical Trials (UG3/UH3 Clinical Trial Required).

NOT-OD-23-039 Firearm Injury and Mortality Prevention Research. The purpose of this Notice is to highlight interest in research to improve understanding of the determinants of firearm injury, the identification of those at risk of firearm injury (including self- and other-directed, victims and perpetrators, accidental injury), the development, piloting, and testing of innovative interventions to prevent firearm injury and mortality, and the examination of approaches to improve the implementation of existing, evidence-based interventions to prevent firearm injury and mortality. Research encouraged by this NOSI is consistent with a broad public health approach to firearm injury and mortality prevention including:

- identifying those at risk for firearm injury and mortality (self- and other-directed; victims and perpetrators; accidental injury)
- development, piloting, and/or testing of theoretically-grounded programs to prevent firearm injury and mortality
- implementation research to explore the barriers and facilitators to support broader adoption of effective programs.

NIH funds may not be used, in whole or in part, to advocate or promote gun control or to support lobbying activities. Research proposed in applications must be ideologically and politically unbiased as defined in the NIH Grants Policy Statement (GPS) sections 4.1.10 and 4.1.17. 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 NOSI. This notice applies to due dates on or after February 5th, 2023 and subsequent receipt dates through February 5th, 2026.

NOT-MD-23-001 Administrative Supplements to Support Addiction Science and Related Neuroscience Pilot Research Projects at NIMHD-Funded Research Centers in Minority Institutions (RCMI). This NOSI invites applications for administrative supplements to NIMHD Research Centers in Minority Institutions (RCMI) U54 awards to support pilot research projects led by early-stage investigators (ESIs) and new investigators (NIs) focused on research on substance use, addiction, and/or neuroscience, as a bridge to independently funded careers. It is expected that pilot project PIs will work with their institutions to prepare and submit follow-up research grant or career development applications to NIH based on the research supported by these supplemental funds. To be eligible for an Administrative Supplement under this NOSI, the parent RCMI U54 award must:

- be awarded under either RFA-MD-17-003, RFA-MD-17-006, RFA-MD-18-012, RFA-MD-20-006, or RFA-MD-22-002.
- be an active NIH award at the time of application (i.e., within five years of the start date of the originally reviewed and approved project period of the existing parent RCMI U54's

NOT-MH-23-115 BRAIN Initiative: Developing Data Archive, Informatics Tools and Data Standards for Brain Behavior Quantification and Synchronization (BBQS). The purpose of thisNOSI is to encourage new applications for developing informatics infrastructure for the Brain Behavior Quantification and Synchronization (BBQS) research program of the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative. Specifically, the NOSI supports a) creation of data archive(s) to store and manage BBQS-relevant data; b) development of computational

tools or software for analyzing, visualizing and integrating BBQS-related data, and for predicting and modeling the complex dynamics of the brain-behavior system; and c) establishment of data standards or ontologies that support the BBQS-related studies. Submission of an application in response to this NOSI should use one of the FOAs listed or any reissues of the FOAs. Applicants planning to submit an application in response to this NOSI are strongly encouraged to contact and discuss their proposed research plans or aims with the Scientific Contact listed on this NOSI in advance of the application receipt date to better determine appropriateness.

NOT-OD-23-040 Advance Data Science Approaches Through Secondary Data Analysis to Reveal Scientific Insights of COVID-19 Testing Technologies (R21). The purpose of this Notice of Special Interest (NOSI) is to support secondary data analysis to address questions and advance scientific inquiry related to SARS-CoV-2 through the existing data resources in the Rapid Acceleration of Diagnostics Data Hub (RADx DataHub), including and in conjunction with other data resources. The research topic areas may include, but are not limited to, biomedical, clinical, social, ethical, and behavioral issues. Examples of secondary analyses projects include, but are not limited to:

- Validate public health measures
- Inform patient care
- Reduce health disparities for underserved and vulnerable populations
- Drive innovation in technologies offering more user-friendly designs
- Help stop and/or track the spread of COVID-19 virus or co-infectious materials
- Address better strategies to timely equip the biomedical workforce to test and identify future pathogens and other diseases

Applicants must select the IC and associated FOA to use for submission of an application in response to the 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. First Available Due Date: February 16, 2023. Expiration Date: May 31, 2023.

Funding Opportunity Announcements (FOA)

1. Implementation Research on Noncommunicable Disease Risk Factors among Low- and Middle-Income Country and Tribal Populations Living in City Environments (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-042** **Type: R01**

Application Due Date: March 09, 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 National Institutes of Health (NIH) participating Institutes and Centers (ICs), in collaboration with the Global Alliance for Chronic Diseases (GACD), invite applications for implementation research focused on addressing risk factors for common noncommunicable diseases (NCDs) in World Bank-defined low- and middle-income countries (LMICs) and American Indian/Alaska Native (AI/AN) populations in the United States (US). Air, water, and soil pollution; lack of greenspace; urban heat islands; lack of safe infrastructure for walking, cycling, and active living; lack of access to healthcare facilities, lack of health insurance, and cost of medications; housing condition; and wide availability of tobacco, alcohol, and unhealthy foods and beverages contribute to the NCD epidemic in city environments. In the context of this Funding Opportunity Announcement (FOA), "cities" include urban centers, informal settlements, slums, and periurban areas. This FOA supports applications that propose implementation research to reduce the risks of NCDs in the context of cities in LMICs and/or among AI/AN populations in US cities, with the potential to equip policymakers and practitioners with evidence-based strategies for prevention and/or management of NCDs among disadvantaged populations globally. NIH defines implementation research as the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health. All applications must be within the scope of the mission of one of the Institutes/Centers listed above (see "Components of Participating Organizations," excluding the Fogarty International Center which manages this program but does not support awards). Applications will be accepted from US and World Bank-defined LMIC institutions only.

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. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application.

2. Implementation Research on Noncommunicable Disease Risk Factors among Low- and Middle-Income Country and Tribal Populations Living in City Environments (R61/R33 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-043** **Type: R61/R33**

Application Due Date: March 09, 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 National Institutes of Health (NIH) participating Institutes and Centers (ICs), in collaboration with the Global Alliance for Chronic Diseases (GACD), invite applications for implementation research focused on addressing risk factors for common noncommunicable diseases (NCDs) in World Bank-defined low- and middle-income countries (LMICs) and American Indian/Alaska Native (AI/AN) populations in the United States (US). Air, water, and soil pollution; lack of greenspace; urban heat islands; lack of safe infrastructure

for walking, cycling, and active living; lack of access to healthcare facilities, lack of health insurance, and cost of medications; housing condition; and wide availability of tobacco, alcohol, and unhealthy foods and beverages contribute to the NCD epidemic in city environments. In the context of this Funding Opportunity Announcement (FOA), "cities" include urban centers, informal settlements, slums, and periurban areas. This FOA supports applications that propose implementation research to reduce the risks of NCDs in the context of cities in LMICs and/or among AI/AN populations in US cities, with the potential to equip policymakers and practitioners with evidence-based strategies for prevention and/or management of NCDs among disadvantaged populations globally. NIH defines implementation research as the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health. This FOA uses the bi-phasic, milestone driven R61/R33 grant mechanism. Awards made under this FOA will initially support a one-year milestone-driven initiation (R61) phase, with possible transition to an implementation (R33) phase of up to four additional years. Only projects that meet the scientific milestones and award requirements of the R61 phase may transition to the R33 phase. Applications submitted in response to this FOA must address both the R61 and R33 phases. All applications must be within the scope of the mission of one of the Institutes/Centers listed above (see "Components of Participating Organizations," excluding the Fogarty International Center which manages this program but does not support awards). Applications will be accepted from US and World Bank-defined LMIC institutions only.
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. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application.

3. National Cancer Institute (NCI) Small Grants Program for Cancer Research for Years 2023, 2024, and 2025 (NCI Omnibus) (R03 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-058** **Type: R03**
Application Due Date: February 22, 2023 through to January 07, 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) supports small research projects on cancer that can be carried out in a short period of time with limited resources. The R03 grant mechanism supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology.
Budget: A budget for direct costs of up to $50,000 per year may be requested. The maximum project period is 2 years.

4. Clinical Studies of Mental Illness (Collaborative R01) (Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-050** **Type: R01**
Application Due Date: February 05, 2023 through to January 07, 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) seeks to support collaborative clinical studies, that primarily focus on mental health genetics, biomarker studies, and studies of mental illnesses (e.g., psychopathology, neurodevelopmental trajectories of psychopathology). Applicants should apply to this FOA when two or more sites are needed to complete the study. Accordingly, the collaborating studies share a specific protocol across the sites and are organized as such in order to increase sample size, accelerate recruitment, or increase the inclusion of women and minorities (NOT-OD-18-014) and NIH-defined health disparity populations. (see https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html). It is expected that one site will be submitted as a coordinating R01 for data management and/or other centralized administration. For a linked set of collaborative R01s, each application has its own Program Director/Principal Investigator (PD/PI). The collaborative R01 program provides a mechanism for cross-R01 coordination, quality control, database management, statistical analysis, and reporting.
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. Application budgets need to reflect the actual needs of the proposed project. The maximum amount available per individual application within the collaborative is not to exceed $500,000 direct costs per year.

5. Co-infection and Cancer (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-055** **Type: R01**
Application Due Date: February 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 enhance mechanistic and epidemiologic investigations addressing the roles of co-infection and cancer to shed light on presently unestablished pathways in carcinogenesis that may inform prevention and treatment strategies for infection-related cancers. Co-infection is defined as the occurrence of infections by two or more infectious (pathogenic or non-pathogenic) agents – either concurrently or sequentially – and includes both acute and chronic infections by viruses, bacteria, parasites, and/or other microorganisms. Preference will be given to investigations of co-infections with known oncogenic agents (excluding human immunodeficiency virus [HIV]) and of co-infections that engender novel opportunities for prevention and treatment.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The project period may not exceed 5 years.

6. Co-infection and Cancer (R21 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-056** **Type: R21**

Application Due Date: February 16, 2023 through to October 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 enhance mechanistic and epidemiologic investigations addressing the roles of co-infection and cancer to shed light on presently unestablished pathways in carcinogenesis that may inform prevention and treatment strategies for infection-related cancers. Co-infection is defined as the occurrence of infections by two or more infectious (pathogenic or non-pathogenic) agents – either concurrently or sequentially – and includes both acute and chronic infections by viruses, bacteria, parasites, and/or other microorganisms. Preference will be given to investigations of co-infections with known oncogenic agents (excluding human immunodeficiency virus [HIV]) and of co-infections that engender novel opportunities for prevention and treatment.

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.

7. Rapid Translation of Epidemiological Findings into Interventions to Prevent Substance Use and Addiction (R61/R33 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DA-24-010** **Type: R61/R33**

Application Due Date: March 15, 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: This Funding Opportunity Announcement (FOA) supports research led by multidisciplinary teams to advance translation of epidemiological research into interventions to prevent substance use and addiction. The R61/R33 Phased Innovation Award mechanism is used to support exploratory/developmental research with the potential for high impact. Applications are required to use a Multiple-Principal Investigator (MPI) structure and clearly demonstrate how epidemiological findings from the R61 phase will inform intervention research in the R33 phase.

Budget: NIDA intends to commit up to $3 million in FY 2024 to fund 4-7 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. Unless well-justified, it is strongly recommended that applicants not request a budget of more than $500,000 in direct costs per year in either the R61 or R33 phases. 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 4 years for the R33 phase. The scope of the proposed project should determine the requested project period.

8. Mechanisms and Targets at the Intersection of HIV and Substance Use (R01 Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DA-24-013** **Type: R01**

Application Due Date: August 09, 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 Funding Opportunity Announcement (FOA) is to support research on the discovery and development of novel chemical and biological approaches to prevent and/or treat central nervous system (CNS) complications associated with HIV infection and substance use. NIDA is specifically interested in supporting basic research on signaling pathways, virus-host protein interactions, and post-translational protein modifications, which are commonly affected by HIV and substance use and lead to neuropathology and neurocognitive dysfunction.

Budget: NIDA intends to commit $3,000,000 in FY 2024 to fund 4-6 awards in response to this FOA and the companion FOA. Application budgets are limited to $400,000 in direct costs per year and need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

9. Mechanisms and Targets at the Intersection of HIV and Substance Use (R21 Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DA-24-014** **Type: R21**

Application Due Date: August 09, 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 Funding Opportunity Announcement (FOA) is to support research on the discovery and development of novel chemical and biological approaches to prevent and/or treat central nervous system (CNS) complications associated with HIV infection and substance use. NIDA is specifically interested in supporting basic research on signaling pathways, virus-host protein interactions, and post-translational protein modifications, which are commonly affected by HIV and substance use and lead to neuropathology and neurocognitive dysfunction.

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. Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data (R03 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-075** **Type: R03**

Application Due Date: February 16, 2023 through to October 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 NIH Common Fund has established the Gabriella Miller Kids First Pediatric Research Program (Kids First) to develop a pediatric research data resource populated by genome sequence and phenotypic data that will be of high value for the communities of investigators who study the genetics of childhood cancers and/or structural birth defects.
Kids First has established and continues to develop a Data Resource including a collection of curated genomic and phenotypic data from childhood cancer and structural birth defects cohorts and a central portal where these data and analysis tools are accessible to the research community. Access to these data will promote comprehensive and cross-cutting research and collaboration leading to more refined diagnostic capabilities and ultimately more targeted therapies. This FOA is intended to support meritorious small research projects focused on analyses of childhood cancer and/or structural birth defects genomic datasets generated by the Kids First program and/or associated phenotypic datasets. Development of approaches, tools, or algorithms appropriate for analyzing genomic, phenotypic, and/or clinical data relevant to Kids First may also be proposed.
Budget: The combined budget for direct costs for the two year project period may not exceed $200,000. A project duration of up to two years may be requested

11. Biomedical Knowledgebase (U24 - Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-078** **Type: U24**
Application Due Date: January 25, 2023. Aids: May 08, 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: This funding opportunity announcement is designed to support biomedical knowledge bases. Biomedical knowledge bases under this announcement should have the primary function to extract, accumulate, organize, annotate, and link growing bodies of information related to core datasets. Support for data curation should include efficient and effective methods of curation that scale to the needs of the community and include semi-automated methods. Support for software and tool development must be limited to that which provides essential functions or significantly increases the efficiency of operation of the knowledgebase. Applications that have a significant focus on software or tool development are not appropriate for this activity.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. Applications may request up to five years of support for a biomedical knowledgebase. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application

12. Biomedical Data Repository (U24 - Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-079** **Type: U24**
Application Due Date: January 25, 2023. Aids: May 08, 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: This funding opportunity announcement is designed to support biomedical data repositories. Biomedical data repositories under this announcement should have the primary function to ingest, archive, preserve, manage, distribute, and make accessible the data related to a particular system or systems. Support for data curation must be limited to that which improves the efficiency and accessibility of data ingestion, management, and use and reuse by the user communities. Support for software and tool development must be limited to that which provides essential functions or significantly increases the efficiency of operation of the repository. Applications that have a significant focus on software and tool development are not appropriate for this activity.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. Applications may request up to five years of support for a biomedical data repository. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application.

13. Early and Late Stage Clinical Trials for the Spectrum of Alzheimer's Disease/Alzheimer's Related Dementias and Age-Related Cognitive Decline (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-081** **Type: R01**
Application Due Date: February 05, 2023 through to October 05, 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 1) invite applications that propose to develop and implement early to late stage clinical trials of promising pharmacological and non-pharmacological interventions for cognitive and neuropsychiatric changes associated with age-related cognitive decline and Alzheimer's disease (AD) and Alzheimer's disease-related Dementias (ADRD) across the spectrum from pre-symptomatic to more severe stages of disease, and 2) stimulate studies to enhance trial design and methods.
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. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application.

14. Pilot Studies for the Spectrum of Alzheimer's Disease/Alzheimer's Disease-Related Dementias and Age-Related Cognitive Decline (R61 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-083** **Type: R61**

Application Due Date: February 17, 2023 through to October 18, 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 1) invite research grant applications that enable the collection of pilot data to support early stage testing of promising pharmacological and non-pharmacological interventions for cognitive and neuropsychiatric changes associated with age-related cognitive decline and Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD) across the spectrum from pre-symptomatic to more severe stages of disease, and 2) stimulate studies to enhance trial design and methods.

Budget: NIH intends to fund an estimate of up to 5 awards, corresponding to a total of $2.5 million, for fiscal year 2022. Future year amounts will depend on annual appropriations. Application budgets are limited to $325,000 direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is 2 years.

15. Genomic Community Resources (U24 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-085** **Type: U24**

Application Due Date: January 25, 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: To facilitate genomic research and the dissemination of its products, NHGRI supports genomic resources that are crucial for basic research, disease studies, model organism studies, and other biomedical research. Awards under this FOA will support the development and distribution of genomic resources that use cost-effective approaches and will be valuable for the broad research community. Such resources include (but are not limited to) databases and informatics resources (such as human and model organism databases, ontologies, and analysis toolsets), comprehensive identification and collections of genomic features (such as functional genomic elements), and standard data types produced using central sets of samples (such as structural variants in 1000 Genomes or GTEx samples).

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. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application

16. Development of Innovative Informatics Methods and Algorithms for Cancer Research and Management (R21 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-014** **Type: R21**

Application Due Date: June 13, 2023; November 17, 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 Funding Opportunity Announcement (FOA) is to invite exploratory/developmental research grant applications (R21) for innovative informatics methods and algorithms to improve the acquisition, analysis, visualization, or interpretation of data across the cancer research continuum including cancer biology, cancer treatment and diagnosis, early cancer detection, risk assessment and prevention, cancer control and epidemiology, and/or cancer health disparities. As a component of the NCI's Informatics Technology for Cancer Research (ITCR) Program, the emphasis of this FOA is on supporting the development of novel informatics capabilities that involve a high degree of innovation that have the potential to accelerate or enhance research. To be successful, there must be a clear rationale for how the proposed informatics method or algorithm is novel and how it will benefit the cancer research field. Projects with a significant level of data generation and/or data analysis will not be considered responsive to this funding opportunity.

Budget: NCI intends to fund an estimate of 5 awards, corresponding to a total of $1,020,000, for fiscal year 2024. 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.

17. Early-Stage Development of Informatics Technologies for Cancer Research and Management (U01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-015** **Type: U01**

Application Due Date: June 13, 2023 & November 17, 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 Funding Opportunity Announcement (FOA) is to invite Cooperative Agreement (U01) applications for the development of enabling informatics technologies to improve the acquisition, management, analysis, and dissemination of data and knowledge across the cancer research continuum including cancer biology, cancer treatment and diagnosis, early cancer detection, risk assessment and prevention, cancer control and epidemiology, and/or cancer health disparities. As a component of the NCI's Informatics Technology for Cancer Research (ITCR) Program, this FOA focuses on early-stage development from prototyping to hardening and adaptation. Early-stage development is defined for the purpose of this FOA as initial tool development or the significant modification of existing tools for new applications. The central mission of ITCR is to promote research-driven informatics technology across the development lifecycle to address priority needs in cancer research. In order to be successful, proposed development plans must have a clear rationale on why the proposed technology is needed and how it will benefit the cancer research field. In addition, mechanisms to solicit feedback from users and collaborators throughout the development process must be included.

Budget: NCI intends to commit $2,250,000 in FY 2024 to fund 5-6 awards. Budgets are limited to $300,000 Direct Costs (excluding consortium F&A) per year. The maximum project period is three years.

18. Advanced Development of Informatics Technologies for Cancer Research and Management (U24 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-016** **Type: U24**

Application Due Date: June 13, 2023 & November 17, 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 Funding Opportunity Announcement (FOA) is to invite Cooperative Agreement (U24) applications for advanced development and enhancement of emerging informatics technologies to improve the acquisition, analysis, visualization, and interpretation of data across the cancer research continuum including cancer biology, cancer treatment and diagnosis, early cancer detection, risk assessment and prevention, cancer control and epidemiology, and cancer health disparities. As a component of the NCI's Informatics Technology for Cancer Research (ITCR) Program, this FOA focuses on emerging informatics technology, defined as one that has passed the initial prototyping and pilot development stage, has demonstrated potential to have a significant and broader impact, has compelling reasons for further improvement and enhancement, and has not been widely adopted in the cancer research field. To be successful, proposed development plans must have a clear rationale on why the proposed technology is needed and how it will benefit the cancer research field. In addition, mechanisms to solicit feedback from users and collaborators throughout the development process must be included. Potential applicants who are interested in early-stage development or informatics resource sustainment should consult the companion FOAs listed above.

Budget: NCI intends to fund an estimate of 4 awards, corresponding to a total of $3.6M, for fiscal year 2024. Budgets are limited to $600,000 Direct Costs (excluding consortium F&A) per year. The maximum project period is five years.

19. Sustained Support for Informatics Technologies for Cancer Research and Management (U24 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-017** **Type: U24**

Application Due Date: 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 invite Cooperative Agreement (U24) applications for the continued development and sustainment of high value informatics research resources to improve the acquisition, management, analysis, and dissemination of data and knowledge across the cancer research continuum including cancer biology, cancer treatment and diagnosis, early cancer detection, risk assessment and prevention, cancer control and epidemiology, and/or cancer health disparities. As a component of the NCI's Informatics Technology for Cancer Research (ITCR) Program, this FOA focuses on sustaining operations and improving the user experience and availability of existing, widely-adopted informatics tools and resources. This is in contrast to early-stage and advanced development efforts to generate these tools and resources that are supported by companion ITCR FOAs. The central mission of ITCR is to promote research-driven informatics technology across the development lifecycle to address priority needs in cancer research. In order to be successful, the proposed sustainment plan must provide clear justification for why the research resource should be maintained and how it has benefited and will continue to benefit the cancer research field. In addition, mechanisms for assessing and maximizing the value of the resource to researchers and supporting collaboration and deep engagement between the resource and the targeted research community should be described.

Budget: NCI intends to fund an estimate of 1 award, corresponding to a total of $1,130,000, for fiscal year 2024. Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is five years.

20. Ancillary Studies to the NIDDK Inflammatory Bowel Disease Genetics Consortium (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DK-22-023** **Type: R01**

Application Due Date: March 09, 2023 & November 08, 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: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Inflammatory Bowel Disease Genetics Consortium (IBDGC), in collaboration with the International IBD Genetics Consortium, has identified over 250 susceptibility loci for inflammatory bowel disease (IBD). The IBDGC was renewed recently with a continued mission to characterize the genetic architecture of IBD phenotypes in diverse populations and to elucidate the biological mechanisms by which genetic variants influence IBD pathophysiology and clinical course. However, current resources permit functional investigation of only a limited number of loci, genes and physiological domains, while the biological mechanisms underlying most of the identified IBD risk loci remain unknown. The purpose of this Funding Opportunity Announcement (FOA) is to expand the number of IBD susceptibility loci, causal variants and effector genes, and IBD-related phenotypes and physiological domains under investigation via Ancillary Studies utilizing the extensive resources, including subjects, samples and datasets, established by the IBDGC. Proposed Ancillary Studies should focus on causal variant identification and/or functional characterization of effector genes within IBD risk loci and must not duplicate studies that are either ongoing or already completed by the IBDGC.

Budget: NIDDK intends to commit $3,300,000 in FY 2024 to fund up to 7 awards. Application budgets are limited to $300,000 direct costs per year. The maximum project period is 4 years for applications submitted to the first due date (March 09, 2023), and 3 years for applications submitted to the second due date (November 08, 2023).

21. Site Selection in Oncology Clinical Trials: Considerations for Selecting Sites in Limited Geographic Regions or Areas of Political Unrest, Limiting Inspection Capabilities (U13) Clinical Trial not allowed.

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-007** **Type: U13**

Application Due Date: March 7, 2023, by 11:59 PM Eastern Time. 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 support a series of conferences and workshops developed with substantial FDA input to explore challenges regarding site selection of clinical trials sites in studies that are submitted to FDA for regulatory approval of oncology indications.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for ONE(1) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA /OC intends to commit up to $300,000 in FY 2023 to fund 1-2 awards. Application budgets need to reflect the actual needs of the proposed project. and should not exceed the following in total costs (direct and indirect): Y1 =$150 000 and Y2 =$150 000. The scope of the proposed project should determine the project period. The maximum project period is TWO (2) years.

22. BRAIN Initiative: Brain Behavior Quantification and Synchronization (R61/R33 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-MH-23-335** **Type: R61/R33**

Application Due Date: February 17, 2023 & February 15, 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: This Funding Opportunity Announcement (FOA) supports the development and validation of next-generation tools, methods, and analytic approaches to precisely quantify behaviors and combine them with simultaneous recordings of brain activity in humans. Tools used for measuring and analyzing behavior should be multi-modal, with the appropriate accuracy, specificity, temporal resolution, and flexibility necessary for integration with existing tools used to measure and modulate the brain circuits that give rise to those behaviors. This R61/R33 FOA is intended to support biphasic applications for novel tools development (i.e., hardware/software) in the R61 phase, followed by the integration/synchronization of these novel tools with established methods for recording human brain activity in the R33 phase. Applications must propose one or more milestones, which clearly define the criteria for the success of the R61 project objectives. Transition to the R33 phase will depend on demonstration of milestone completion. Applications should be submitted by multi-disciplinary teams with expertise spanning behavior and behavioral measurement, neurobiology, social systems, computer/data systems, engineering, biostatistics, neuroethics, and artificial intelligence. Applicants pursuing brain-behavior quantification and synchronization tool development in non-human animals, or pursuing comparative animal studies including humans, are not responsive to this FOA and should consider related Brain-Behavior Quantification and Synchronization (BBQS) opportunities listed on the BRAIN Initiative website, or reach out to the contacts (see Section VII: Agency Contacts) for guidance on relevant opportunities.

Budget: NIMH and partner components intend to commit an estimated total of $10 million to fund 8-10 awards in FY2024 and an estimated total of $10 million to fund 8-10 awards in FY2025. Application budgets are not limited but need to reflect the actual needs of the proposed project. The proposed project period for the R61 must not exceed 4 years. The proposed project period for the R33 must not exceed 2 years. The total duration of the R61 and R33 may not exceed 5 years.

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