Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

National Institute of Nursing Research (NINR)

National Institute of Mental Health (NIMH)

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Sexual and Gender Minority Research Office (SGMRO)

Office of Research on Women's Health (ORWH)

Funding Opportunity Title

Understanding the Intersection of Social Inequities to Optimize Health and Reduce Health Disparities: The Axes Initiative (R01 Clinical Trial Optional)

Activity Code

R01 Research Project Grant

Announcement Type

New

Related Notices

- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198.
- **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189.

Funding Opportunity Number (FON)

RFA-NR-24-006

Companion Funding Opportunity

None

Number of Applications

See Part 2, Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.361, 93.242, 93.313

Funding Opportunity Purpose

Research shows that intersecting systems of privilege and oppression produce and sustain wide and unjust variations in health. The Axes Initiative will support research to understand health at the intersections of social statuses such as race, ethnicity, socioeconomic status, sexual orientation, and ability, by examining contributions of social and other determinants of health.

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 Applications that fail to include a PEDP will be considered incomplete and will be withdrawn.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.

Key Dates

Posted Date

April 25, 2024

Open Date (Earliest Submission Date)

June 05, 2024

Letter of Intent Due Date(s)

30 days before application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
July 05, 2024	Not Applicable	July 29, 2024	November 2024	January 2025	April 2025
February	February 14, 2025	March 10, 2025	July 2025	October	December

14, 2025				2025	2025

All 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.

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

Expiration Date

March 11, 2025

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide, except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts).

Conformance to all requirements (both in the How to Apply - Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply - Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply - Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.
   Apply Online Using ASSIST
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

This funding opportunity solicits research to examine the pathways through which social determinants of health (SDOH), and related biological, psychological, and behavioral factors impact health and health disparities at intersections of privileged and/or oppressed social statuses such as race, ethnicity, socioeconomic status, sexual orientation, and ability. SDOH is a required pathway of focus. Observational research, evaluation studies, simulation studies, and predictive modeling studies are of interest. Also of interest are mixed-methods studies that combine quantitative and qualitative data to contextualize intersectional forms of privilege and oppression. Projects using longitudinal study designs are encouraged.

The primary populations of focus for the Axes Initiative are those that experience health disparities in the U.S., including racial and ethnic minority populations, people with lower socioeconomic status, underserved rural populations, sexual and gender minority populations, and people with disabilities. Inclusion of social statuses such as gender and gender identity, sex assigned at birth, national origin, and immigration status are also of interest. Studies must clearly convey the populations of interest for the proposed research and how the populations comprise intersecting statuses that are privileged or have been oppressed.

Key Definitions

Intersectionality: The complex, cumulative way in which the effects of interlocking forms of privilege or oppression (e.g., racism, sexism, classism) converge or intersect to advantage some individuals, communities, or populations and disadvantage others.

Social status: A person's standing or importance in relation to other people within a society.

Social determinants of health: Social determinants of health (SDOH) are the conditions in which people are born, grow, learn, work, play, live, and age, and the wider set of structural factors shaping the conditions of daily life. These structural factors include social, economic, and legal forces, systems, and policies that determine opportunities and access to high quality jobs, education, housing, transportation, built environment, information and communication infrastructure, food, and health care; the social environment; and other conditions of daily life. See https://www.ninr.nih.gov/researchandfunding/nih-sdohrcc#tabs2 for additional detail on the NIH SDOH Conceptualization.

Background

Intersectionality, which has conceptually expanded in focus over the decades, illuminates the importance of considering how individual experiences are differentially shaped by the intersection of one's social status in society. Simultaneous systems of privilege and oppression (e.g., racism, sexism, classism) are key drivers of good health and prosperity, but also of poor health and hardship. Membership in majority groups based on axes of race, ethnicity, gender identity, socioeconomic status, and sexual orientation affords access to systems and conditions of privilege. In contrast, members of minority groups live within systems of oppression that limit access to health-promoting resources, services, and opportunities. These systems of privilege and oppression do not operate independently at a single axis (e.g., race) but instead intersect at multiple axes (e.g., race, class, sex assigned at birth) to manifest in systematically different conditions of daily life and, in turn, wide and unjust variations in health and quality of life. For example, the lived experience of an Afro-Latina woman cannot be understood from the perspective of a separate and distinct axis (ethnicity), but rather requires recognition that such experiences are

shaped by the simultaneous impacts of her intersecting social statuses (i.e., Black, female, Latino). Thus, an intersectional lens is necessary to fully account for the health-promoting or compromising conditions experienced by individuals and populations at the convergence of social statuses. Overall, intersectional research can uncover how social statuses intersect to create new and complex health exposures and experiences for individuals and populations that would be otherwise obscured when assessed independently.

To date, most intersectional health research has simply documented that health disparities exist at axes of social statuses. However, there is less empirical knowledge about the underlying causes of these disparities. Expanding intersectionality research to identify the pathways and mechanisms underlying health disparities moves the field beyond simply documenting health disparities into pinpointing the factors that contribute to unjust and avoidable variations in health outcomes at these intersections. SDOH play a key role in determining the health trajectory of individuals, families, communities, and entire populations. Thus, SDOH are central to understanding intersectional health disparities. Moreover, there is a need for a multilevel intersectional approach to understand not only the pathways through which SDOH impact health outcomes, but also the related biological, psychological, and behavioral pathways and mechanisms at axes of privilege and oppression. Knowledge derived from this line of research can inform targeted approaches to interrupt the pathways that influence downstream SDOH health impacts. Lastly, in the extant literature only a narrow set of social statuses are documented, with the greatest proportion examining axes of race, ethnicity, and gender. This knowledge gap presents an opportunity to expand our understanding of the health of people who hold other privileged and oppressed social statuses to identify paths to reducing health disparities and advancing health equity.

Progress in intersectionality research will require methods suited to identifying complex pathways and mechanisms through which social and other determinants of health impact individual and population health. However, much of the existing quantitative literature is limited by theoretical and methodological weaknesses such as the use of analytic methods that do not account for the complexity of intersectional inquiry, the use of intersectionality lenses that are not embedded within systems of privilege and oppression, or a combination of these factors. The dearth of rigorous quantitative intersectionality research prohibits comprehensive identification of the most salient and impactful proximal and distal factors that compromise health.

Largely, applying an intersectional lens would advance efforts to achieve greater precision in understanding social inequities simultaneously across systems that advantage some and disadvantage others. Analytical examination intended to reveal factors that are most ascribed to differential health outcomes across and within social statuses is needed to inform and reform interventions, practices, and public policies to adequately address the experiences of populations living within systems of oppression. Acknowledging that, for example, racism and not race, classism and not class, homophobia and not sexual orientation are the underlying causes of poor health is central to advancing health equity.

Research Objectives

The Axes Initiative invites applications to examine the pathways and mechanisms through which SDOH, and related biological, psychological, and behavioral factors impact health and health disparities at intersections of privileged and oppressed social statuses such as race, ethnicity, socioeconomic status, sexual orientation, and ability. SDOH is a key pathway of interest, therefore examination of federal, state, local, or organizational level policies, programs, or practices, and/or conditions of daily life (e.g., concentrated disadvantage, quality employment and education, housing, and food) on health outcomes at intersections of social statuses is required. Studies can also incorporate individual and family economic and social circumstances to elucidate proximal pathways and mechanisms through which SDOH influence health. Studies that incorporate novel methods, measures, and analytical approaches that account for the complexity of intersectionality research are encouraged.

The primary populations of focus for the Axes Initiative are those that experience health disparities in the U.S., including racial and ethnic minority populations, people with lower socioeconomic status, underserved rural populations, sexual and gender minority populations, and people with disabilities. Inclusion of social statuses such

as gender and gender identity, sex assigned at birth, national origin, and immigration status are also of interest. Studies must clearly convey the populations of interest for the proposed research and how the populations comprise intersecting statuses that are privileged and/or have been oppressed.

All studies must be guided by an intersectionality framework to identify the hypothesized pathways and mechanisms between intersecting social statuses and health outcomes. As appropriate, involvement of the priority populations in the research process, through for example formation of a community advisory board, focus groups and interviews, listening sessions, or community forums, to increase the relevance and resonance of study findings are encouraged. Observational research, evaluation studies, simulation studies, and predictive modeling studies are of interest. Also of interest are mixed-methods studies that combine quantitative and qualitative data to contextualize intersectional forms of privilege and oppression. Projects using longitudinal study designs are strongly encouraged**.** Projects may utilize primary data collection and/or analysis of secondary data from project-specific or publicly available data sources at the federal, state, local, or organizational level and across sectors such as healthcare, human and social services, housing, justice, commerce, transportation, economic development, and education. The primary health outcome may reflect health or functional status, quality of life, and morbidity and mortality, including outcomes relevant for specific health conditions.

Examples of projects that may be supported by the Axes Initiative include, but are not limited to:

- Comparative studies that examine similarities and differences in pathways and mechanisms of health and health disparity impacts across intersectional statuses.
- Studies that focus on embodiment or biological embedding, i.e., how exposure to various forms of privilege and oppression converge to affect SDOH experienced by people at intersections of social statuses and, in turn, affect underlying biological processes (e.g., epigenome, allostatic load, inflammation, microbiome, neurological signatures).
- Longitudinal and life course studies that examine pathways and mechanisms over time and across generations at intersections of social statuses.
- Studies that examine the multilevel pathways and mechanisms through which concentrated disadvantage impacts health at different intersections of social statuses.
- Studies that examine pathways and mechanisms to explain unexpected positive health outcomes across intersecting social statuses.
- Studies that identify protective factors at multiple levels (e.g., individual, interpersonal, institutional, community, societal) and the ways these protective factors buffer effects of oppression on health disparities.
- Studies that examine the differential impact of policies and laws at the federal, state, and/or local levels at varied axes of privilege and oppression.
- Simulation studies that estimate the impacts of strategies to ameliorate adverse SDOH to reveal pathways or mechanisms of action that affect change at the individual, community, and population levels.

Non-Responsive Applications

Projects NOT responsive to this opportunity:

- Projects that do not focus on intersectional social statuses.
- Projects that only use individual- or interpersonal-level data.
- Projects that do not incorporate an intersectionality framework to guide research questions and interpretations.
- Projects that do not focus on populations experiencing health disparities in the U.S.
- Projects that do not include a Plan for Enhancing Diverse Perspectives.

Areas of Interest of Participating Institutes, Centers, and Offices (ICOs)

National Institute of Mental Health (NIMH)

The mission of the National Institute of Mental Health (NIMH) is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. NIMH is interested in applications (not clinical trials) relevant to priorities described in this NOFO and that support the NIMH Strategic Plan for Research. NIMH Division of AIDS Research is also interested in applications relevant to the priorities described in the NIH Strategic Plan for HIV and HIV-Related Research by NIH Office of AIDS Research (NIH OAR; https://www.oar.nih.gov/hiv-policy-and-research/strategic-plan).

HIV/AIDS Areas of Research Interest
While the areas of intersectional social-structural determinants of health are vast, it is expected that some may be more amenable to HIV-related research questions than others. Therefore, applicants in collaboration with their relevant communities and stakeholders should carefully consider their non-intervention research aims in determining which intersectional social-structural factors they propose to examine. Proposed research must be in the context of their impact on HIV prevention or treatment outcomes.

Specific areas of research interest may include, but are not limited to:

- Multilevel studies that elucidate the mechanisms and causal pathways between intersectional social-structural factors and HIV outcomes to inform future interventions.
- Studies that use innovative approaches to identify modifiable intersectional social-structural factors across various sectors (e.g., economic security, housing security, food access, transportation, healthcare) and provide evidence-based simulation or prediction of the impact of effective interventions delivered in real-world settings to address these barriers to improve HIV outcomes and reduce HIV disparities.
- Studies that examine relevant laws, policies, and practices that reinforce intersectional social-structural determinants and identify social-structural interventions for development and testing to improve HIV outcomes and reduce HIV disparities.

Division of Services and Intervention Research (DSIR) Areas of Research Interest
For the purposes of this NOFO, the Division of Services and Intervention Research (DSIR) is particularly interested in (but not limited to) projects that explicitly align to Goals 3.2, 3.3, and 4 of the NIMH Strategic Plan for Research, aimed at improving treatment, services and outcomes for people with mental illnesses or autism spectrum disorders.

Specific areas of research interest may include, but are not limited to:

- Multilevel studies that elucidate the mechanisms and causal pathways between intersectional social-structural factors and mental health outcomes to inform future interventions.
- Studies that use innovative approaches to identify modifiable intersectional social-structural factors across various sectors (e.g., economic security, housing security, food access, transportation, healthcare) and provide evidence-based simulation or prediction of the impact of effective interventions delivered in real-world settings to address these barriers to improve mental health outcomes and reduce disparities.
- Studies that examine relevant laws, policies, and practices that reinforce intersectional social-structural determinants and identify social-structural interventions for development and testing to improve mental health outcomes and reduce disparities.

NIMH encourages a deployment-focused model of intervention design and testing that takes into account the perspective of relevant end-users (e.g., service users, providers, administrators, payers) and the key characteristics of the settings (e.g., resources, including workforce capacity; existing clinical workflows). To this end NIMH strongly encourages meaningful inclusion of end-users in the research (e.g., member of an advisory panels and/or inclusion as key personnel). This attention to end-user perspectives is intended to help ensure the research findings will have clear utility to communities, practices, and/or policy makers who may benefit from those findings.

Non-responsive criteria:

- Applications proposing the following will be considered non-responsive and will not be reviewed by NIMH:
  - Applications that propose a clinical trial
  - Applications for HIV/AIDS that do not include an HIV prevention or treatment outcome

Office of Research on Women's Health (ORWH)

ORWH is part of the Office of the Director, NIH, and works with the 27 NIH Institutes and Centers to advance rigorous research of relevance to the health of women. ORWH does not award grants but co-funds women's health-related applications and research projects that have received an award from one of the participating NIH Institutes and Centers (ICs) listed in the announcement. Applications seeking ORWH co-funding should ensure that the proposed work is aligned with at least one goal and objective outlined in the Trans-NIH Strategic Plan for Women's Health Research (https://www.nih.gov/women/strategicplan).

For this announcement, ORWH supports intersectional research projects centered on cisgender and transgender women, gender-diverse people, or people assigned female at birth.

Sexual & Gender Minority Research Office (SGMRO)

The SGMRO coordinates research and activities related to the health and well-being of sexual and gender minority (SGM; defined for NIH research in NOT-OD-19-139) populations by working directly with the NIH institutes, centers, and offices (ICOs) and serves as a liaison for the research community to ensure SGM populations are considered and represented in research activities across the agency. The SGMRO does not have grant-making authority and can only support grants deemed meritorious after review by one of the ICs participating in this announcement and after a co-funding request is initiated through the IC. Please reach out to the relevant scientific/research contact(s) identified in this announcement with any questions about IC-specific research priorities and funding. More SGM- and SGMRO-specific information is available in the NIH Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities FY 2021-2025 and on the Office's Research Resources webpage.

For this NOFO, SGMRO encourages research across the life course that explores health at the intersection of sexual orientation, gender identity, or sex characteristics (SOGISC) and other social identities, as well as related social and structural determinants of health. When appropriate, SGMRO encourages consideration and incorporation of relevant concepts (e.g., minority stress, social safety, intersectionality, stigma), research strategies (e.g., community-led or -engaged research, trauma-informed research, strengths-based approaches), and frameworks (e.g., SGM Health Disparities Research Framework, NIMHD Research Framework).

Plan for Enhancing Diverse Perspectives

This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP) as described in NOT-MH-21-310, submitted as Other Project Information as an attachment (see Section IV).

Applicants are strongly encouraged to read the NOFO instructions carefully and view the available PEDP guidance material. The PEDP will be assessed as part of the scientific and technical peer review evaluation, as well as considered among programmatic matters with respect to funding decisions.

Pre-Application Webinar

NINR will hold a Pre-Application Webinar for prospective applicants for the Axes Initiative on Tuesday, May 21, 2024, from 1:00–2:00pm ET. Please register to attend the webinar at https://us02web.zoom.us/webinar/register/WN_JAYvb8koTz2IE1Pg6_ZZDA.

Attending the pre-application webinar is encouraged for all potential applicants, but is not required for submission of an application. Prospective applicants are also encouraged to reach out to the NIH staff listed on this funding

opportunity with specific questions. For applicants unable to attend the webinar, a recording will be archived on the event website.

See Section VIII. Other Information for award authorities and regulations.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources website for information about developing statistical methods and study designs.

Section II. Award Information

Funding Instrument

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission

The OER Glossary and the How to Apply - Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

The National Institute of Nursing Research (NINR) intends to commit $3,000,000 in FY 2025 to fund 3-5 awards, depending on receipt of meritorious awards and availability of funds.

Award Budget

Application budgets cannot exceed $500,000 in direct costs per year and must reflect the actual needs of the proposed project.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible.

Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications for additional information

- System for Award Management (SAM) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement NIH Grants Policy Statement Section 1.2 Definition of Terms.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

NOFOReviewContact@csr.nih.gov

Page Limitations

All page limitations described in the How to Apply – Application Guide and the Table of Page Limits must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply – Application Guide and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the How to Apply - Application Guide must be followed.

Other Attachments:

Plan for Enhancing Diverse Perspectives

- In an "Other Attachment" entitled "Plan for Enhancing Diverse Perspectives," all applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity.
- The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and

supported throughout the application and can incorporate elements with relevance to any review criteria (significance, investigator(s), innovation, approach, and environment) as appropriate.
- Where possible, applicant(s) should align their description with these required elements within the research strategy section.
- The PEDP will vary depending on the scientific aims, expertise required, the environment and performance site(s), as well as how the project aims are structured.
- The PEDP may be no more than 1-page in length and should include a timeline and milestones for relevant components that will be considered as part of the review.

Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:

- Discussion of engagement with different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
- Description of any planned partnerships that may enhance geographic and regional diversity.
- Plan to enhance recruiting of women and individuals from groups historically underrepresented in the biomedical, behavioral, and clinical research workforce.
- Proposed monitoring activities to identify and measure PEDP progress benchmarks.
- Plan to utilize the project infrastructure (i.e., research and structure) to support career-enhancing research opportunities for diverse junior, early- and mid-career researchers.
- Description of any training and/or mentoring opportunities available to encourage participation of students, postdoctoral researchers and co-investigators from diverse backgrounds.
- Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
- Publication plan that enumerates planned manuscripts and proposed lead authorship.
- Outreach and planned engagement activities to enhance recruitment of individuals from diverse groups as research participants including those from under-represented backgrounds.

For further information on the Plan for Enhancing Diverse Perspectives (PEDP), please see https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp

SF424(R&R) Senior/Key Person Profile

All instructions in the How to Apply - Application Guide must be followed.

R&R or Modular Budget

All instructions in the How to Apply - Application Guide must be followed.

PEDP implementation costs

- Applicants may include allowable costs associated with PEDP implementation (as outlined in the Grants Policy Statement section 7: https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.1_general.htm).

R&R Subaward Budget

All instructions in the How to Apply - Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the How to Apply - Application Guide must be followed.

PHS 398 Research Plan

All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:

The Research Strategy section must include the following information:

- Detail how the proposed research examines pathways and mechanisms through which social determinants of health (SDOH) impact health.
- Clearly describe the intersecting population(s) of interest.
- Indicate and discuss the intersectionality framework used to guide the project's research questions and interpretations.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply - Application Guide.

Other Plan(s): Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the How to Apply - Application Guide.

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply - Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply - Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the How to Apply - Application Guide must be followed.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next

business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the How to Apply – Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Applications must include annual milestones. Applications that fail to include annual milestones will be considered incomplete and will be withdrawn. Applications must include a PEDP submitted as Other Project Information as an attachment. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn before review.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy

Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

For this particular NOFO, note the following:

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Specific to this NOFO:

- Does the proposed research aim to examine pathways or mechanisms through which social determinants of health (SDOH) impact health?
- Does the proposed research focus on a population comprising intersecting social statuses that are privileged or have been oppressed?
- To what extent do the efforts described in the Plan for Enhancing Diverse Perspectives further the significance of the project?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Specific for this NOFO:

- To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Specific for this NOFO:

- To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver

interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Specific to this NOFO:

- Does the proposed research include an intersectionality framework to guide research questions and interpretations?
- Are the timeline and milestones associated with the Plan for Enhancing Diverse Perspectives well-developed and feasible?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Specific for this NOFO:

- To what extent will features of the environment described in the Plan for Enhancing Diverse Perspectives (e.g., collaborative arrangements, geographic diversity, institutional support) contribute to the success of the project?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policies and practices, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals of initial peer review will not be accepted for applications submitted in response to this NOFO.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Council for Nursing Research. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement Section 2.4.4 Disposition of Applications.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement. This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this NOFO will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain “applicable clinical trials” on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities, including of note, but not limited to:

- Federalwide Standard Terms and Conditions for Research Grants
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

- Acknowledgment of Federal Funding

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website.

HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to System for Award Management (SAM.gov) requirements. SAM.gov requires Federal agencies to review and consider information about an applicant in the designated integrity and performance system (currently SAM.gov) prior to making an award. An applicant can review and comment on any information in the responsibility/qualification records available in SAM.gov. NIH will consider any comments by the applicant, in addition to the information available in the responsibility/qualification records in SAM.gov, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

Awardees will provide updates at least annually on implementation of the PEDP.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement. NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over the

threshold. See the NIH Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (Responsibility/Qualification in SAM.gov, formerly FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

Scientific/Research Contact(s)

Shalanda A. Bynum, PhD, MPH
National Institute of Nursing Research (NINR)
Telephone: 301-755-4355
Email: shalanda.bynum@nih.gov

Gregory Greenwood, Ph.D.
Division of AIDS Research
National Institute of Mental Health
Telephone: 240-669-5532
Email: gregory.greenwood@nih.gov

Jennifer Humensky, Ph.D.
Division of Services and Intervention Research
National Institute of Mental Health
Telephone: 301-480-1265
Email: jennifer.humensky@nih.gov

Elizabeth Anne Barr
ORWH - Office of Research on Women's Health

Phone: 301-402-7895
E-mail: elizabeth.barr@nih.gov

Christopher Barnhart, PhD
Sexual & Gender Minority Research Office (SGMRO)
Telephone: 301-594-8983
Email: christopher.barnhart@nih.gov

Peer Review Contact(s)

Center for Scientific Review (CSR)
Email: NOFOReviewContact@csr.nih.gov

Financial/Grants Management Contact(s)

Randi Freundlich
National Institute of Nursing Research (NINR)
Telephone: 301-594-5974
Email: freundlichr@mail.nih.gov

Rita Sisco
National Institute of Mental Health (NIMH)
Telephone: 301-443-2805
Email: rita.sico@mail.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 2 CFR Part 200.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.