Department of Health and Human Services

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Section I. Notice of Funding Opportunity Description

Purpose

This funding opportunity supports unusually innovative intervention research which, if successful, would have a major impact on preventing, reducing, or eliminating health disparities and advancing health equity. Interventions addressing research questions that target social determinants of health (SDOH), which include structural factors and conditions of daily life, are required for this initiative (See NIH SDOH conceptualization here https://www.ninr.nih.gov/researchandfunding/nih-sdohrcc#tabs2). SDOH can be addressed alone or in combination with other determinants of health and as part of a single or multilevel intervention approach. Although a formative research phase may be necessary for some projects, an intervention research component is required for each proposed project. Applicants may propose interventions addressing disparities in any health condition, disease, or health behavior that align with the priority research areas of listed NIH Institutes, Centers, and Offices.

This initiative invites intervention research focused on transformative research ideas. To be considered transformative, projects should reflect ideas substantially different from traditional concepts and have high potential to lead to major improvements in health through the development, implementation, or dissemination of innovative interventions to address health disparities and health inequities. To accelerate progress in reducing health disparities, this funding opportunity seeks to support interventions that advance or solidify strategies, policies, programs, and environmental changes to address the Nation's most pressing health challenges. Innovative interventions could take many forms depending on the population of interest and health disparity being addressed. Note that "innovation" can include development and testing of an innovative intervention, new implementation and/or dissemination strategies for evidence-based interventions, and/or creative evaluation of a novel or unusual policy, program, or environmental change to provide insight into their health impacts.

Several key features of this funding opportunity are designed to emphasize that Transformative Research to Address Health Disparities and Advance Health Equity applications are different from conventional, investigator-initiated research applications. These applications focus on the significance of the problem, the novelty of the hypothesis and/or the proposed methodology, and the magnitude of the potential impact rather than on preliminary data or experimental details. No preliminary data are required for applications submitted in response to this funding opportunity, but could be included if available. Applicants should keep the goal of the Transformative Research to Address Health Disparities and Advance Health Equity initiative in mind throughout the process – to develop, implement, disseminate, and/or evaluate innovative

interventions and strategies that address health disparities and that seek to advance health equity.

To support the most innovative and impactful research, the NIH recognizes the need to promote a diverse research workforce (see NOT-OD-20-031 for NIH Interest in Diversity). Applications to this award program should reflect the full diversity of potential applicants and applicant institutions. Applications from researchers with diverse backgrounds underrepresented across roles and positions in research, including underrepresented racial and ethnic groups, persons with disabilities, and women are strongly encouraged to apply. Outstanding research is conducted at a broad spectrum of institutions. To support the highest quality research, this funding opportunity encourages applications from the full range of eligible institutions, including those that may serve primarily underrepresented groups, those that may be less research-intensive, and from all domestic geographic locations.

Key Definitions for this NOFO

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 for additional detail on the NIH SDOH Conceptualization.

Background

Despite scientific and technological discoveries that improved the health of the U.S. population overall, racial and ethnic minority populations and other populations marginalized by society continue to bear a disproportionate burden of disease and premature death. The life expectancy at birth for Black/African American and American Indian/Alaska Native populations is 6 and 11 years lower than for the non-Hispanic White population. Across diseases and conditions, these disparities deepen with a large variance attributed to historical injustices and present social inequities that limit the opportunity of communities and populations to live and maintain lives that are health-promoting. These factors are known as SDOH which shape individual, community, and population health across the life span.

Populations that experience health disparities have higher levels of cumulative exposure to adverse SDOH such as concentrated poverty, lower-quality education and employment opportunities, poor housing affordability, and lower accessibility of healthy food. Health disparity populations also have limited access to health-promoting social conditions, which further limits the optimization of health. Structural factors, rooted in racism, sexism, classism, homophobia, and other discriminatory systems, shape the extent to which conditions of daily life are equitably distributed or unfairly distributed by race, ethnicity, sex, gender identity, socioeconomic position, sexual orientation, or geography, and their intersections. Inequitable

exposure to health-promoting or adverse conditions of daily life are underlying causes of persistent and pervasive health disparities.

To make greater progress in fulfilling the NIH mission to enhance health, lengthen life, and reduce illness and disability, innovative and transformative approaches to addressing and removing longstanding barriers to advancing health equity are critical. This requires a sustained focus on addressing adverse SDOH and expanding access to health-promoting SDOH among populations at a health disadvantage. To effectively accomplish this, strong community partnerships are necessary to ensure relevance and resonance of approaches to tackle and ultimately eliminate longstanding and pervasive issues that contribute to poor health outcomes. Community partnerships are essential for developing feasible and acceptable approaches and achieving acceptance, uptake, and sustainability of proposed interventions and strategies. Partnerships within and across sectors such as education, housing, transportation, commerce, agriculture, economic and urban development, justice, human and social services, and public health are critical to advancing the translation of findings into sustainable community- and system-level changes that will have lasting impacts on health and advance health equity.

Research Objectives

Projects are expected to propose exceptionally innovative and transformative activities that are urgently needed to prevent, reduce, or eliminate health disparities and advance health equity. Projects may prospectively test new or adapted interventions (referred to as prospective interventions), evaluate existing or upcoming novel or unusual policy, programmatic, or environmental changes to generate significantly novel insights, or conduct innovative dissemination and implementation research. Research projects must address one or more SDOH as conceptualized by the NIH (https://www.ninr.nih.gov/researchandfunding/nih-sdohrcc#tabs2). SDOH can be addressed alone or in combination with other determinants of health and as part of a single or multilevel intervention approach. Studies should be guided by a conceptual framework identifying hypothesized pathways between the intervention or program and outcome(s). All projects should examine the mechanisms by which the intervention alters health and health disparities.

Projects must include a focus on one or more NIH-designated populations that experience health disparities in the US, which includes racial and ethnic minority populations, people with lower socioeconomic status, underserved rural populations, sexual and gender minority populations, people with disabilities, and any subpopulations that can be characterized by the intersection of two or more of these descriptors. As appropriate, studies are encouraged to explicitly examine whether the intervention mitigates differences in health outcomes between health disparity and non-health disparity populations. Given the heterogeneity within health disparity populations, within-group comparisons of intervention effects that allow for discovery of health risk and resilience factors are also encouraged.

Innovative approaches to identifying, understanding, and developing strategies for overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based

interventions, tools, policies, and guidelines are of interest. Projects that focus on elimination of interventions that are ineffective, unproven, low-value, or harmful in advancing health equity are also invited. Implementation research aims should be guided by equity-oriented theoretical models and frameworks. Modeling studies that evaluate the impact of specific interventions and implementation strategies to identify leverage points on costs and prioritizing strategies, particularly across the broad multi-sector nature of SDOH to inform scale up of interventions across communities and contexts, would also be responsive. Research that directly tests the effectiveness of SDOH interventions in narrowing health gaps between health disparity and non-health disparity populations is also strongly encouraged.

Community Partnerships: Projects must document or demonstrate throughout the research process meaningful community partnerships to foster the development of feasible and acceptable approaches as well as acceptance, uptake, and sustainability of proposed interventions and strategies. Community partners can include, but are not limited to, those in the housing, transportation, food system, economic development, education, social services, and criminal legal system sectors. Applicants should provide details on the nature and extent of the partnerships by clearly describing the roles of partners and providing evidence of support from partners.

Prospective Interventions to Address SDOH may develop and test the effectiveness of new or adapted interventions in a variety of settings in the U.S., such as neighborhoods, community-based organizations, child welfare and human service settings, workplaces, businesses, stores and restaurants, schools, criminal justice settings, faith-based organizations, public works and facilities, healthcare systems, and recreational settings. Approaches may include group or cluster randomized controlled trial (RCT), stepped wedge RCT, stepped wedge group or cluster RCT, pragmatic RCT, pragmatic trials, adaptive designs (e.g., multiphase optimization strategy [MOST], sequential multiple assignment randomized trials [SMART]), implementation trials (including hybrid effectiveness/implementation designs), and rigorous quasi-experimental designs.

Examples of projects supported in this category include, but are not limited to, studies that develop and evaluate the effectiveness of interventions to improve health or reduce health disparities by:

- Improving community conditions through community revitalization investment projects
- Improving economic stability, such as through increased job opportunities or quality employment
- Improving housing access, quality, or affordability
- Improving education quality
- Reducing community-level violence, including firearm violence
- Improving the availability or quality of green spaces or recreational spaces
- Improving community childcare availability together with providing access to parental support groups
- Improving nutritious food availability in the community in addition to providing primary care-based nutritional counseling to individuals

Evaluation of Existing or Upcoming Interventions may examine policies, programs, interventions, or environmental changes that are existing or upcoming in the U.S. to address SDOH (structural factors or conditions of daily life) (regardless of NIH funding) by states/territories, cities, counties, tribal communities, healthcare systems, public health departments, school systems, employers, or other organizations. Projects including multiple sites, locations, or settings are strongly encouraged to allow for the analysis of variability across and within settings. Studies that compare outcomes across populations in the U.S. with other countries are also allowed, if the comparison elucidates intervention mechanisms to reduce health disparities in the U.S. In addition to examination of individual level impacts as primary outcomes, examination of secondary outcomes that address unintended consequences of a policy or program, degree of implementation (including acceptance, uptake, spread, and sustainability), and implementation barriers and facilitators, are encouraged.

Examples of projects supported in this category include, but are not limited to studies that evaluate impacts on health and health disparities of:

- Federal, tribal, state, local, or organizational demonstration projects aimed at addressing SDOH
- Tribal policies or programs aimed to address SDOH among American Indian/Alaska Native populations
- New standards of care, changes in health insurance coverage, expansion of access to social services, and other factors that influence SDOH
- Programs or policies designed to improve access, quality, or affordability of housing, transportation, and food on health within communities
- Infrastructure changes related to housing, transportation, the food environment, or the built environment
- Programs, policies, or environmental changes targeting SDOH in addition to factors targeting individual or family circumstances such as housing instability, transportation access, nutrition insecurity
- Community economic development policy or program in addition to job training for individuals
- Program or policy to increase community availability of affordable housing, while also implementing screening and referrals for housing insecurity in healthcare settings

Study Designs: Randomization may not be possible for all intervention studies, e.g., where it is not possible to assign participants to high versus low discrimination conditions or in small sample sizes where cross intervention contamination is likely to occur or be a problem. Alternative rigorous research designs that provide robust evidence of intervention effectiveness include quasi-experimental designs, such as multiple baseline or repeated measures design or interrupted time series design. Also, hybrid effectiveness-implementation designs allow observational investigation of implementation processes while also testing intervention effectiveness. Investigators should justify their research and analytic design selection and provide adequate evidence of their ability to execute a rigorous and appropriate analysis of randomized or non-randomized study data.

Non-Responsive Applications

The following studies will be considered non-responsive for this announcement:

- Projects that do not address one or more SDOH as conceptualized as structural factors and conditions of daily life
- Projects that intervene solely at the individual/family level and not on SDOH as conceptualized by the NIH
- Intervention projects that do not include a community partnership
- Projects that do not focus on a population at higher risk of morbidity or mortality based on race, ethnicity, socioeconomic status, rurality, sexual orientation, and/or ability status
- Projects focusing on populations outside of the United States
- Projects that do not include a Plan for Enhancing Diverse Perspectives
- Construction and major renovations costs are unallowable through this RFA. Applications that propose to use grant funds to support construction or major alteration and renovation projects will be considered non-responsive.

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

National Heart, Lung, and Blood Institute (NHLBI)

The National Heart, Lung, and Blood Institute (NHLBI) provides national leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, blood and sleep disorders or conditions. The NHLBI is interested in innovative applications for preventing, reducing, or eliminating health disparities of heart, lung, blood and sleep disorders/conditions in underserved communities through late-stage translation research, notably dissemination and implementation science. Investigators are required to meaningfully engage community partners at the onset and throughout their research project. This engagement includes co-creation of research objectives, active community participation in the intervention, bi-directional communication, reasonable compensation for community partners, and shared leadership. Applicants are strongly encouraged to contact Scientific/Research staff noted in this RFA about proposed activities prior to submission.

National Institute on Aging (NIA)

NIA supports mechanism-based intervention research to prevent, reduce, or eliminate health disparities and inequities over the life course, especially among older adults and people living with Alzheimer's disease and Alzheimer's disease related dementias (AD/ADRD), as well as their caregivers. Applicants are encouraged to consider the priorities outlined in NIA's strategic directions for health disparities research and in the AD+ADRD Research Implementation Milestones related to health disparities , and those reflected within NIA's Health Disparities framework .

Similarly, NIA encourages applicants to draw upon the NIH Stage Model for Behavioral Intervention Development, which offers a framework to: (1) support development and testing of effective interventions that are defined by their principles and (2) ensure that efficacious interventions can be administered in the community or in health systems with fidelity to the intervention's principles. This includes the development, testing, and validation of scalable training materials and procedures so that these interventions can be delivered with fidelity in community settings or health systems. In keeping with the Stage Model, applications should

propose contemporary analytic techniques to evaluate mechanisms by which the focal intervention impacts health and health disparities.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

NIAAA is interested in supporting unusually innovative intervention research, which, if successful, would have a major impact on preventing, reducing, or eliminating health disparities and advancing health equity by addressing research questions that target social determinants of harmful drinking and alcohol use disorder. While prior research on the impact of SDOH on the onset, progression, and recovery from alcohol use disorder (AUD) has primarily focused on SDOH at the individual level, more recent research examining community-level SDOH has found that communities with lower socioeconomic status experience more consequences from alcohol consumption, even though higher socioeconomic status communities consume more alcohol. Lower socioeconomic status communities also have higher densities of alcohol outlets, which is associated with greater alcohol consumption and harms. Under this Initiative, NIAAA seeks to investigate strategies that address the social determinants of harmful drinking at all levels of influence, including at the individual, family, community, and government/policy levels. Special emphasis will be placed on interventions to address the social determinants of harmful drinking, AUD onset and progression, and long-term recovery from AUD at higher levels of influence (e.g., communities, government) and on multi-level interventions. Examples include but are not limited to strategies that address employment/income, housing, and access to mental health and primary care services among people who drink at harmful levels. Applications that include a partnership between Research Centers in Minority Institutions and other institutions with extensive programs in community-partnered alcohol prevention and treatment research are strongly encouraged.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

The mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases. Research areas include rheumatology, orthopaedics, dermatology, metabolic bone diseases, heritable disorders of bone and cartilage, inherited and inflammatory muscle diseases, and sports and rehabilitation medicine. In the context of this NOFO, the NIAMS is particularly interested in innovative intervention research that integrates biomedical and behavioral mechanisms, on both individual and community levels, to reduce and encourage elimination of health disparities for patients with multiple chronic condition within the NIAMS mission relevant diseases, such as osteoarthritis (for specifics, please visit the website of the Health Disparities in Osteoarthritis Workshop). Clinical trial applications will only be supported by NIAMS if submitted to a NIAMS clinical trials specific NOFO. A current list of active NIAMS clinical trials NOFOs is available at https://www.niams.nih.gov/grants-funding/conducting-clinical-research/investigator-clinical-trial-policies. Applicants are encouraged to discuss potential applications with the appropriate NIAMS program director.

National Institute of Dental and Craniofacial Research (NIDCR)

NIDCR is interested in supporting highly meritorious research that evaluates, implements, and or tests policies, programs, and/or interventions to promote equitable access to services, goods, and/or health care to help eliminate disparities in dental, oral, and craniofacial (DOC) diseases and conditions. Applicants are encouraged to employ multi-sector collaboration and

methodologies to elucidate mechanisms and solidify strategies for advancing DOC health equity by:

- Eliminating implementation barriers, unintended consequences, and enhancing facilitators
- Addressing social determinants of health, common risk factors, and structural/system barriers impacting co-morbidities of DOC diseases and conditions
- Enhancing acceptability/uptake, effectiveness, cost-saving, sustainability, and value
- Eliminating ineffective, low-value, and discriminatory practices, behaviors, and/or care

National Institute on Drug Abuse (NIDA)

NIDA is interested in innovative research determining the extent to which interventions at the policy, community, or organizational levels that address SDOH reduce health disparities and improve substance use and associated negative outcomes. Specific outcomes of interest include: 1) preventing or reducing substance use risk, substance use initiation, substance misuse, and escalation from misuse to substance use disorder (SUD); 2) reducing health disparities and the severity of health, social, and criminal legal outcomes for people with SUD; and 3) improving access to, engagement with, and benefits from SUD treatment, harm reduction services, recovery support services, and efforts to prevent fatal and non-fatal overdose among populations who experience health disparities. NIDA prioritizes research that examines the mechanisms through which addressing the SDOH will reduce health disparities and have an impact on substance use outcomes.

Examples of research areas that would be of interest to NIDA include, but are not limited to:

- Policies and programs to improve the coordination of treatment/prevention of SUD with housing affordability, accessibility, and permanency.
- Policies that enhance financial well-being within a population. Policy interventions may be implemented by multiple community-based organizations, and include efforts to provide direct cash payments, address food insecurity, promote workforce engagement, increase health insurance coverage, or other reforms to reduce economic insecurity.
- Criminal and legal system policy and practice changes to address discrimination against racially and/or ethnically minoritized populations. Reforms may include efforts by criminal and legal system entities (i.e., law enforcement agencies, courts, community corrections), community empowerment organizations, crisis response providers, educational entities, and other sectors.
- Policies or programs to prevent violence, including efforts by police, education, community groups, public health, and recreation organizations to reduce firearms access, increase availability of recreational opportunities for youth, or encourage healthy relationships.
- Child welfare policies or programs intended to prevent child welfare system involvement and improve family functioning on substance use, adverse childhood experiences, family separation, and other negative outcomes for the family, parent(s), and/or child(ren).
- Interventions designed to reduce misinformation, stigma, and discrimination associated with substance use, SUD, and SUD services.

- GED, high school completion, job-seeking support, or apprenticeship training program paired with mentorship for individuals aging out of child welfare, affected by regional job loss, in the criminal legal system, or experiencing multigenerational poverty.
- Policies or programs to improve equitable quality of, access to, and engagement in treatment and prevention services.
- Efforts to coordinate SDOH-related programs and services across sectors/agencies and test the cost and public health impacts of those initiatives.

Applicants may choose to study a single intervention or a combination of interventions. To maximize the acceptability, feasibility, scalability, and sustainability of the SDOH intervention being studied, applicants are encouraged to engage relevant end users in study conceptualization, design, execution, and interpretation. For the purpose of this NOFO, end user is broadly defined and may include policymakers, state and local level decision makers, practitioners, intervention implementers, families, youth, and community members, among others. Studies supported by NIDA must include a substance use outcome, and applicants are encouraged to test the mediational processes by which addressing the SDOH reduces health disparities and improves substance use and related outcomes.

National Institute of Environmental Health Sciences (NIEHS)
NIEHS' mission is to discover how the environment affects people in order to promote healthier lives and has long worked to reduce environmental health disparities and promote environmental justice. NIEHS is interested in innovative intervention research that addresses the interaction of SDOH with chemical and other environmental exposures that compromise health and contribute to health disparities. Examples of environmental exposures which are considered of primary interest for NIEHS include but are not limited to: industrial chemicals or manufacturing byproducts, metals, pesticides, herbicides, air pollutants and other inhaled toxicants, particulates, or fibers, fungal, and bacterial or biologically derived toxins. Applicants are strongly encouraged to reach out to the Scientific Contact in the NOFO to discuss if the application fits the NIEHS mission. Applications responsive to NIEHS are required to clearly identify the environmental exposure(s) of interest and describe the intersection of the exposure(s) with SDOH. The use of a conceptual model demonstrating the relationship of SDOH with the environmental exposure(s) of interest is highly encouraged. While the Transformative Research to Address Health Disparities and Advance Health Equity initiative supports the evaluation of existing or upcoming interventions, NIEHS is particularly interested in: 1) prospective interventions that develop and test interventions addressing the intersection of social and environmental determinants of health at multiple levels and 2) implementation research (including hybrid effectiveness-implementation studies) focused on strategies to adopt and integrate evidence-based interventions that eliminate environmental health disparities and advance environmental health equity. For applications proposing prospective interventions and implementation research, the use of implementation science frameworks is strongly suggested to promote acceptability, scalability, and sustainability.

National Institute of Mental Health (NIMH)

The National Institute of Mental Health (NIMH) is interested in applications relevant to priorities described in this NOFO and that support the NIMH Strategic Plan for Research. For the purposes of this NOFO, NIMH is particularly interested in (but not limited to) projects that:

- Develop and test new mental health preventive, treatment, and services interventions and/or strategies for implementing interventions with established effectiveness, with a focus on social determinants of health (SDOH) as primary mechanisms.
- Develop and test multi-level mental health interventions that target social and structural determinants of mental health disparities.
- Identify SDOH that mediate or moderate intervention and/or implementation effectiveness.
- Identify risk and protective SDOH that drive disparities in intervention and/or implementation outcomes.
- Investigate whether and to what extent financing mechanisms, policies, regulations, and healthcare system rules optimize patient-level outcomes, and identify mutable factors and policy interventions that can improve mental health outcomes.

All applications that propose clinical trials should follow the NIMH's experimental therapeutics approach to intervention development and testing (see https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml). That is, the scope of work should include specification of targets/mechanisms and assessment of intervention induced changes in the presumed targets/mechanisms that are hypothesized to account for the intervention's outcomes. In this manner, the results of the trial will advance knowledge regarding therapeutic change mechanisms and be informative regardless of trial outcomes (e.g., in the event of negative results, information about whether the intervention was successful at engaging its targets can facilitate interpretation.

Depending on the research question, a variety of methodologically rigorous approaches may be indicated. For example, for studies that involve testing and comparing alternative strategies, designs may include randomized controlled trials (RCTs) and variants (e.g., stepped wedge cluster randomized trial designs), quasi-experimental designs with non-randomized comparison groups, time-series designs, and other designs of equivalent rigor and relevance. Considerations for selecting a research design for the proposed study include the scientific question that the study is designed to answer, practical constraints, ethical issues, and the tradeoff between maximizing internal and external validity; the design that is proposed should be justified, accordingly, in the application.

NIMH is committed to supporting research that reduces disparities and advances equity in mental health interventions, services, and outcomes. Accordingly, this NOFO encourages research studies that examine approaches that can be used to reduce disparities for racial and ethnic minority groups, individuals limited by language or cultural barriers, sexual and gender minorities, individuals living in rural areas, socioeconomically disadvantaged persons, persons living with disabilities, and other underserved groups.

NIMH encourages a deployment-focused model of intervention and services design and evaluation that takes into account the perspective of relevant stakeholders (e.g., service users, providers, administrators, payers) and the key characteristics of the settings (e.g., resources, including workforce capacity; existing clinical workflows) that are intended to implement optimized mental health interventions. This attention to end-user perspectives and characteristics of intended clinical and/or community practice settings is intended to ensure the resultant interventions and service delivery strategies are acceptable to consumers and providers, the approaches are feasible and scalable in the settings where individuals are served, and the research results will have utility for end users.

NIMH encourages research on potentially scalable preventive, therapeutic, and services interventions that focuses on practice-relevant questions. Accordingly, collaborations between academic researchers and clinical or community practice partners or networks are encouraged. Studies should capitalize on practice infrastructure, including but not limited to SAMHSA-supported 988 Suicide and Crisis Lifeline services and training infrastructure, and when possible, NIMH encourages applications that leverage existing research resources (e.g., practice-based research networks such as the NIMH-sponsored Mental Health Research Network (MHRN), NIMH-supported ALACRITY and Practice-based Suicide Prevention Research Centers, institutions with Clinical and Translational Science Awards). To facilitate the ultimate translation into practice, NIMH encourages research and clinical approaches that incorporate the use of routinely collected data (e.g., electronic medical records, patient registries, other administrative databases) to increase the efficiency of participant recruitment (i.e., more rapid identification and enrollment) to facilitate the collection of practice-relevant data (e.g., clinical characteristics; stakeholder-relevant outcomes, including mental health and general health care utilization; data on longer-term outcomes; data regarding the value and efficiency of intervention approaches).

National Institute of Neurological Disorders and Stroke (NINDS)
The National Institute of Neurological Disorders and Stroke (NINDS) is interested in applications within the NINDS mission (NINDS Disorders Index: https://www.ninds.nih.gov/health-information/disorders). NINDS aims to support exceptionally innovative and transformative community-engaged health equity research to improve outcomes specifically related to neurological disorders and advance neurological health equity in populations experiencing health disparities.

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

- Studies that examine the role of specific and modifiable SDOH in neurological health disparities
- Studies that examine the role of stigma, bias and/or discrimination as risk factors contributing to neurological health disparities in NIH-designated HDPs
- Studies that identify strategies to address structural barriers, organizational practices, policies and other social, cultural, and contextual factors that impact disparate neurological health outcomes among NIH-designated HDPs

Applicants are encouraged to utilize the NINDS SDOH framework for addressing health inequities and incorporate community engagement strategies into their clinical study designs. Many core principles of community engagement (trust, inclusivity, culturally-centered, etc.) are outlined in the National Academy of Medicine's Advancing Health Equity and Systems Transformation through Community Engagement. The NINDS encourages the use of common data elements (see NINDS CDE Project: https://www.commondataelements.ninds.nih.gov/). NINDS will not support clinical trials under this NOFO. For clinical studies, describe the rationale for the study design, population(s) and hypotheses being tested. Describe recruitment and retention plans and back-up strategies that are likely to reduce obstacles to study participation and ensure the appropriate inclusion of participants from NIH-designated populations that experience health disparities. The proposed study design should additionally describe potential biases and/or challenges in the protocol and how they will be addressed. NINDS explicitly emphasizes the NIH application instructions related to rigor and transparency (https://grants.nih.gov/policy/reproducibility/guidance.htm) and provides additional guidance to the scientific community (https://www.ninds.nih.gov/Funding/grant_policy). A letter of intent and communication with appropriate NINDS program staff prior to submission of an application is strongly encouraged.

National Center for Complementary and Integrative Health (NCCIH)
The mission of NCCIH is to determine, through rigorous scientific investigation, the fundamental science, usefulness, and safety of complementary and integrative health approaches and their roles in improving health and health care. Examples of complementary and integrative health approaches include those with physical and/or psychological therapeutic inputs, often called mind and body interventions (e.g., acupuncture, yoga, tai chi, qi gong, meditation/mindfulness, hypnosis, music therapy, art therapy, and massage), and approaches with dietary or nutritional therapeutic inputs (e.g., special diets). Applications will not be considered by NCCIH if they propose trials of regulated products (e.g., dietary supplements, devices, or biologics) for indications that have not been approved or cleared by the U.S. Food and Drug Administration. NCCIH will only support applications that include complementary and integrative health approaches. As discussed in NCCIH's Strategic Plan, expanding the portfolio of research on complementary and integrative health approaches to address and eliminate health disparities across the lifespan is a high priority.

Under this RFA, NCCIH is interested in supporting studies that develop, adapt, test, and/or implement culturally appropriate interventions with a complementary and integrative health component among populations experiencing health disparities. Research involving interventions with a high potential for sustainability and/or examinations of implementation strategies to facilitate sustainability are encouraged. In addition, a central focus of NCCIH's Strategic Plan is whole person health, which emphasizes that health exists across multiple interconnected body systems and domains, including biological, behavioral, social, and environmental. Multicomponent prevention interventions that intervene on social determinants of health to reduce risk and/or enhance protective factors across multiple levels of influence are aligned with a whole person health framework. Accordingly, under this RFA, research involving multicomponent behavioral or systems-level interventions that aim to

improve health and prevent disease in multiple interconnected therapeutic modalities and/or pathways are encouraged.

Investigators are encouraged to review the NCCIH Clinical Research Toolbox to learn more about NCCIH's requirements, policies, guidelines, and required templates for clinical trials. Applicants are strongly encouraged to discuss their proposed research interest with the designated NCCIH Scientific/Research Contact listed below to confirm its relevance to the NCCIH mission areas.

Office of Disease Prevention (ODP)
The ODP is the lead office at the NIH responsible for assessing, facilitating, and stimulating research in disease prevention. In partnership with the 27 NIH Institutes and Centers, the ODP strives to increase the scope, quality, dissemination, and impact of NIH-supported prevention research. The ODP is interested in providing co-funding support for research that has strong implications for disease and injury prevention and health equity and that include innovative and appropriate research design, measurement, and analysis methods. For this RFA, ODP is interested in multi-site and/or multi-sectoral interventions that address common risk factors for morbidity and mortality among populations that experience health disparities, including tobacco use, overweight/obesity, poor diet, physical inactivity, alcohol misuse, drug misuse, risky sexual behavior, injury and violence, infectious disease, and environmental health. For additional information about ODP's research priorities and interests, please refer to the ODP Strategic Plan for Fiscal Years 2019–2023.

Office of Research on Women's Health (ORWH)
The Office of Research on Women's Health (ORWH), which is part of the Office of the Director of NIH, works in partnership with the 27 NIH Institutes and Centers to ensure that women's health research is part of the scientific framework at the NIH, and throughout the health research community. ORWH is interested in studies focused on the influence of sex and gender and other social determinants of health on wellness and disease across women's lifespan. Within the focus of this announcement, the Office is open to co-funding research intervening across multiple levels to improve behavioral, psychosocial, and physiological health broadly and among women in NIH-designated health disparities populations. Interdisciplinary research using tools and methods with the potential to transform understanding of and ability to mitigate impacts of social and structural determinants on disease risk, etiology and progression are encouraged. Strategies to improve women's health equity, tackle research questions prioritized by women in underserved communities, and seeking to advance dissemination and implementation of the evidence from diverse perspectives are of particular interest.

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.

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
Cooperative Agreement: A financial assistance mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this NOFO.

Application Types Allowed
New
Resubmission
Revision
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
Issuing IC and partner components intend to commit an estimated total of $13,125,000 in FY 2024 to fund approximately 17 awards.
The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

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 SF 424 (R&R) 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 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 Ho 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:

Specific Aims: Do not list specific objectives of the proposed research. Instead, the specific aims page must contain a section entitled "Significance, Innovation, and Impact" and a section entitled "Insight and Rationale". The content of these two sections is described below. Together these sections should provide a cogent overview of your proposed research and its motivations.

Significance, Innovation, and Impact: What is the challenge and/or opportunity that is the focus of your proposed research? Why is this significant for advancing health equity? Describe your overall research approach for addressing the challenge or leveraging the opportunity. Does the proposed research meaningfully address SDOH – alone or in combination with other factors? What are the most innovative aspects of your application? If successful, what impact would the research have on reducing health disparities and advancing health equity?

Insight and Rationale: What is the fundamental new insight that is motivating the proposed research? What is the underlying logic or rationale that provides support for pursuing this insight despite little or no preliminary data?

Research Strategy: Organize the Research Strategy as a single document in the specified order using the instructions provided below. Start each section with the appropriate section heading as indicated. The presentation must be clear and compelling, even to those not in the immediate field of the proposed research.

Overview of research project: Briefly describe what is being proposed, including the SDOH and health disparities population that the research will address. Also describe why and how the proposed research is important to advancing health equity. Describe briefly the innovative aspects of the proposed research that illuminate its transformative potential.
Approach: No detailed experimental plan or substantial preliminary data should be provided. Though preliminary data are not required, if limited preliminary data are provided, they will be evaluated. Prominently state that, per the funding opportunity instructions, a detailed intervention plan and substantial preliminary data are not being provided. In lieu of preliminary data, provide the underlying logic or rationale for pursuing this project in the manner proposed. Summarize what you believe to be the major challenges or risks in the project and alternate approaches that may need to be pursued. Describe your approach for ensuring meaningful engagement with relevant community partners.
Innovation: Describe how your proposed research is unusually innovative and transformative compared to current approaches, paradigms, practices, or perspectives.
Appropriateness for the Transformative Research to Address Health Disparities and Advance Health Equity funding opportunity: Why is the proposed research well suited to the goals of the Transformative Research to Eliminate Health Disparities and Advance Health Equity funding opportunity rather than a more traditional research grant program?
Timeline: The Transformative Research to Address Health Disparities and Advance Health Equity project must be designed to have deliverables by the end of the project period that have the potential for transformative impact. The project should not be framed as initiating a line of research that will have the potential for transformative impact only after subsequent periods of support. Provide a timeline within the project period for the proposed research indicating points where intermediate objectives will be assessed, the measurable outcomes that will be used to monitor progress, and the timing and process for reaching decisions regarding the course and direction of the continuing research effort. Given the high degree of risk involved in applications submitted under the Transformative Research to Address Health Disparities and Advance Health Equity program, it is anticipated that investigators will need to continually reassess approaches based on intervention outcomes and potentially alter course to meet project goals. Possible alternative paths that may be followed at critical junctures in the project plan should be indicated on the timeline.

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 for this NOFO:

- Does the proposed research have clear transformative potential to reduce health disparities and advance health equity?
- Does the proposed research meaningfully address SDOH – alone or in combination with other factors?
- 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:

- Is the paradigm being challenged or proposed fundamental to the scientific field?
- 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 for this NOFO:

- Does the proposed research meaningfully involve engagement of community partners that are relevant to the science and population(s) of interest?
- 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

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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.
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 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 the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, 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

The following special terms of the award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 2 Part CFR 200, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH's purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or adopt a dominant role in the activities. Consistent with this concept, the

dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the NIH as defined below.

The PD(s)/PI(s) will have primary responsibility for:

- Providing scientific leadership for all aspects of the study, including planning, any modification of study design, the conduct of the study, quality control, data analysis and interpretation, preparation of publications, dissemination of data, tools, and technologies, and collaboration with other investigators.
- Agreeing to accept close coordination, cooperation, and participation of NIH staff in those aspects of scientific and technical management of the study as stated in these terms and conditions.
- Finalizing study design milestones, including a robust statistical plan for analysis, with NIH staff.
- Upon implementation of the study, following the procedures required by the agreed-upon study design regarding study conduct and monitoring, participant management, data collection, quality control, and statistical analysis.
- Providing summaries of progress toward goals and milestones at least yearly, as requested by NIH. The milestones will be reviewed annually (and at other times, if necessary), and new milestones will be negotiated, as needed by working with the NIH staff as appropriate.
- Retaining custody of and having primary rights to the data developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.
- Managing involvement of industry or any other third party in the study. Except for licensing of patents or copyrights, support or involvement of any third party will occur only following notification of and concurrence by the NIH.
- Making all study materials, procedure manuals, and final datasets available in the public domain, managed by the recipient institution. Recipients are expected to publish and publicly disseminate results, data, and other products of the study, concordant with NIH governance policies and protocols. Publications and oral presentations of work performed under this agreement will require appropriate acknowledgment of support by the NIH and the awarding IC.
- Obtaining prior written approval of the awarding IC Grants Management Specialist, in consultation with the Program Officer and Project Scientist, for changes in any of the key personnel identified in the Notice of Grant Award.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below.

The Project Scientist will:

- Consult with the PD(s)/PI(s) regarding study design milestones prior to finalizing the study design and as needed thereafter.

- Serve as a resource to provide scientific/programmatic support by providing input on experimental and clinical approaches and study protocols, and advising in the management and operational aspects of study development and implementation.
- Provide scientific and programmatic support to the PD(s)/PI(s) as the Project Scientist deems necessary, including contributing to data analysis, key personnel selection, and promoting the availability of data and resources.
- Participate in teleconferences or other discussions with PDs/PIs to monitor study development and implementation progress, adherence to the study protocol, the conduct of the study, and recruitment and retention of study participants.
- Review the progress of the study through consideration of routine reporting, site visits, oversight committee recommendations, etc. This review may include, but not be limited to, compliance with the study protocol, achievement of participant enrollment targets, and the timeliness and quality of data reporting.
- Periodically review reports of study progress. NIH staff may use information obtained from the data for the preparation of internal reports on the activities of the study. However, recipients will retain custody of and have primary rights to all data developed under these awards, subject to Government right of access consistent with HHS, PHS, and NIH policies.

The Project Scientist will not make decisions about the funding of this project and will not be involved in any special reviews of the project that make recommendations about funding.

The NIH Program Official will:

- Carry out a continuous review of all activities to ensure that the objectives are being met and that all regulatory, fiscal, and administrative matters are handled according to NIH and IC guidelines.
- Have the option to withhold support to a participating institution if technical performance requirements/milestones are not met.
- Conduct special reviews of the project as the Program Official deems necessary. NIH may engage outside experts to assist in these reviews. If concerns about the project arise and are not resolved, NIH may reduce or restrict the budget or reduce the term of support to phase out the project.
- An agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the notice of award.”.

The NIH reserves the right to terminate or curtail a study or any portion of a project in the event of (a) substantive changes in the project not approved in advance, (b) use of funds for activities not within the scope of the award, (c) failure to make sufficient progress toward the project milestones, (d) failure to comply with the terms and conditions of the award or establish necessary statutory, regulatory, policy approval required for conducting the project, or (e) ethical or conflict of interest issues.
Joint Responsibilities:

No joint responsibilities. All responsibilities and activities assigned to PI/PDs and NIH staff (PO, SDO, SD) are separate and distinct.

Dispute Resolution:
Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. Members will be: a designee chosen by the PD/PI, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

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 (currently 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.