NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 15 Sep 2023 (#31)

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

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-OD-23-173 Findings of Research Misconduct. Findings of research misconduct have been made against Surangi (Suranji) Jayawardena, Ph.D. (Respondent), who was an Assistant Professor of Chemistry, University of Alabama in Huntsville (UAH). Respondent engaged in research misconduct in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R21 AI154256, R21 AI152064, R21 AI149142, and R15 AI146978 submitted to the National Institute of Allergy and Infectious Diseases (NIAID). Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating data by reusing data from the same source and falsely relabelling the data as representing different experimental conditions with antibiotic particles or bacteria.

NOT-OD-23-161 NIH Application Instruction Updates – Data Management and Sharing (DMS) Costs. Effective for applications submitted for due dates on or after October 5, 2023, NIH will no longer require the use of the single DMS cost line item. NIH recognizes that DMS costs may be requested in many cost categories. Therefore, in line with our standard budget instructions, DMS costs must be requested in the appropriate cost category, e.g., personnel, equipment, supplies, and other expenses. While the single cost line item is no longer required, NIH will require applicants to specify estimated DMS cost details within the "Budget Justification" attachment.

NOT-OD-23-165 Notice of NIH Participation in the National Science Foundation Solicitation NSF 23-614: Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science. The purpose of this Notice is to announce the collaboration between the NIH and the National Science Foundation (NSF) on an interagency funding opportunity, NSF-23-614, Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science. The Smart Health program supports innovative, high-risk/high-reward research with the promise of disruptive transformations in biomedical and public health research. Proposals submitted must make fundamental contributions to two or more disciplines, such as computer or information sciences, engineering, social, behavioural, biomedical, cognitive and/or economic sciences, to improve the fundamental understanding of biomedical and health related processes and address a key health problem. Traditional disease-centric medical, clinical, pharmacological, biological, or physiological studies and evaluations are outside the scope of this solicitation.

In addition, fundamental biological research with humans that also does not advance other fundamental science or engineering areas is out of scope for this program.
The solicitation aims to address technological and data science challenges that require fundamental research and development of new tools, workflows, and methods across many dimensions including, but not limited to:

- Fairness and Trustworthiness
- Transformative Analytics in Biomedical and Behavioral Research
- Next Generation Multimodal and Reconfigurable Sensing Systems
- Cyber-Physical Systems
- Robotics
- Biomedical Image Interpretation
- Unpacking Health Disparities and Health Equity

The general interests of the participating NIH Institutes, Centers, and Offices are outlined in the notice. **Anticipated Funding Amount:** $15,000,000 to $20,000,000. Projects will be funded for up to a four-year period and for up to a total of $300,000 per year. Budgets should include travel funds to attend one Smart Health PI meeting annually for the project PIs, co-PIs and other team members as appropriate from all collaborating institutions. For NIH, indirect costs on foreign subawards/subcontracts will be limited to eight (8) percent. **Due dates:** November 09, 2023; October 03, 2024; October 3, 2025

NOT-OD-23-167 Notice of Pre-Application Webinar for NIH – National Science Foundation (NSF) Initiative: Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science. This Notice is to inform prospective applicants of a pre-application webinar for the NIH-NSF Initiative: Smart Health and Biomedical Research in the Era of Artificial Intelligence and Advanced Data Science. During the webinar NIH and NSF staff will provide an overview of the NSF-NIH Smart Health solicitation (NSF-23-614) and NIH Notice (NOT-OD-23-165) unique program features and requirements, the application review process, and answer questions from prospective applicants. Registration is required.
The webinar will be hosted through Zoom.
Date: September 25, 2023
Time: 3pm – 4pm Eastern Time
Registration Link: https://nsf.zoomgov.com/webinar/register/WN_ctCzc3alRQyXZAX0rS1Fww

NOT-AG-23-051 Notice of Pre-Application Webinar for Funding Opportunity PAR-23-258, "Analytical and Clinical Validation of Biomarkers for Alzheimer's Disease (AD) and AD-Related Dementias (ADRD) (U01 Clinical Trial Optional)". The purpose of this Notice is to inform potential applicants that the National Institute on Aging (NIA) will hold two informational pre-application webinars for Notice of Funding Opportunity (NOFO) PAR-23-258, "Analytical and Clinical Validation of Biomarkers for Alzheimer's Disease (AD) and AD-Related Dementias (ADRD) (U01 Clinical Trial Optional)" on **Thursday, September 14, at 1:00 PM ET** and **Thursday, September 21, at 1:00 PM ET.** Prospective applicants are required to register in advance using the registration link: Zoom Registration Link. Prospective applicants are strongly encouraged to submit their questions or comments to yuan.luo@nih.gov in advance of the webinar.

NOT-DE-23-013 Notice to Extend Expiration Date for NOFO PAR-21-084 " National Institute of Dental and Craniofacial Research (NIDCR) Small Grant Program for New Investigators (R03 Clinical Trial Not Allowed)" The purpose of this Notice is to inform interested applicants that the expiration date for the PAR-21-084, NIDCR Small Grant Program for New Investigators (R03 Clinical Trial Not Allowed) by two application cycles. Due to the extension, **Part I. Key Dates, Expiration Date** has been modified as follows: **Expiration Date** *Modified to Read* ***September 12, 2024***

NOT-OD-23-177 Notice of Change: Extension of AIDS Due Date for PA-21-051 "Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellows (Parent F31)" The purpose of this Notice is to inform potential applicants of a change to the AIDS application due date for PA-21-051 "Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31)". To provide the applicant community adequate time to develop responsive applications, the September 7, 2023 AIDS application due date has been extended to October 10, 2023. The deadline has been extended for the September 7, 2023 AIDS applications only.

NOT-HL-23-114 Notice of Intent to Publish a Funding Opportunity Announcement for NHLBI Program Project Applications (P01 Clinical Trials Optional). The National Heart, Lung and Blood Institute (NHLBI) intends to publish a

reissue of the notice of funding opportunity (NOFO) PAR-21-088 NHLBI Program Project Applications (P01 Clinical Trial Optional). This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects. The National Heart, Lung, and Blood Institute (NHLBI) Program Project Grant (P01) supports research related to fundamental processes and diseases of the heart, blood and lymphatic vessels, lungs, and blood, including transfusion medicine, blood resources, and sleep disorders other programs including implementation science, health disparities, and translation research that address the mission of the Institute. This NOFO requires a minimum of three interrelated research projects that investigate a complex biomedical theme or research question. The projects may be supported by core units, if justified, to facilitate economy of effort, space, and equipment. The NHLBI provides support for Program Project Grants (PPGs) in the belief that collaborative research efforts can accelerate the acquisition of knowledge more effectively than a simple aggregate of research projects that have no interaction or thematic integration. NHLBI is particularly interested in encouraging new scientific directions in PPGs. Use of the P01 activity code is viewed as an opportunity to attract scientists who have not traditionally been supported by the NHLBI. Further, the PPG environment presents an opportunity for emerging scientific leaders to gain insight into how to lead a successful scientific Program, and applicants will have the opportunity to include a project led by an Early Stage Investigator (ESI). All projects in the Program must be interrelated and have objectives that address a central theme within the scientific mandate of the NHLBI. **First Estimated Application Due Date:** January 25, 2024.

NOT-OD-23-174 Notice of Intent to Publish a Funding Opportunity Announcement for Stephen I. Katz Early-Stage Investigator Research Project Grant (R01 Clinical Trial Not Allowed). NIH Institutes and Centers intends to reissue the Stephen I. Katz Early-Stage Investigator Research Project Grant. The Katz award supports an innovative project that represents a change in research direction for an early-stage investigator (ESI) and for which no preliminary data exist. Applications submitted to this Notice of Funding Opportunity (NOFO) must not include preliminary data. See previous NOFO PAR-21-038. This NOFO is appropriate for ESIs who wish to initiate a research project in an area different from their previous research focus and/or training experience, and therefore have not produced preliminary data. Applications must include a separate attachment describing the change in research direction. PD/PI's who wish to proposed research projects consistent with their past work or training and/or supported by preliminary data, should apply to other NOFOs allowing for preliminary data. **First Estimated Application Due Date:** January 26, 2024.

NOT-OD-23-175 Notice of Intent to Publish a Funding Opportunity Announcement for Stephen I. Katz Early Stage Investigator Research Project Grant (R01 Basic Experimental Studies with Human Required). The Stephen I. Katz Early-Stage Investigator Research Project Grant supports an innovative project that represents a change in research direction for an early-stage investigator (ESI) and for which no preliminary data exist. See previous NOFO PAR-21-039. Applications submitted to this Notice of Funding Opportunity (NOFO) must not include preliminary data. Applications must include a separate attachment describing the change in research direction. The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions. This Funding Announcement is for basic science experimental studies involving humans, referred to in NOT-OD-18-212 as "prospective basic science studies involving human participants." These studies fall within the NIH definition of a clinical trial and also meet the definition of basic research. Types of studies that should submit under this notice include studies that prospectively assign human participants to conditions (i.e., experimentally manipulate independent variables) and that assess biomedical or behavioral outcomes in humans for the purpose of understanding the fundamental aspects of phenomena without specific application towards processes or products in mind. Studies that are NOT conducted with specific applications toward processes or products in mind and which also do not meet the clinical trial definition should submit under the appropriate 'Clinical Trial Not Allowed' NOFOs. This Notice is being provided to allow potential applicants sufficient time to develop meaningful collaborations and responsive projects. **First Estimated Application Due Date:** January 26, 2024.

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

Notice of Special Interest

NOT-AG-23-037 Investigation of Biomolecular Condensates in Aging and Alzheimer's Disease (AD) and AD-related Dementias (ADRD). This NOSI invites research that investigates cell-specific mechanisms of biomolecular condensates (BMC) formation and function, investigate the role the nuclear pore complex plays in regulating BMC formation and cell specific impact, and exploit existing tools or develop new tools to study the neurobiology of BMCs in aging and AD/ADRD. This notice applies to due dates on or after October 5, 2023 and subsequent receipt dates through November 13, 2024. Submit applications for this initiative using one of the NOFOs listed or any reissues of these announcements through the expiration date of this notice.

NOT-AA-23-018 Epidemiology and Prevention in Alcohol Research. The purpose of this NOSI is to solicit applications to advance basic, applied, translational, and methodological research on the epidemiology and prevention of hazardous alcohol consumption and related behaviours, alcohol use disorder, alcohol-related mortality and morbidity, and other alcohol-related problems and consequences. Applicants must select the IC and associated notice of funding opportunity (NOFO) to use for submission of an application in response to this NOSI. Applicants using NIH Parent Announcements (listed below) will be assigned to those ICs on this NOSI that have indicated those NOFOs are acceptable and based on usual application-IC assignment practices. This notice applies to due dates on or after October 5, 2023 and subsequent receipt dates through September 6, 2026.

NOT-HL-23-113 Promoting implementation research to address HIV-associated comorbidities and risk factors within well-established longitudinal studies (R01 Clinical Trial Optional). This NOSI seeks to support dissemination and implementation (D&I) research proposals leveraging well-established longitudinal studies of people living with HIV (PLWH) to increase the acceptability, feasibility, implementation, scale-up, scale-out, and sustainability of evidence-based interventions (EBIs) that target comorbid conditions and diseases. ***This NOSI hopes to promote new or existing collaborative efforts between observational, interventional, and D&I scientists, which is a crucial next step to ensure maximal public health impact of clinical trial and cohort studies.*** Investigators are encouraged to utilize lessons learned from ongoing or legacy longitudinal studies alongside other data sources to strengthen D&I research projects targeting PLWH. Further, there are opportunities to evaluate both the effectiveness and D&I outcomes of the selected EBIs, based on the level evidence to support their implementation. This notice applies to due dates on or after October 5, 2023 and subsequent receipt dates through September 7, 2026. Submit applications for this initiative using PAR-22-105 - Dissemination and Implementation Research in Health (R01 Clinical Trial Optional).

NOT-CA-23-089 Mechanisms Driving Obesity and Prostate Cancer Risk. The purpose of this NOSI is to promote studies examining the mechanisms by which obesity drives aggressive prostate cancer (PCa) risk. About 80% of overall PCa is non-aggressive. The biologic mechanisms driving both overall and aggressive PCa are uncertain. The identification of differences in the mechanisms driving aggressive vs. overall (mostly non-aggressive) disease are critical to optimizing clinical care among men who develop the disease. PCa has an outsized impact on African Americans who are more likely to develop aggressive disease and twice as likely to die from the disease compared to other racial and ethnic groups. This NOSI applies to Application Due Dates on or after ***October 5, 2023***, and subsequent receipt dates. Submit applications for this initiative using one of the notices listed in the NOSI. *Please note that each NOFO has a specific expiration date.*

NOT-DA-24-012 Xylazine: Understanding Its Use and the Consequences. The purpose of this NOSI is to encourage research on the prevalence and consequences of xylazine co-use with opioids or opioid/stimulant combinations. This NOSI also encourages research into how xylazine impacts treatment of opioid use disorders and overdose. Xylazine is an alpha-2 adrenergic receptor agonist with sedative and analgesic properties that is FDA-approved for veterinary use. Xylazine can be mixed (adulterated) with illegal drugs, such as fentanyl, heroin, cocaine, either to enhance drug effects or increase street value by increasing their weight. When used in combination with opioids/stimulants, xylazine is known to produce synergistic effects in analgesic activity and respiratory depression, as well as other deleterious effects, such as vascular constriction and severe skin lesions/infection. Whether and how xylazine adulteration affects

the treatment of opioid overdose or opioid use disorder is not known. There are no FDA-approved agents to reverse xylazine effects in humans, although veterinary adrenergic antagonists have been used for emergency treatment of accidental xylazine injection. This notice applies to due dates on or after October 16, 2023, and subsequent receipt dates through January 8, 2025. Submit applications for this initiative using one of the NOFOs listed in the NOSI or any reissues of these announcements through the expiration date of this notice.

NOT-OD-23-166 Research on Family Support and Rejection in the Health and Well-Being of sexual and gender minority (SGM) Populations. The mission of the NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH is committed to supporting research that will increase scientific understanding of health and well-being and lead to the development of effective evidence-based strategies, interventions, and services for people of all ages and backgrounds. NIH places a high priority on research with individuals and populations at increased risk for adverse health outcomes, and especially those who have received insufficient attention from the scientific research enterprise. To this end, and in response to Executive Order 14075 on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, this Notice of Special Interest (NOSI) announces an interest in research on the impact and consequences of family support and family rejection on the health and well-being of sexual and gender minority (SGM, defined for NIH purposes in NOT-OD-19-139) individuals across the life course. The goal of this NOSI is to boost research on the impact and consequences of family rejection and family support on the health and well-being of SGM persons across the life course. Research proposed under this NOSI may include behavioral, social, clinical, implementation, basic, complementary, integrative, and any other relevant research approaches that probe the influences of family rejection, acceptance, affirmation, support, and belonging on the immediate and long-term health and health outcomes of SGM individuals at any life stage. Studies may also include prevention, intervention, and service delivery research that seeks to prevent, reduce, or treat adverse effects associated with family rejection and/or improve or maintain SGM people's health. Applicants must select the IC and associated NOFO 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 notice of funding opportunity (NOFO). Non-responsive applications will be withdrawn from consideration for this initiative. In addition, applicants using NIH Parent announcements will be assigned to those ICs on this NOSI that have indicated those NOFOs are acceptable and based on usual application-IC assignment practices. **Expiration Date:** May 08, 2026. Investigators are strongly encouraged to reach out to the relevant contacts listed in the Inquiries section of this NOSI to determine whether the NOFO and funding mechanism selected are appropriate for the proposed research. DPCPSI offices may consider co-funding meritorious applications depending on the alignment with office-specific missions and priorities and the availability of funds.

Notice of Funding Opportunity (NOFO)

1. Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship

Letter of Intent: 30 days prior to the application due date **Hyperlink: PA-23-272** **Type: Parent F31**

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 the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31) award is to enable promising predoctoral students to obtain individualized, mentored research training from outstanding faculty sponsors while conducting dissertation research in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training must reflect the candidate's dissertation research project and 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. Candidates for the F31 must be candidates for the PhD degree and have identified a dissertation research project and sponsor(s). The Kirschstein-NRSA Individual Predoctoral Fellowship (F31) program may provide up to five years (typically 2-3 years) of support for research training which leads to the PhD or equivalent research degree, the combined MD/PhD degree, or another formally combined professional degree and research doctoral degree in the biomedical, behavioral, or clinical sciences. Because this F31 program only supports dissertation research training, the Kirschstein NRSA Individual Predoctoral MD/PhD or Other Dual-Doctoral Degree Fellowship (Parent F30) program will be more appropriate for the training goals of individuals enrolled in dual-degree programs who seek support for both dissertation research training and clinical training. Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective candidates are strongly encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts, to make sure that their application is appropriate for the requirements of one of the participating NIH ICs.

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.

2. Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PA-23-262** **Type: F32**

Application Due Date: December 08, 2023 through to August 08, 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: he purpose of the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32) is to support research training of highly promising postdoctoral candidates who have the potential to become productive, independent investigators in scientific health-related research fields relevant to the missions of the participating NIH Institutes and Centers. Applications are expected to incorporate exceptional mentorship. This NOFO is designed specifically for candidates proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial, but does allow candidates to propose research experience in a clinical trial led by a sponsor or co-sponsor. *This 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. See Ruth L. Kirschstein National Research Service Award (NRSA) webpage.

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.

3. Ruth L. Kirschstein National Research Service Award (NRSA) Individual Senior Fellowship

Letter of Intent: 30 days prior to the application due date **Hyperlink: PA-23-263** **Type: Parent F33**

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 National Institutes of Health (NIH) awards senior individual research training fellowships to experienced scientists who wish to make major changes in the direction of their research careers or who wish to broaden their scientific background by acquiring new research capabilities as independent investigators in research fields relevant to the missions of participating NIH Institutes and Centers. This NOFO is designed specifically for applicants proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial, but does allow candidates to propose research experience in a clinical trial led by a sponsor or co-sponsor. *This 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. Senior fellowship (F33) support is typically requested for 2 years or less.

4. Population Approaches to Reducing Alcohol-related Cancer Risk (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-244** **Type: R01**

Application Due Date: February 05, 2024 through to October 05, 2026. 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 NOFO aims to support research on interdisciplinary population approaches to increasing awareness of the relationship between alcohol and cancer risk, understanding and changing social norms related to alcohol consumption, developing and/or evaluating alcohol policy approaches, and the development, testing, and implementation of population-level interventions to reduce alcohol-related cancer risk. Applications that address multiple levels of consumption, such as moderate and heavy drinking, are of particular interest, as well as those focusing on alcohol use disorder (AUD) from the perspective of cancer prevention and control. Proposals addressing understudied areas are encouraged, as is attention to underrepresented minority (URM) populations experiencing cancer and alcohol-related disparities such as American Indian, Alaskan Native, and sexual and gender minority populations.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. 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.

5. Device Based Treatments for Substance Use Disorders (UG3/UH3 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-253** **Type: UG3/UH3**

Application Due Date: December 18, 2023 through to August 13, 2026 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 NOFO is to accelerate the development of devices to treat Substance Use Disorders (SUDs). The continuing advances in technologies offer unprecedented opportunities to develop neuromodulatory or neurophysiological devices that are safe and effective SUD treatments. The objective is to move devices to their next step in the FDA approval process, with the ultimate goal of generating new, FDA approved device-based treatments for SUDs. Applications may focus on the pre-clinical and/or clinical development and testing of new devices or existing devices approved for other indications. Applications may evaluate the mechanism of action of a device. The UG3/UH3 Cooperative Agreement involves two phases. The UG3 phase, for up to two years, is designed to support a project with specific milestones to be accomplished by the end of the period. The UH3 phase is to provide funding for up to three additional years following successful completion

of the UG3. UG3 projects that meet their milestones will be administratively considered by the National Institute on Drug Abuse and prioritized for transition to the UH3 phase. Investigators submitting to this NOFO must address both UG3 and UH3 phases.
Budget: Application budgets are limited to $500,000 direct costs for each year of the UG3 phase, but are not limited for the UH3 phase. However, budgets need to reflect the actual needs of the proposed project. The project period is limited to 2 years for the UG3 phase and 3 years for the UH3 phase.

6. Analytical and Clinical Validation of Biomarkers for Alzheimer's Disease (AD) and AD-Related Dementias (ADRD). (U01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-258** **Type: U01**
Application Due Date: November 03, 2023 through to February 05, 2026, 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 NOFO invites applications to accelerate the establishment of effective and reliable biomarkers of Alzheimer's disease (AD) and AD-related dementias (ADRD) for use in therapy/medical product discovery and development, clinical trials, and/or clinical practice. Specifically, this NOFO will support analytical and/or clinical validation of a biomarker, composite biomarker, or biomarker signature, with rigor comparable to the expectations described in the Food and Drug Administration (FDA's) Biomarker Qualification Program (BQP) or recommended by other FDA regulatory pathways.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. For projects proposing research on both analytical and clinical validations, or clinical validation only, the maximum project period is 5 years. For projects proposing research on analytical validation only, the project period is limited to 4 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.

7. Research Projects to Enhance Applicability of Mammalian Models for Translational Research (R01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-281** **Type: R01**
Application Due Date: October 05, 2023 through to June 05, 2026, 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: Through this NOFO, the National Cancer Institute (NCI) invites applications for projects to expand, improve, or transform the utility of mammalian cancer and tumor models for translational research. The NCI, through this NOFO encourages submission of projects devoted to demonstrating that mammalian models, including organoids, tumoroids and cell models, used for translational research are robust representations of human biology, are appropriate to test questions of clinical importance, and provide reliable information for patient benefit. These practical goals contrast with the goals of many mechanistic, NCI-supported R01 projects that use mammals, or develop and use mammalian cancer models, transplantation tumor models, or models derived from mammalian or human tissues or cells for hypothesis-testing, non-clinical research. Among many other possible endeavors, applicants in response to this NOFO could propose demonstrations of how to overcome translational deficiencies of mammalian oncology models, define new uses of mammalian models or their genetics for unexplored translational challenges, advance standard practices for use of translational models, test approaches to validate and credential models, or challenge current practices for how models are used translationally.
Budget: Application budgets are limited to $499,000 direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is 5 years.

8. Planning for Product Development Strategy (R34 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-24-029** **Type: R34**
Application Due Date: March 13, 2024 through to December 04, 2026, 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 NOFO is to support the development of a comprehensive and well-defined product development strategy for next-generation treatments for HIV and HIV-associated comorbidities, coinfections and complications and preventive strategies for HIV, as well as facilitating the translation of research findings into drug products that enables submission of an Investigational New Drug (IND) application to the FDA.
Budget: NIH intends to fund an estimate of 2-3 awards, corresponding to a total of $1,000,000, for fiscal year 2025. Future year amounts will depend on annual appropriations. Application budgets are limited to $225,000/year in direct costs. The maximum project period is 1 year.

9. Seamless Early-Stage Clinical Drug Development (Phase 1 to 2a) for Novel therapeutic Agents for the Spectrum of Alzheimer's Disease (AD) and AD-related Dementias (ADRD) (UG3/UH3 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-274** **Type: UG3/UH3**
Application Due Date: February 21, 2024 through to October 19, 2026, 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 NOFO is to invite applications that bundle independent protocols for phase 1 clinical trials with phase 1b/phase 2a clinical trials to streamline the early-stage evaluation of promising pharmacological interventions for Alzheimer's disease (AD) and AD-related dementias (ADRD). Candidate interventions evaluated through this program, which can include small molecules or biologics for example, must engage non-amyloid/non-tau mechanisms and aim to address cognitive and/or neuropsychiatric symptoms in individuals across

the spectrum, from pre-symptomatic to more severe stages of disease. This NOFO uses a phased award activity code. Applications must include prespecified, go/no-go safety and tolerability milestones that must be met to advance from phase 1 to latter stages of clinical development.
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 proposed project period for the UG3 phase must not exceed 2 years. The total duration of the UG3/UH3 phases combined must not exceed 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.

10. Mechanisms that Impact Cancer Risk with Use of Incretin Mimetics (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-279** **Type: R01**
Application Due Date: February 05, 2024 through to October 05, 2026, 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: Through this NOFO, the National Cancer Institute (NCI) invites applications for investigator-initiated studies addressing mechanisms by which incretin mimetics, specifically glucagon-like peptide (GLP)-1 or dual GLP-1/ glucose-dependent insulinotropic polypepide (GIP)-1 receptor agonists (RAs), impact cancer risk. The focus on these agents is due to their reported effects on thyroid, prostate and other cancer risks, and the generally more favourable efficacy and side effect profile compared to other classes of incretin mimetics. In addition, this NOFO seeks to draw in talented scientists to the cancer biology field who may study incretin mimetic effects on diseases other than cancer. Investigators wishing to study incretin mimetics other than GLP-1 RAs or GLP-1/GIP-1 RAs, such as dipeptidyl peptidase (DPP)-4 inhibitors, must justify why the agent(s) they propose to study are more effective and/or have a more favourable side effect profile than GLP-1 or GLP-1/GIP-1 RAs. Route of agent administration (oral vs. other) is, by itself, not an adequate justification.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

11. Mechanisms that Impact Cancer Risk with Use of Incretin Mimetics (R21 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-280** **Type: R21**
Application Due Date: February 16, 2024 through to October 16, 2026, 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: Through this NOFO, the National Cancer Institute (NCI) invites applications for investigator-initiated studies addressing mechanisms by which incretin mimetics, specifically glucagon-like peptide (GLP)-1 or dual GLP-1/glucose-dependent insulinotropic polypeptide (GIP)-1 receptor agonists (RAs), impact cancer risk. The focus on these agents is due to their reported effects on thyroid, prostate and other cancer risks, and the generally more favourable efficacy and side effect profile compared to other classes of incretin mimetics. In addition, this NOFO seeks to draw in talented scientists to the cancer biology field who may study incretin mimetic effects on diseases other than cancer.
Budget: Application budget direct costs are limited to $275,000 over a maximum two year period, with no more than $200,000 in any single year. The proposed project period must not exceed 2 years.

12. Chimeric Antigen Receptor (CAR) Approaches to AD/ADRD (R61/R33 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-AG-24-046** **Type: R61/R33**
Application Due Date: February 07, 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 NOFO aims to provide a proof-of-principle for a novel strategy for Alzheimer's disease (AD) and AD-related dementias (ADRD) immunotherapies. Specifically, the goal is to examine whether a novel immunotherapeutic approach in cancer immunotherapy with chimeric antigen receptor (CAR) immune cells can be customized as treatments for AD/ADRD. This NOFO utilizes the R61/R33 Exploratory/Developmental Phased Award activity code. The R61 phase provides up to 2 years of support for initial developmental activities. The R33 phase provides up to 3 years of support for expanded activities.
Budget: NIA intends to commit $5 million in fiscal year 2024 to fund 8-10 awards. Application budgets are not limited but need to reflect the actual needs of the proposed project. The duration of the entire R61/R33 award may not exceed 5 years. The R61 phase may not exceed 2 years of support. The R33 phase may not exceed 3 years of support.

13. Engaging Survivors of Sexual Violence and Trafficking in HIV and Substance Use Disorder Services (R34 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DA-25-018** **Type: R34**
Application Due Date: August 05, 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: The goal of this NOFO is to support exploratory research and preliminary interventions to address the interrelated and compounding contextual factors that contribute to substance use and HIV risk among survivors of sex trafficking. This would be accomplished through research that builds new interventions and models of care that can effectively engage survivors of sex trafficking in care for substance use disorder (SUD), HIV, trauma, and other mental health outcomes and addresses key structural and social determinants of health that contribute to risk for sexual trafficking, as well as barriers to and facilitators of escaping continued exploitation. This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP), which will be assessed as part of the scientific and technical peer review evaluation. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn. Applicants are strongly encouraged to read the NOFO instructions carefully and view the available PEDP guidance material.

Budget: NIDA intends to commit $1.5M in FY 2025 to fund 5-6 awards. The combined budget for direct costs for the three-year project period may not exceed $450,000. No more than $225,000 may be requested in any single year. Application budgets should reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 3 years.

14. Improving Choice, Use, and Equitable Implementation of Biomedical HIV Prevention for Women (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-MH-24-160** **Type: R01**
RFA-MH-24-161 **R21**
RFA-MH-24-162 **R34**

Application Due Date: November 22, 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 NOFO invites applications to understand factors that impact uptake and adherent and persistent use of biomedical HIV prevention options, to inform and advance approaches to support choice and use among these options, and to understand and advance equitable delivery of biomedical HIV prevention options for cisgender and transgender women in settings where multiple prevention options are available. This NOFO uses the R01 grant mechanism, while RFA-MH-24-161 uses the R21 mechanism and RFA-MH-24-162 uses the R34 mechanism. High risk/high payoff projects that lack preliminary data or utilize existing data may be most appropriate for the R21 mechanism. Applications with preliminary data and/or those including longitudinal analysis or proposing a large-scale clinical trial should consider using the R01 mechanism. Applicants proposing to develop and pilot test an intervention should consider the R34 mechanism.
Budget: NIMH intends to commit a total of $2,000,000 in FY 2024 to fund 3-5 awards in response to this NOFO and the companions (RFA-MH-24-161 and RFA-MH-24-162). NICHD intends to commit a total of $500,000 in FY 2024 to fund 1-2 awards in response to this NOFO and the R21 companion (RFA-MH-24-161).
R01 = 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.
R21 = 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.
R34 = Direct costs are limited to $450,000 over the entire project period, with no more than $225,000 in direct costs in any single year. The scope of the proposed project should determine the project period. The maximum project period is 3 years.

15. Early-stage Biomedical Data Repositories and Knowledgebases (R24 Clinical Trial Not Allowed)

Letter of Intent: 60 days prior to the application due date **Hyperlink: PAR-23-236** **Type: R24**

Application Due Date: October 30, 2023 through to January 25, 2026, 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 NOFO supports the development of early-stage or new data repositories and knowledgebases that could be valuable for the biomedical research community.
Budget: The following NIH components intend to commit the following amounts: NINDS intends to support up to 2 awards in each fiscal year & NHGRI intends to support up to 2 awards in each fiscal year. Application budgets need to reflect the actual needs of the proposed project and may not exceed $350K direct costs per year. The scope of the proposed project should determine the project period. The maximum project period is four (4) years.

16. Enhancement and Management of Established Biomedical Data Repositories and Knowledgebases (U24 Clinical Trial Not Allowed)

Letter of Intent: 60 days prior to the application due date **Hyperlink: PAR-23-237** **Type: U24**

Application Due Date: October 30, 2023 through to January 25, 2026 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 NOFO is designed to support established biomedical data repositories and knowledgebases as distinct and separate resources that have demonstrated impact and have potential for continued benefit to the community served.
Budget: NINDS intends to support up to 2 awards in each fiscal year. Application budgets are not limited but need to reflect the actual needs of the proposed project. Applications may request up to five (5) years of support for an established biomedical data repository or knowledgebase. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact the ODSS Scientific/ Research Contact at least 6 weeks before submitting the application

17. Research Tools for Difficult to Culture Eukaryotic Pathogens (R61/R33 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-AI-23-055** **Type: R61/R33**

Application Due Date: February 02, 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: The purpose of this NOFO is to support high risk, milestone-driven approaches for the development of robust culture techniques, and/or genetic and molecular tools to better understand the biology of select human eukaryotic pathogens including the microsporidian Enterocytozoon bieneusi; Pneumocystis jirovecii; Plasmodium vivax; and Babesia microti. This NOFO will use a milestone-driven, biphasic award mechanism. Transition to the second phase will depend on the successful completion of milestones.
Budget: NIAID intends to commit $3.25 million in FY 2025 to fund 6-8 awards. Budgets for the R61 phase are not expected to exceed $250,000 annually in direct costs. Budgets for the R33 phase are not expected to exceed $350,000 annually in direct costs. The maximum project period

for the R61 phase is three years and the maximum project period for the R33 phase is two years, for a total of five years for the entire R61/R33 award.

18. BRAIN Initiative: Research on the Ethical Implications of Advancements in Neurotechnology and Brain Science (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-MH-24-190** **Type: R01**

Application Due Date: October 11, 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: Guided by the goals established in BRAIN 2025: A Scientific Vision and reinforced by the Advisory Council to the Director Working Group on BRAIN 2.0 Neuroethics Subgroup, this Notice of Funding Opportunity (NOFO) from the NIH Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative is intended to support efforts addressing core ethical issues associated with research focused on the human brain and resulting from emerging technologies and advancements supported by the BRAIN Initiative. This NOFO encourages research project grant applications from multi-disciplinary teams focused on key ethical issues associated with BRAIN Initiative supported research areas. Efforts supported under this NOFO are intended to be both complementary and integrative with the transformative, breakthrough neuroscience discoveries supported through the BRAIN Initiative.

Budget: Issuing IC and partner components intend to commit an estimated total of $3 million in FY2022 to fund up to 8 awards. For future years the intended commitment will depend on annual appropriations. Application budgets are limited to $300,000 in direct costs in any project year and 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 4 years.

19. Biotypes of CNS Complications in People Living with HIV (P01 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-MH-24-235** **Type: P01**

Application Due Date: December 11, 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: The goal of this NOFO is to understand the heterogeneity of central nervous system (CNS) outcomes in people with HIV on Anti-retroviral therapy (ART), employing quantitative assessments that are linked to psychopathology to identify distinct disease phenotypes, known as biotypes. This NOFO encourages research studies to aid in the identification/ validation of biologically quantifiable readouts in domestic and international settings. Applications responding to this NOFO are strongly encouraged to propose research strategies that are novel and have the potential to lead science beyond its current state. Multidisciplinary research teams and collaborative alliances are encouraged. The application should consist of the following components:

- Overall: Required: (1)
- Administrative Core: Required (1)
- Clinical Core: Required (1)
- Data Management Core: Required (1)
- Resource and Analytic Core: Optional (0-3)
- Research Projects: Required (3)

Budget: NIMH, NINDS and NIDA intend to commit $6,000,000 in total costs per year to fund 1 award in response to this NOFO. Future year amounts will depend on annual appropriations. 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.

20. HEAL INITIATIVE: Development and validation of remote or patient wearable device derived objective biosignatures or functional assessments to monitor pain for use as endpoints in clinical trials (UG3/UH3 - Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-NS-24-023** **Type: UG3/UH3**

Application Due Date: January 30, 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: The purpose of this NOFO is to promote the discovery, development, and validation of real-world digital endpoints derived from data generated by existing remote or wearable devices. These endpoints will be used for monitoring the experience of pain, its progression, response to interventions, and impact on quality of life. In this NOFO, endpoints refer to biosignatures obtained from functional and physiological assessments captured by remote or wearable devices. Development of digital endpoints will involve clinical research using existing wearable or remote devices, with a specific focus on selecting and validating novel measurements as appropriate digital endpoints for pain assessment. The proposed digital endpoints may focus on a specific pain condition or encompass multiple pain conditions. Applications aiming to identify digital endpoints across various pain conditions should involve Multiple Principal Investigator (MPI)-led teams that represent each relevant pain condition and associated clinical networks. These teams should collaborate to discover, develop, and validate digital endpoints that accurately measure pain and related outcomes, such as quality of life or appropriate pain-related functional measures. In addition, the applicant should include experts in digital technology, data analysis, and advanced statistical methods to handle real-world data. Applicants must establish centralized resource groups responsible for coordinating clinical trials, standardizing sample or data collection methods, technology development, statistical analysis, and algorithm development across all pain conditions under investigation. For applications focused on developing digital endpoints for a single pain condition, MPI-led teams with cross-functional expertise should be included, along with centralized resource groups responsible for coordinating clinical trials, standardizing sample or data collection methods, technology development, and statistical analysis. Furthermore, the inclusion of people with lived experience in the team is required to incorporate patient perspectives, concerns, and valuable input regarding the relevance and acceptability of digital measurements in the study. The final products of this effort would be algorithms and software designed to analyze data from existing remote or wearable technologies. The goal is to

demonstrate that digital biosignatures or digital functional assessments, serving as digital endpoints, are sensitive and objective measures of clinical benefit.
Budget: The NIH HEAL (Helping to End Addiction Long-term) Initiative intends to commit an estimated total of $5.1 million to fund 4-6 awards in FY 2024. Awards pursuant to this funding opportunity are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. Application budgets are limited to $500,000 in direct costs per year for the UG3 phase and up to $1,500,000 in direct costs per year of the UH3 phase. Applicants may seek two years of UG3 funding. The UH3 phase cannot exceed three years, since the total period of the UG3/UH3 award cannot be more than 5 years. The actual duration of individual projects will depend on successful achievement of milestones and conditions as described in Milestones Section of the program overview.

21. Improving Care and Outcomes for Cancer Survivors from Sexual and Gender Minority (SGM) Populations (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-292** **Type: R01**
Application Due Date: February 05, 2024 through to October 05, 2026 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: Through this NOFO, the National Cancer Institute (NCI) intends to support the rigorous assessment of barriers to quality cancer treatment and follow-up care for sexual and gender minority (SGM) cancer survivors. This funding opportunity is intended to address a critical need for improved care delivery and outcomes for SGM cancer survivors. The goal is to address the disease burden in an underserved and understudied population that is at higher risk of poorer health outcomes. The NCI solicits proposals for observational and/or interventional studies of SGM survivors designed to understand barriers and/or improve care and outcomes for SGM people with cancer, using interoperable sexual orientation and gender identity (SOGI) data collection in cancer care settings, where appropriate.
Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The maximum project period is 5 years.

22. Limited Competition: The Harmonized Cognitive Assessment Protocol (HCAP) Network (U24 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-AG-24-035** **Type: U24**
Application Due Date: November 01, 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 NOFO invites applications to provide critical network support for advancing development in a specific high-priority area of behavioral and social research on Alzheimer's disease (AD) and AD-related dementias (ADRD): The Harmonized Cognitive Assessment Protocol (HCAP) Network. Network activities include, but are not limited to: meetings to develop novel research areas and strategize on the development of infrastructure; small-scale pilots to test or tailor measures in new populations or contexts; development of guidance on selected topics such as biomarkers, diagnosis and classification of dementia, protocol development, fieldwork challenges, statistical harmonization, and analytic methods; educational activities such as intensive summer institutes, series of workshops and related network activities, or advanced seminars on methodology; dissemination and outreach activities; and coordination of activities with other related networks on AD/ADRD.
Budget: NIA intends to commit $600,000 in fiscal year 2024 to fund 1 award. Application budgets are limited to $385,000 in direct costs and 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.

23. Continuation of the Childhood Liver Disease Research Network (ChiLDReN) Clinical Centers (U01 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-DK-23-017** **Type: U01**
Application Due Date: November 08, 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: The purpose of this NOFO is to continue the support the Childhood Liver Disease Research Network (ChiLDReN) to conduct clinical and translational research on rare pediatric liver diseases. ChiLDReN is composed of a Scientific and Data Coordination Center (SDCC) and Clinical Centers (CC). ChiLDReN will continue clinical and expand translational research that may include translational science coordination center(s) focused on supporting research on pediatric liver diseases that include: Biliary Atresia; Alagille syndrome; alpha-1-antitrypsin deficiency; Progressive Familial Intrahepatic Cholestasis syndromes; Bile acid synthesis defects; Mitochondrial hepatopathies; Idiopathic Neonatal Hepatitis; and primary sclerosing cholangitis (PSC).
Budget: The NIDDK intends to commit $3.650 million in FY 2024 to support two related approaches to the continuation of the ChiLDReN Network as embodied in RFA-DK-23-017 and RFA-DK-23-018 (non-US foreign application not allowed). It is expected that up to 14 awards will be supported in FY 2024 in total under these two RFAs. 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.