NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 27 Feb 2023 (#09)

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

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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

NOT-HG-23-021 Notice of Participation of the National Human Genome Research Institute (NHGRI) in PA-20-163: Competing Revisions to Existing NIH Grants and Cooperative Agreements (Clinical Trial Optional). The purpose of this Notice of Participation is to add the National Human Genome Research Institute (NHGRI) to the list of participating NIH Institutes in the Notice of Funding Opportunity (NOFO) PA-20-163 - Competing Revisions to Existing NIH Grants and Cooperative Agreements (Clinical Trial Optional).

NOT-NS-23-068 Notice of Intent to Publish a Funding Opportunity Announcement for Understanding Neurological Effects of COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (R01 Clinical Trial Optional). National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Mental Health (NIMH) and the National Institute on Aging (NIA) intend to promote a new initiative by publishing a Funding Opportunity Announcement (FOA) to invite applications focused on the neurological and neuropsychiatric manifestations of COVID-19 (neuro-COVID) and Post-Acute Sequelae of SARS-CoV-2 Infection (neuro-PASC) and on the effect of COVID-19 on pre-infection neurologic conditions. Applications investigating the pathophysiology and mechanisms of neuro-COVID and neuro-PASC and neurologically-focused human subjects research, as well as those proposing studies of scientifically compelling pathways to prevent the development of neuro-PASC or to accelerate the development of effective treatments for PASC-related neurological complications are of particular interest for this FOA. NINDS intends to commit up to $4.5M to fund 3-5 awards contingent upon NIH appropriations and a sufficient number of meritorious applications. Application budgets are limited to $500,000 Direct Cost in any given year. This FOA will utilize the R01 activity code.First Estimated Application Due Date: June 02, 2023. For this FOA and its companion funding opportunity, NIA intends to support meritorious applications scoring within its FY24 AD/ADRD and General paylines.

NOT-NS-23-069 Notice of Intent to Publish a Funding Opportunity Announcement for Understanding Neurological Effects of COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (R21 Clinical Trial Optional). National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Mental Health (NIMH) and the National Institute on Aging (NIA) intend to promote a new initiative by publishing a Funding Opportunity Announcement (FOA) to invite exploratory and innovative research applications focused on the neurological and neuropsychiatric manifestations of COVID-19 (neuro-COVID) and Post-Acute Sequelae of SARS-CoV-2 Infection (neuro-PASC) and on the effect of COVID-19 on pre-infection neurologic conditions. Applications investigating the pathophysiology and mechanisms of neuro-COVID and neuro-PASC and neurologically-focused human subjects research, as well as those proposing studies of scientifically compelling pathways to prevent the development of neuro-PASC or to accelerate the development of effective treatments for PASC-related neurological complications are of particular interest for this FOA. NINDS intends

to commit up to $1.6M to fund 3-5 awards contingent upon NIH appropriations and a sufficient number of meritorious applications. NINDS intends to commit up to $1.6M to fund 3-5 awards contingent upon NIH appropriations and a sufficient number of meritorious applications.

NOT-AI-23-034 Pre-Solicitation Notice: Rational Systemic Characterization and Selection of Adjuvants for HIV Vaccine Candidates (R-CASA), RFP: 75N93022R00017. The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), of the Department of Health and Human Services (DHHS) supports research related to the basic understanding of microbiology and immunology leading to the development of vaccines, therapeutics, and medical diagnostics for the prevention, treatment, and diagnosis of infectious and immune-mediated diseases. The NIAID, has a requirement for assessment of HIV immunogens-adjuvants formulations to allow better prediction of immune response prior to transitioning into clinical trials. Contractors supported through the R-CASA program will be expected to: 1) generate standardized protocols and endpoint assays for rational and systematic vaccine formulation screening and 2) apply those protocols and assays to screen immunogens and adjuvants formulations, and 3) screen additional immunogens and adjuvants at the direction of NIAID. The efforts will delineate a standardized set of assays, algorithms and signatures that can identify correlates of protection (immune biomarker(s) associated with vaccine efficacy), and which maximize the successful transition of immunogen-adjuvant formulations from the pre-clinical testing to First-in-Humans (FIH) trials. Henceforth, the goal would be to select adjuvants via qualified parameters and not by convenience or availability. Contractors supported through the R-CASA program will be expected to: 1) generate and propose standardized protocols and endpoint assays for rational and systematic down-screening of HIV immunogen-adjuvant formulations, 2) apply those protocols and assays to screen HIV immunogen-adjuvant formulations, and 3) screen additional immunogens and adjuvants at the direction of NIAID. The efforts will delineate a standardized set of assays for biochemical and immunologic characterization of HIV immunogen-adjuvant formulations, down-selection workflow and go-no-go criteria to maximize the successful transition of immunogen-adjuvant formulations from the pre-clinical testing to First-in-Humans (FIH) trials. Henceforth, the overarching goal is to select HIV immunogen-adjuvant formulations via qualified parameters and not by convenience or availability.
It is anticipated that one to two cost reimbursement, completion type contracts will be awarded for a 5-year period of performance beginning on or about June 3, 2024 through June 2, 2029. Any responsible offeror may submit a proposal which shall be considered by the Agency. This BAA will be available electronically end February 21, 2023 and may be accessed through SAM.gov.

Notices of Special Interest (NOSI)

NOT-AI-23-031 Advancing Research Needed to Develop a Coccidioidomycosis (Valley fever) Vaccine. The purpose of this Notice of Special Interest (NOSI) is to highlight NIAID's interest in supporting research in the areas outlined in the NIAID Strategic Plan For Research To Develop A Valley Fever Vaccine. The proposed research should have clear relevance to the strategic priorities defined in the strategic plan, which encompasses three major research areas: 1) address gaps in Coccidioides basic research to support the development of a vaccine; 2) develop tools and resources to support vaccine development; 3) develop and advance vaccines to prevent coccidioidomycosis. Submit applications for this initiative using one of the FOAs listed in the NOSI. This notice applies to application receipt dates on or after April 5, 2023, and subsequent receipt dates through January 14, 2026.

NOT-CA-23-044 Administrative Supplement to Support Health Policy Research in Cancer Prevention and Control. The purpose of this Notice is to encourage ***currently funded NCI extramural investigators*** to apply for administrative supplements to support cancer-related policy research including empirical evaluation of policy or evaluation of policy implementation or dissemination methods. The goals of these administrative supplements on cancer-related health policy are to: 1) generate new or utilize secondary data that operationalize policies hypothesized to affect cancer control at the geographic, provider, patient, and/or temporal level; 2) examine the effects of existing policies and/or simulate the potential effects of new policies, with an emphasis on understanding health disparities by examining differential impacts on disadvantaged groups; 3) identify effective community-engaged strategies for dissemination or implementation of evidence to inform policymaking. The budget cannot exceed $125,000 in total costs for the entire allowable 1-year project period of the application/award. Administrative supplement applications are limited to currently funded R01, R21, R33, R37, P01, P20, P30, P50, U01, UH3, U19, UM1, U54, and UG1 projects supported by NCI. Applications for this initiative must be submitted using the following opportunity or its subsequent reissued equivalent.

- PA-20-272 - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

NOT-CA-23-046 Administrative supplements to conduct systematic evidence reviews on the clinical utility of cancer-site specific polygenic risk scores (PRS) for cancer risk assessment. The purpose of this Notice is to encourage ***currently funded NCI extramural investigators*** to apply for administrative supplements to conduct systematic evidence reviews assessing the state of the science on the clinical utility (CU) of cancer-site specific polygenic risk scores (PRS) for cancer risk assessment and inform future trials and research directions for clinical translation and implementation. The goals of this supplement opportunity are to 1) identify the potential for CU of cancer-site specific PRS for cancer risk assessment; 2) describe the state of the science in terms of cancer-site specific PRS development and evaluation; 3) assess the current evidence for efficacy and/or effectiveness of PRS CU and potential benefits and harms of their clinical use (including consideration of available screening and prevention interventions based on risk); and 4) propose criteria and optimal study designs and methods for which PRS are candidates for evaluation of CU through clinical trials. *Submissions must be received by April 21, 2023,* at 5:00 PM local time of applicant organization for FY 2023 funding. The budget should not exceed $150,000 in total costs.
At least one full year on the parent grant must remain at the time of funding (September 2023). The application budget is limited to 1 year only. Applications for this initiative must be submitted using the following opportunity or its subsequent reissued equivalent.

- PA-20-272 - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

NOT-HL-23-080 Enhancing Research on Deciphering Mechanisms of COVID-19-Associated Coagulopathy. This Notice of Special Interest (NOSI) aims to accelerate a comprehensive understanding of the mechanisms of COVID-19-Associated Coagulopathy (CAC) which are provoked by vascular endothelial cell injury, hyperimmune responses, and hypercoagulability at genomic, molecular, and cellular levels. Knowledge obtained from such studies may be applied to the future design of early diagnostics and effective treatment for high-risk patients as well as enable CAC research findings to be applied to on-going COVID-19 clinical trials. This notice applies to due dates on or after June 5, 2023 and subsequent receipt dates through July 5, 2025. This NOSI expires on July 6, 2025, thus no applications will be accepted on or after July 6, 2025. Applications proposing clinical trials are not appropriate for this NOSI, will be deemed nonresponsive, and will not proceed to review. Applications for this NOSI must be submitted using the following opportunity or its reissue:

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

NOT-RM-23-005 Research supplements to promote workforce diversity and enhance utility and use of Common Fund datasets. The NIH has a strong interest in the diversity of the NIH-funded research enterprise (see NIH notice NOT-OD-20-031) and encourages institutions to diversify their scientific workforce by enhancing the participation of individuals from diverse backgrounds, including those groups identified as underrepresented in the biomedical, clinical, behavioral, and social sciences. This notice encourages eligible awardees to apply for administrative supplements in response to PA-21-071 (or any reissue of this announcement through the expiration date of this NOSI) with the goal of promoting innovative research that enhances the utility and/or use of selected Common Fund datasets. Providing these supplements may help enhance the utility and use of Common Fund data, promote the diversity of researchers using data generated by programs supported by the NIH Common Fund and, more broadly, may help promote the diversity of the scientific research workforce, which is a key component of the NIH strategy to identify, develop, support, and maintain the quality of our scientific human capital. applications must be submitted on or before ***June 30, 2023***, by 5:00 PM local time of applicant organization. **Late applications to this NOSI will not be accepted.** The parent award must have at least 12 months remaining in its approved project period as of September 1, 2023; and may not be in a terminal no-cost extension. Applications for this initiative must be submitted using the following opportunity or any reissue of this announcement through the expiration date of this NOSI:

- PA-21-071 Research Supplements to Promote Diversity in Health-Related Research (Admin Supp - Clinical Trial Not Allowed)

Parent Announcements

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

- **PA-20-185** NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- **PA-20-184** Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)
- **PA-20-183** Research Project Grant (Parent R01 Clinical Trial Required)

- **PA-20-200** NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
- **PA-20-195** NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)
- **PA-20-194** NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)
- **PA-20-196** NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

Funding Opportunity Announcements (FOA)

1. Genomics Centers for Infectious Diseases (U19 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-AI-23-015** **Type: U19**

Application Due Date: June 02, 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 solicit applications for a Genomic Centers for Infectious Disease (GCID) Program. This renewal initiative will support GCIDs to advance the development and use of innovative genomic and bioinformatics tools with an emphasis on human pathogens and their interactions with the host and microbiome, and to rapidly respond to emerging needs, especially during disease outbreaks. The Program will address basic, translational, and clinically relevant questions in host-pathogen interactions and support the development of genomics-based tools to diagnose, prevent, and treat infectious diseases. In the event of an infectious disease outbreak, the GCIDs will be poised to leverage the expertise and resources within the network to assist in a coordinated research response.

Budget: NIAID intends to commit $9.24 million in 2024 to fund 2-3 awards. Application budgets are not expected to exceed $2.85 million in direct costs per year, which includes up to $50,000 in direct costs for one Collaborative Pilot Project per year. Application budgets need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum period is 5 years.

2. Leveraging Big Data Science to Elucidate the Mechanisms of HIV Activity and Interaction with Substance Use Disorder (R01 Clinical Trials Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DA-24-008** **Type: R01**

Application Due Date: August 10, 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 encourage research using data science and computational approaches to generate new insights into mechanisms and consequences of the interaction of HIV and addictive drugs. The development and application of novel computational, bioinformatic, statistical, and analytical approaches to mine big data sets will advance knowledge of the effects of addictive drugs on viral activity, latency, and disease progression, as well as new aspects of addiction biology.

Budget: NIDA intends to commit up to $1M in FY 2024 to fund 2-3 awards for this and the companion R21 FOA (RFA-DA-24-009). NLM intends to commit up to $1M in FY 2024 to fund up to 5 awards for this and the companion R21 FOA (RFA-DA-24-009). Application budgets are limited to direct costs of $350k. Project periods cannot exceed 5 years.

3. Natural History and Biomarker Studies of Rare Neurodegenerative Diseases (U01) Clinical Trials Optional

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-028** **Type: U01**

Application Due Date: May 4, 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 funding opportunity announcement (FOA) is to support efficient natural history studies and/or biomarker studies that fill unmet needs for rare neurodegenerative diseases for children and adults. Through the support of prospective natural history and/or biomarker studies with high quality and interpretable data elements, FDA expects to address critical knowledge gaps, remove major barriers to progress in the field, exert a significant and broad impact on a specific rare neurodegenerative disease or multiple rare neurodegenerative diseases with similar pathophysiology, and facilitate rare disease product development.

Budget: FDA/OOPD intends to fund approximately $2,500,000 for FY 2023 in support of this grant program. Application budgets need to reflect the actual needs of the proposed project and should not exceed $400,000 in total costs (direct and indirect) and maximum 4 years of support.

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