

# **NIH** funding opportunities



Faculty of Medicine and Health Sciences: Research Development and Support 19 Sep 2023 (#32)

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

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

- 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 application, taking into consideration other responsibilities
- 5. Time for internal review

Before starting your application, attend the 1) Generic Grant Writing Workshop and then the 2) NIH Grant Writing Workshop.

# **Important Notices**

NOT-OD-23-182 NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements. This is not new policy. The policy clarification is intended to remind NIH recipients that they must comply with longstanding policy requirements as outlined in NIH Grants Policy Statement Chapter 15, Consortium Agreements, which implements 2 CFR 200.332(a)(5) and 45 CFR 75.352(a)(5) as a standard term and condition of all NIH awards. These regulations state that subaward agreements must have a "requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." Regulations require primary recipients to have effective internal controls in place to ensure that the awards are being carried out in compliance with terms and conditions (45 CFR 75.303) and they must monitor the activities of subrecipients as necessary to ensure that the subaward is used for authorized purposes which include the need to review and monitor financial and performance reports. Primary recipients acting as pass-through entities "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award..." (45 CFR 75.364). A provision requiring the subrecipient to provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.

**Learn about NIH subaward requirements:** Join experts from the NIH Office of Policy for Extramural Research Administration (OPERA) for a walk-through of subaward agreements.

• Register: NIH Subaward Requirements webinar

• Date: October 17, 2023

NOT-CA-23-091 Notice of Pre-Application Webinar for PAR-23-244: Population Approaches to Reducing Alcohol-related Cancer Risk (R01 Clinical Trial Optional). The pre-application webinar, to be held on Thursday, October 19, 2023, from 2:00 pm - 3:00 pm ET, will include an overview of the notice of funding opportunity (NOFO) as well as specific requirements for applications submitted in response to the NOFO. *Registration for the webinar is required.* Register at <a href="https://cancercontrol.cancer.gov/brp/events/pre-application-webinar-population-approaches-reducing-alcohol-related-cancer-risk">https://cancercontrol.cancer.gov/brp/events/pre-application-webinar-population-approaches-reducing-alcohol-related-cancer-risk</a>.

NOT-HL-23-111 Notice of Technical Assistance Webinar and FAQs for NOT-HL-23-113 (NOSI): Promoting implementation research to address HIV-associated comorbidities and risk factors within well-established longitudinal studies (R01 CT Optional). A pre-submission technical assistance webinar is being offered Monday, October 23, 2023, at 2:00 pm EDT to inform potential applicants about NOT-HL-23-113. This will include a review of the purpose and objectives of the Notice. Register in advance for this meeting: https://nih.zoomgov.com/meeting/register/vJltf--pqjwrExfobQjbu1F3Q2qbOWZcQEo

<u>NOT-MH-23-375</u> Consolidated Notice on NIMH Clinical Trials Policies. This notice replaces <u>NOT-MH-20-105</u> and clarifies NIMH support for clinical trials involving preventive, therapeutic, and services interventions. NIH defines a clinical trial as, "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes" (<u>NOT-OD-15-015</u>). Please see additional information on the <u>Support for Clinical Trials at NIMH</u> webpage.

NOT-TW-23-007 Notice of NIH Participation in the NIH-NSF Ecology and Evolution of Infectious Diseases Program. The purpose of this Notice is to announce that the NIH is collaborating on the multi-agency funding opportunity, the Ecology and Evolution of Infectious Diseases (EEID) (NSF 23-616). This Notice updates and supersedes the previous Guide Notice. The Fogarty International Center (FIC), the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health (NIH), the United States Department of Agriculture (<u>USDA</u>), and the National Science Foundation (<u>NSF</u>) will continue this multi-year collaboration that supports research on the ecological, evolutionary, organismal, and social drivers that influence the transmission dynamics of infectious diseases. The central theme of submitted EEID projects must be quantitative or computational understanding of pathogen transmission dynamics. The intent is discovery of principles of infectious disease (re)emergence and transmission and testing mathematical or computational models that elucidate infectious disease systems. Projects should be broad, interdisciplinary efforts that go beyond the scope of typical studies. They should focus on the determinants and interactions of transmission among humans, non-human animals, and/or plants. This includes, for example, the spread of pathogens; the influence of environmental factors such as climate; the population dynamics and genetics of reservoir species or hosts; the feedback between ecological transmission and evolutionary dynamics; and the cultural, social, behavioural, and economic dimensions of disease transmission. Research may be on zoonotic, environmentally borne, vector-borne, or enteric diseases of terrestrial, freshwater, or marine systems and organisms, including diseases of animals and plants, at any scale from specific pathogens to inclusive environmental systems. Proposals for research on disease systems of public health concern to Low- or Middle-Income Countries (LMICs) are strongly encouraged, as are disease systems of concern in agricultural systems. Investigators are encouraged to develop the appropriate multidisciplinary team, including for example, modelers, ecologists, bioinformaticians, genomics researchers, social scientists, economists, epidemiologists, evolutionary biologists, entomologists, parasitologists, microbiologists, bacteriologists, virologists, pathologists or veterinarians, with the goal of integrating knowledge across disciplines to enhance our ability to predict and control infectious diseases. Applications must be submitted to the NSF in accordance with (NSF 23-616), and not to the NIH. Following a jointly-conducted initial peer review of these applications, meritorious proposals may be recommended for funding by NSF, NIH, or USDA, at the option of the agencies. For those applications that are selected for funding by participating NIH Institutes and Centers, the PD/PI will be invited to submit the proposal in an NIH-approved format directly to the Center for Scientific Review (<a href="http://www.csr.nih.gov/">http://www.csr.nih.gov/</a>) of the NIH for further processing. Subsequent submission and grant administration procedures will be in accordance with NIH policy. Potential applicants are strongly encouraged to contact NIH or NSF program officials prior to submitting an application. The deadline for submission to NSF is November 15, 2023. In subsequent years, the deadline is the third Wednesday in November. Detailed information about this program can be obtained on the

- NSF website at http://www.nsf.gov/funding/pgm\_summ.jsp?pims\_id=5269&org=DEB&from=home
- NIH website at <a href="http://www.fic.nih.gov/programs/Pages/ecology-infectious-diseases.aspx">http://www.fic.nih.gov/programs/Pages/ecology-infectious-diseases.aspx</a>.

#### **Parent Announcements**

NOT-OD-23-105 Notice to Extend Parent R01/R03/R21 Parent Notices of Funding Opportunities. Current Key Dates Expiration Date: May 8, 2023. Modified Expiration Date: May 8, 2024

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)
- <u>PA-20-196</u> NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

# **Notice of Special Interest**

NOT-HL-23-106 Advancing Rheumatic Heart Disease Research (R01). This Notice of Special Interest (NOSI) seeks to advance Rheumatic Heart Disease (RHD) research. *There is a critical need to reduce RHD burden within low- and middle-income countries and low-resource settings in high-income countries.* The NOSI calls for research proposals across the translational science spectrum (e.g., basic science, clinical research, and implementation and dissemination studies) within endemic settings to improve health outcomes. This notice applies to due dates on or after February 5, 2024 and subsequent receipt dates through January 7, 2027. Submit applications for this initiative using one of the notices or any reissues listed in the NOSI of these announcements through the expiration date of this notice.

# **Notice of Funding Opportunity (NOFO)**

 Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)

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

Hyperlink: PA-23-271

Type: Parent F31-Diversity

Application Due Date: December 08, 2023 through to September 07, 2025. 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.

Announcement: The purpose of this Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research award is to enhance the diversity of the health-related research workforce by supporting the research training of predoctoral students from diverse backgrounds, including those from groups that are underrepresented in the biomedical, behavioural, or clinical research workforce. Through this award program, promising predoctoral students will obtain individualized, mentored research training from outstanding faculty sponsors while conducting well-defined research projects in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist. This Notice of Funding Opportunity (NOFO) does not allow applicants to propose to lead an independent clinical trial, but does allow applicants to propose research experience in a clinical trial led by a sponsor or co-sponsor.

**Budget:** Award budgets are composed of stipends, tuition and fees, and institutional allowance. Individuals may receive up to 5 years of aggregate Kirschstein-NRSA support at the predoctoral level (up to 6 years for dual degree training, e.g., MD/PhD), and up to 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of support from institutional training grants (e.g., T32) and an individual fellowship award. See <a href="https://researchtraining.nih.gov/resources/policy-notices">https://researchtraining.nih.gov/resources/policy-notices</a>.

#### 2. HEAL Initiative: Developing an Evidence Base for Co-Occurring OUD-AUD Interventions (R01 Clinical Trial Optional)

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

Hyperlink: RFA-AA-23-005

Type: R01

**Application Due Date: December 14, 2023.** 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.

Announcement: This notice of funding opportunity (NOFO) seeks to support studies that will inform safe and effective medication-assisted, psychosocial, and complementary interventions for people with co-occurring Opioid Use Disorder (OUD) and Alcohol Use Disorder (AUD). Alcohol increases lethal opioid overdose risk. As a result, treatment providers may under-prescribe or be reluctant to provide opioid agonist therapies (OATs) such as methadone and buprenorphine to people with OUD who also have AUD or misuse alcohol. There is also scant research on non-pharmacological therapies for people with OUD-AUD. Reciprocal relationships between opioid use and alcohol use has been observed for OUD-AUD patients such that reduced opioid intake may result in increased drinking which heightens opioid relapse and overdose risk and suggests an urgent need for targeted therapies in this population. Research projects dedicated to OUD treatment and prevention, while not excluding subjects who drink, seldom explicitly recruit subjects with AUD. The purpose of this NOFO is to support secondary analysis of data from relevant clinical projects and archives, and to support new hypothesis-clarifying studies to identify how people with OUD-AUD are being treated and associated treatment outcomes, identify challenges for treating people with OUD-AUD, and formulating best treatment practices for this population.

**Budget:** The NIH HEAL (Helping to End Addiction Long-term) Initiative intends to commit an estimated total of \$1 million to fund 2-3 awards in FY 2024. Application budgets should not exceed \$250,000 direct costs per year and should be consistent with the complexity and needs of the proposed project. Annual inflationary increases are not allowed. Applications may request up to 3 years of support.

#### 3. HEAL Initiative: Developing an Evidence Base for Co-Occurring OUD-AUD Interventions (R34 Clinical Trial Optional)

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

Hyperlink: RFA-AA-23-006 Type: R34

**Application Due Date: December 14, 2023.** 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.

Announcement: This notice of funding opportunity (NOFO) seeks to support studies that will inform safe and effective medication-assisted, psychosocial, and complementary interventions for people with co-occurring Opioid Use Disorder (OUD) and Alcohol Use Disorder (AUD). Alcohol increases lethal opioid overdose risk. As a result, treatment providers may under-prescribe or be reluctant to provide opioid agonist therapies (OATs) such as methadone and buprenorphine to people with OUD who also have AUD or misuse alcohol. There is also scant research on non-pharmacological therapies for people with OUD-AUD. Reciprocal relationships between opioid use and alcohol use has been observed for OUD-AUD patients such that reduced opioid intake may result in increased drinking which heightens opioid relapse and overdose risk and suggests an urgent need for targeted therapies in this population. Research projects dedicated to OUD treatment and prevention, while not excluding subjects who drink, seldom explicitly recruit subjects with AUD. The purpose of this NOFO is to support clinical research project development, including piloting study design and research protocols, subject recruitment, and initiating data collection and analysis pertinent to studying treatment practices for people with OUD-AUD.

**Budget:** The NIH HEAL (Helping to End Addiction Long-term) Initiative intends to commit an estimated total of \$1 million to fund 2-3 awards in FY 2024. Application budgets should not exceed \$250,000 direct costs per year and should be consistent with the complexity and needs of the proposed project. Annual inflationary increases are not allowed. Applications may request up to 3 years of support.

## 4. Computational Models of Influenza Immunity (U01 Clinical Trial Not Allowed)

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

Hyperlink: RFA-AI-23-056 Type: U01

**Application Due Date: January 26, 2024.** 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.

Announcement: This Notice of Funding Opportunity (NOFO) invites applications for the Computational Models of Influenza Immunity (CMII) Cooperative Agreement Program. The program will employ computational modeling and immunologic studies to advance our understanding of the requirements for improving anti-influenza immunity, including inducing broad immune protection and enhancing immune durability. This program will help inform design of universal or improved seasonal flu vaccines. Projects may lead to a better understanding of how pre-existing immunity and repeat exposures (natural infection and/or vaccines) shape an individual's immune "landscape." Predictive modeling of adjuvants/vaccine formulations and experimental validation supported by this program should lead to enhanced host immune responses and universal or improved seasonal influenza vaccine efficacy.

**Budget:** NIAID intends to commit \$8 million dollars in FY 2025 to fund six to eight (6-8) awards. Application budgets are not expected to exceed \$750,000 direct costs per year but must 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.

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