

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Assessing the Effectiveness of Programs, Policies, or Practices that Affect Social Determinants of Health to Promote Health Equity and Reduce Health Disparities in Chronic Diseases

RFA-DP-23-001

02/23/2023

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:
National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Assessing the Effectiveness of Programs, Policies, or Practices that Affect Social Determinants of Health to Promote Health Equity and Reduce Health Disparities in Chronic Diseases

Activity Code

U01

Amendment I. Made December 12, 2022

Section IV.3 Letter of Intent - Revised letter of Intent (LOI) due date is 1/10/2023

Amendment II. Made January 14, 2023

Application Due Date is revised. Applications are due 2/23/2023

Revisions in the below sections are highlighted.

- Section I.2 Approach, Component B: SDOH Simulation Model Development is revised.
- Section IV. Research Plan, Component B: SDOH Simulation Model Development is revised.
- Section VI. Cooperative Agreement Terms and Conditions is revised.

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-23-001

Assistance Listings Number(s)

93.068

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this announcement is to support research with rigorous study design (i.e., natural experiments, quasi-experimental designs, economic evaluations, and systems simulation modeling) to evaluate the impact of existing programs, policies, or practices that affect social determinants of health (SDOH) and how changes in SDOH impact health disparities related to chronic disease outcomes.

This announcement has three (3) components:

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities
The purpose is to identify and evaluate how existing programs, policies, or practices that address SDOH mitigate health disparities related to chronic disease outcomes by using natural experiment or quasi-experimental study designs.

Component B: SDOH Simulation Model Development
The purpose is to apply a systems science approach to build a simulation model of the interplay of SDOH and their relationship to chronic disease outcomes and related health disparities and be able to assess the long-term (e.g., 5, 10, 20, 30 years) effectiveness and cost-effectiveness of programs, policies, or practices that address SDOH with a focus on the five priorities areas: Built Environment, Community-Clinical Linkages, Food and Nutrition Security, Social Connectedness, and Tobacco Free Policies.

Component C: Coordinating Center
The purpose is to support a coordinating center that provides organizational, logistic, and communication support to enhance the efficiency, productivity, and public health impact of the research centers that are funded under Components A and B.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-23-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:

01/10/2023
01/10/2023

Application Due Date:

02/23/2023
2/23/2023

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 11:59 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552
- Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review:

04/18/2023

Secondary Review:

05/25/2023

Estimated Start Date:

09/30/2023

Expiration Date:

02/24/2023

Required Application Instructions

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

Page Limitations: Pages that exceed the page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Apply electronically

Executive Summary

Purpose
The purpose of this NOFO is to support research with rigorous study design (i.e., natural experiments, quasi-experimental designs, economic evaluations, and system simulation modeling) to evaluate the impact of existing programs, policies, or practices that affect SDOH factors and how changes in SDOH impact health disparities related to chronic disease outcomes. SDOH are the conditions in which people are born, live, learn, work, play, worship, and age. Applied research will focus on SDOH in five areas: (1) built environment, (2) community-clinical linkages, (3) food and nutrition security, (4) social connectedness, and (5) tobacco-free policy.

This NOFO has three (3) components:

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities
The purpose is to identify and evaluate how existing programs, policies, or practices that address SDOH mitigate health disparities related to chronic disease outcomes by using natural experiment or quasi-experimental study designs.

Component B: SDOH Simulation Model Development
The purpose is to apply a systems science approach to build a simulation model of the interplay of SDOH and their relationship to chronic disease outcomes and related health disparities and be able to assess the long-term (e.g., 5,-10, 20, 30-years) effectiveness and cost-effectiveness of programs, policies, or practices that address the SDOH with a focus on the five priorities areas: Built Environment, Community-Clinical Linkages, Food and Nutrition Security, Social Connectedness, and Tobacco Free Policies.

Component C: Coordinating Center
The purpose is to support a coordinating center that provides organizational, logistic, and communication support to enhance the efficiency, productivity, and public health impact of the research centers that are funded under Components A and B.

Mechanism of Support. Cooperative Agreement

Funds Available and Anticipated Number of Awards. The estimated total funding (direct and indirect) for the 3-year period of performance is $28,500,000 to support up to 12 awards across the three components (A, B, and C). Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration, and cost of the applications received.

Budget and Project Period. The estimated total funding (direct and indirect) for the first 12-month budget period, 09/30/2023 to 09/29/2024, is $9,500,000. The estimated total funding (direct and indirect) for the 3-year period of performance, 09/30/2023 to 09/29/2026, is $28,500,000.

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

Period of Performance: 3 years, 09/30/2023 to 09/29/2026
Estimated Funding Per Year (direct and indirect) for each Tier is provided below.
Tier 1 (1 priority area): Up to $600,000
Tier 2 (2 priority areas): Up to $700,000
Tier 3 (3 priority areas): Up to $800,000
Tier 4 (4 priority areas): Up to $900,000
Tier 5 (5 priority areas): Up to $1,000,000

Component B: SDOH Simulation Model Development

Period of Performance: 3 years, 09/30/2023 to 09/29/2026
Estimated Funding Per Year: Up to $1,000,000 (direct and indirect)

Component C: Coordinating Center

Period of Performance: 3 years, 09/30/2023 to 09/29/2026
Estimated Funding Per Year: Up to $500,000 (direct and indirect)

Application Research Strategy Length: Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.

Eligible Institutions/Organizations. Institutions/organizations listed in Section III, are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs). Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply through their organization.

Number of PDs/PIs. Applications may include more than one PD/PI; however, the first PD/PI listed on the application will be the "contact PD/PI" for all correspondence. Any additional PDs/PIs are permitted but would be referred to as Co-PIs.

Number of Applications. Only one application per institution, normally identified by having a Unique Entity ID (UEI), is allowed for Component A or Component B, not both, and for Component C. To be funded for Component C, applicants must apply for and be funded for Component A or Component B. Separate applications are required for Component A, Component B, and Component C.

Application Type. New (type 1).

Special Date(s). None

Application Materials. See Section IV.1 for application materials.

Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

A link to this NOFO on www.grants.gov is available at Chronic Disease Center Notice of Funding Opportunities | CDC.

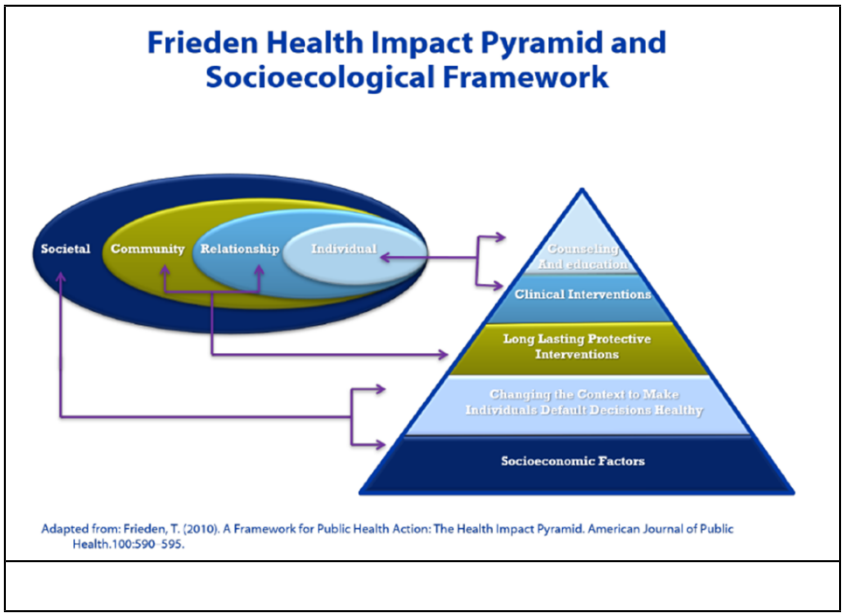
Section I. Funding Opportunity Description

Statutory Authority
Awards are made under the authorization of 317(k) (2) of the Public Health Service Act (PHS Act), 42 U.S.C. 247b(k)(2) and 301(a) of the PHS Act, 42 U.S.C. 241(a).

1. Background and Purpose

Cardiovascular disease, cancer, diabetes, obesity, and lung diseases are the most common causes of illness, disability, and death in the United States, and wide variations exist in their prevalence and outcomes across communities and populations. These disparities in health outcomes are closely linked with social, demographic, environmental, and geographic factors. Many chronic diseases tend to be more common, diagnosed later, and result in worse outcomes for people with lower incomes, people with lower educational attainment, those living in rural or hard-to-reach communities, racial and ethnic minority groups, and people with disabilities [1, 2]. Despite decades of research and interventions to reduce and eliminate these health disparities, they persist and, in some cases, are widening [3]. Disparities in health do not have a single cause. The socioecological framework highlights the interrelationships between aspects of the social and physical environments that operate at multiple levels to influence health [4]. Consistent with this framework, change can occur at individual, interpersonal, community, and structural levels to promote chronic disease prevention and significantly reduce health disparities. The structural social determinants or the social determinants of health (SDOH), the focus of this NOFO,

correspond to the bottom tiers of the Health Impact Pyramid, where action taken can have the greatest population impact [5] (see figure).



The Centers for Disease Control and Prevention (CDC) define SDOH as "conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks." [6]. The U.S. Department of Health and Human Services' Healthy People 2030 highlights the importance of addressing SDOH by including "social and physical environments that promote good health for all" as one of the four overarching goals for the next decade (Social Determinants of Health - Healthy People 2030 | health.gov). The key priorities of CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) support this charge by focusing on advancing health equity and addressing structural social determinants that drive inequity in health outcomes.

Definitions for this NOFO:

Health Equity: The state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and health care; and eliminate preventable health disparities.
Health Disparity: Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged.
Institutional, Structural, or Systemic Racism: The practices, policies, and laws that perpetuate racial/ethnic disparities, uphold, and privilege dominant groups, and serve to the cumulative detriment and harm of persons of color, keeping them in negative cycles of disadvantage while creating advantages for those in the dominant culture.
Social Determinants of Health (SDOH): The nonmedical factors that influence health

outcomes. The conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems.

Underserved Communities: Populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, such as Black, Hispanic/Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

Program: Defined as a set of activities initiated by governmental or other organizational bodies, for the purpose of reducing disparities and promoting health equity in chronic disease.

Policies: A policy is a course or principle of action adopted or proposed by a government, party, business, or individual. These may include both formal public policies at state, tribal, local, territorial, and federal levels of government and organizational level policies such as those implemented by large organizations (including companies or businesses), work sites, parks and recreation, early care and education, charitable food venues, or school districts.

Public Health Practice: Development and application of preventive strategies and interventions to promote and protect the health of populations. The purpose of public health practice is to prevent disease or injury and to improve the health of communities through such activities as disease surveillance, program evaluation, and outbreak investigation.

Priority Areas: Rigorous research designs such as natural experiment research and implementation research of policies, practices, and programs that impact the SDOH can aid in better understanding whether the benefits of these interventions are distributed equitably across different groups (e.g., defined by race/ethnicity, education, income, age, sex, geography [rural/urban], disability status, and sexual orientation or gender identity) and their effectiveness and cost-effectiveness in reducing disparities in chronic disease outcomes. This NOFO directly addresses research aspects of the NCCDPHP's five priorities on SDOH: 1) Built Environment, 2) Community-Clinical Linkages, 3) Food and Nutrition Security, 4) Social Connectedness, and 5) Tobacco-Free Policy. (Social Determinants of Health | CDC).

Systems Science: An interdisciplinary field that studies the complexity of systems in nature, social or any other scientific field. Some of the systems science methodologies include systems dynamics modeling, agent-based modeling, microsimulation, and Big Data techniques. Systems science thinking can help researchers to understand the factors influencing the distribution and determinants of health and disease in populations, by providing information on the broad picture of how individuals and other components of populations are interconnected in society in scenarios in which researchers cannot control the environment.

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

Built Environment

The built environment includes the physical makeup of where people live, learn, work,

worship, and play—our homes, schools, businesses, streets, sidewalks, parks, open public spaces, and transportation options. The built environment can influence overall community health and individual behaviors that drive health such as physical activity. A healthy built environment facilitates access to transportation, places, and resources that enhance quality of life and supports opportunities for physical activity and safe recreation. Numerous features of the human-made physical environment in which people live influence their ability to engage in leisure-time physical activity and to choose public transit or active transportation, which is human-powered transportation like walking or biking to work and school. These features include access to parks and other public or private recreational facilities, sidewalk and trail infrastructure, street connectivity, public transit infrastructure and access, bicycle lanes and infrastructure, and urban planning decisions that promote residential density and mixed land use, which influence the proximity of stores and local destinations to the places where people live, work, and spend their recreation and leisure time.

Lack of physical activity is a key modifiable risk factor for many chronic diseases. Built environment interventions are designed to increase physical activity by creating or modifying environmental characteristics in a community to make physical activity easier or more accessible for all people in the places where they live. Evidence suggests that implementing built environment strategies has the potential to promote active healthy living and improve chronic disease outcomes, and improve safety, social connectedness, air quality and local economies [7, 8]. In 2016 and 2021, the Community Preventive Services Task Force (CPSTF) developed evidence-based recommendations for built environment approaches to increase physical activity [9, 10]. The CPSTF conducted a systematic review of built environment approaches to create or enhance opportunities for physical activity and found sufficient evidence of effectiveness in increasing physical activity to recommend combined built environment strategies designed to enhance active transportation and leisure-time physical activity as well as park, trail, and greenway infrastructure interventions when combined with additional interventions. The CPSTF published through *The Community Guide* recommendations for coordinated approaches to combine interventions to improve pedestrian or bicycling transportation systems with interventions to create or enhance land use and environmental design features. Evidence suggests that features of the built environment may play an important role in reducing disparities in physical activity and chronic diseases in socioeconomically disadvantaged and rural communities, but the *Community Guide* review identified these as evidence gaps [9, 10]. Furthermore, if not implemented with the specific aim of improving physical activity in socioeconomically disadvantaged or rural communities, interventions to improve the built environment have the potential to increase health disparities [11]. While there is sufficient evidence that built environment interventions are effective in increasing physical activity in communities, there is some evidence that the benefits of built environment interventions are not distributed equitably and predominantly benefit socioeconomically advantaged groups [8].

An important gap in research on the built environment is the need to better understand the impact of built environment interventions on disparities in physical activity and chronic diseases. Rigorous natural experiment research of built environment interventions can aid in better understanding whether the benefits of these interventions are distributed equitably across different socioeconomic groups. Specifically, there are gaps in knowledge about the

effectiveness of built environment interventions in different settings with varying community characteristics, as well as intervention effectiveness among different demographic populations (e.g., among racial and ethnic minority groups and populations with varying socioeconomic status). Additionally, research is needed to understand how program effectiveness varies between urban, suburban, and rural settings and how built environment improvements to parks, trails, and greenways can improve perceptions of safety and community cohesiveness. Specifically, there is a need for greater evidence of the effectiveness of built environment interventions in rural areas, as much of the research has focused on urban areas.

Community-Clinical Linkages

Community-clinical linkages are defined as connections made among health care systems and services, public health agencies, agencies from other sectors, and community-based organizations to improve population health [12].

A large body of evidence suggests that social needs such as stable housing, access to nutritious food, reliable transportation, safety, stable and fulfilling employment, education, social connectedness, and financial stability contribute to health outcomes [13-17]. Addressing unmet social needs could potentially reduce morbidity and mortality more than advances in medical care [18]. In response to this evidence, National Academies of Sciences, Engineering, and Medicine (NASEM and the World Health Organization (WHO) have called for the integration of social and clinical care [19-21]. A growing number of health care providers and private and public health care payers are implementing initiatives for addressing social needs of the populations they serve [22]. For example, the Accountable Health Communities (AHC) model, launched in 2016 by the Center for Medicare and Medicaid Innovation (CMMI), aims at connecting Medicare and Medicaid beneficiaries with community services to address unmet social needs. The AHC provides funding for screening for health-related social needs of Medicare and Medicaid beneficiaries, referral to community services, and assisting beneficiaries in navigating community services [23]. A 2017 Kaiser Family Foundation survey of managed care organizations (MCOs) serving Medicaid beneficiaries found a high percentage of MCOs had implemented strategies to address SDOH of their members, focusing primarily on housing, food and nutrition security, and non-emergency medical transportation [24, 25].

Despite the increased uptake of these programs, their overall impact on health outcomes and disparities, quality of life, and costs remain largely undetermined. A 2021 systematic review of the impact of screening and referral programs in health care systems reported some evidence of positive changes in patient screening and referral, connection to resources, patient-reported outcomes, patient satisfaction, and some health indicators. However, because of the potentially high risk of bias in the included studies, no definitive conclusions could be made about the impact of such programs on outcomes related to experience of care, population health, and cost [26]. Further research is required to assess the impact of policies, practices, or programs that impact Community-Clinical Linkages on chronic disease risk factors and outcomes among disadvantaged populations.

Food and Nutrition Security

“Food and nutrition security exists when all people, at all times, have physical, social and economic access to food which is safe and consumed in sufficient quantity and quality to meet their dietary needs and food preferences, and is supported by an environment of adequate sanitation, health services and care, allowing for a healthy and active life” [27]. In 2020, 10.5 percent of U.S. households (13.8 million households) were food insecure [28]. Households with low and very low food security had difficulty at some time during the year providing enough food for all their members because of a lack of resources. In 2020, 3.9 percent of U.S. households (5.1 million households) had very low food security. In this more severe range of food insecurity, the food intake of some household members is reduced, and normal eating patterns are disrupted at times during the year because of limited resources. Among households with children, 7.6 percent (2.9 million households) had food insecurity at some time during 2020. Households with children experiencing food insecurity are unable at times to provide adequate, nutritious food for their children [29].

Food and nutrition security is a public health concern for a variety of reasons. Research shows that adults and children who have food insecurity may be at increased risk of negative health outcomes, such as obesity [30-35]. Additionally, the prevalence of chronic diseases is higher in low-income, food-insecure adults between the ages of 18-65 years as compared to the general population [36, 37]. For example, food insecurity in adults is associated with a higher risk of diabetes, depression, hypertension, and chronic kidney disease [35, 38-43]. Furthermore, among individuals with diabetes, food insecurity is associated with poorer glycemic control and greater health care use, including outpatient visits, emergency department visits and hospitalizations [43-47]. Research has shown that food insecurity may be a key driver in creating the well-documented socioeconomic disparities in chronic disease [48]. Food insecurity in children results in a higher risk of developmental problems compared with food-secure children, and the reduced frequency, quality, variety, and quantity of consumed foods may have a negative effect on children’s mental health [29, 31, 49, 50].

Food and nutrition security programs and policies can improve access to, and affordability of, safe and sufficient food to meet people’s dietary needs and food preferences. Examples of food and nutrition security programs include fruit and vegetable prescription and “Food is Medicine” programs; federal food assistance programs like the Supplemental Nutrition Assistance Program (SNAP) and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); programs and policies that address food waste; agricultural policies; initiatives to establish nutrition policies and standards for food procured and distributed at food banks and pantries; and clinical-community linkage programs to implement food insecurity screening and referral to community resources. Enhancing durable access to and routine consumption of adequate, nutritious food can support overall health, reduce morbidity and mortality associated with chronic disease, and decrease health care utilization. Applied research can evaluate the impact of programs, policies, and environmental improvement strategies that improve access to and affordability of healthy and safe food on health disparities-related chronic disease outcomes.

Social Connectedness

Social connectedness is defined as the degree to which individuals or groups of individuals

have and perceive a desired number, quality, and diversity of relationships that create a sense of belonging, shared identity, and being cared for, valued, and supported [51]. Individuals and groups operate in multiple environments (e.g., workplace, neighborhood, larger geographic communities) that "spill over" and influence each other [52, 53]. Social isolation and loneliness are aspects of social connectedness and are often used interchangeably, although empirically interrelated but distinct concepts. Social isolation is the objective state of having few social relationships or infrequent social contact with others, while loneliness is a subjective feeling of being isolated. Both are serious public health issues and affect a significant portion of the population [52]. All people are affected by social connectedness, but systemic discrimination across social ecological levels makes it difficult for some individuals or groups of individuals who are vulnerable because of their ability, age, gender identity, location, race, ethnicity, or sexual orientation to feel socially connected.

Social connectedness is a significant determinant of mental, emotional, and physical health and serves as a key factor in protecting, improving, and maintaining individual and community well-being. Social relationships shape interpersonal interactions and intrapersonal experiences that can alter physiology across the life course [54, 55]. Being embedded in high-quality, close relationships and feeling socially connected to the people and groups within one's life are associated with decreased risk for all-cause mortality, as well as a range of disease morbidities and adverse maternal outcomes [56, 57]. A high degree of social connectedness can increase the likelihood of individuals engaging in positive health behaviors, ultimately improving health outcomes by moderating the negative health effects of psychological adversities such as stress, trauma, anxiety, and depression. In addition, a high degree of social connectedness can increase the individual's and community's pool of social support resources, facilitating access to health care, dependent care, transportation, economic resources, employment opportunities, etc.

In 2021, CDC's NCCDPHP adopted social connectedness as a population health strategy to promote positive and supportive social relationships and community connections for improved health and well-being [52]. Social isolation and loneliness may be preventable through modifications in living arrangements, social networks and support, and social participation [52, 58]. Multi-level approaches from the individual to population level with community involvement and engagement may be optimal for successful, sustainable social connectedness interventions, programs, and policies [52, 58].

An important gap in the research on social connectedness is understanding whether programs, policies, and interventions designed to promote positive and supportive social relationships and community connections have an impact on disparities across groups (e.g., defined by race/ethnicity, education, income, age, sex, geography [rural/urban], disability status, and sexual orientation or gender identity) and their cost-effectiveness on reducing disparities.

Tobacco-Free Policy

Tobacco-free policies refer to evidence-based interventions and policies designed to protect people from secondhand smoke and aerosol exposure and reduce commercial tobacco use (not including the sacred and traditional use of tobacco by some American Indian

communities). Evidence-based population-based interventions and policies to reduce tobacco use and tobacco-related morbidity and mortality include the following: smokefree/tobacco-free policies that prohibit smoking and "vaping" in public places, including worksites, restaurants and bars; mass-reach media campaigns with hard-hitting messaging (e.g., CDC's Tips From Former Smokers®.); increase in tobacco prices; access to tobacco cessation treatment; and strategies focused on the tobacco retail environment, including availability; pricing and promotion; advertising and display; age of sale; and retail licensure [59, 60]. Disparities in tobacco use, secondhand smoke exposure, related health problems, and access to treatment can exist based on where people live, the type and amount of employment and health insurance they have, and other social and demographic factors such as race, ethnicity, age, sexual orientation, disability status, level of education, income, and/or behavioral health status [61]. Racial/ethnic minority groups; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with low educational attainment; persons with low income; persons with mental health and substance use disorders; and persons living in the Southern and Midwestern geographic areas of the United States have high prevalence of tobacco use compared with their counterparts as they have experienced less progress in reducing tobacco use in the last decade. The disparity gaps based on population characteristics such as education level have grown wider over time.
Menthol cigarettes contribute to tobacco-related health disparities in the United States Fewer people now smoke cigarettes than in the past, but the percentage of people from certain population groups who smoke menthol cigarettes has either increased or remains unchanged [62]. The tobacco industry aggressively targets its marketing to certain populations, including young people, women, and racial and ethnic population groups, particularly Black people. These groups are more likely to smoke menthol cigarettes compared to other population groups [62]. Implementing evidenced-based strategies and policies have proven to be effective in populations with high prevalence of tobacco use and can help eliminate disparities in tobacco use and tobacco-related diseases.

Addressing the SDOH is critical in achieving equity and eliminating disparities in tobacco use and tobacco-related diseases [63, 64]. While education and income are the two main SDOH that negatively impact tobacco use, addressing these two factors for the purpose of reducing disparities in tobacco use alone is probably not feasible as doing so would require fundamental social change and is not within the traditional practice of tobacco control. Addressing other SDOH factors such as the unequal distribution of resources, power, and services could reduce disparities in tobacco use [63]. To date, many of the policy strategies for addressing the SDOH and reducing health disparities has been geared towards improving access, coverage, quality, and intensity of health care. Greater attention should be given to addressing the SDOH outside the health care system.

Research is needed to assess differential impacts of tobacco control policies (including flavor/menthol bans), state preemption policies, and current tobacco prevention and control interventions on health disparities in cancers and cardiovascular disease among US adults.

Component B: SDOH Simulation Model Development

Programs, policies, or practices that address SDOH and reduce health disparities in chronic diseases are not independent and are usually interconnected [65, 66]. They may affect health disparities in chronic diseases at multiple levels [67] and through multiple mechanisms and pathways [1]. In addition, feedback loops exist between social and economic circumstances and health disparities in chronic disease. For instance, income disparities may affect health disparities in chronic disease, and health disparities in chronic disease may also affect income disparities.

A systems science approach mimics the dynamic characteristics of a complex system such as interrelations between multiple components in one system, players at multiple levels (e.g., individual, environments, community), and feedback loops [68], which provides a more accurate depiction of the real world. Simulation modelling using a systems science approach can estimate the effect of different scenarios where various intervention alternatives could be tested for their capacity to reduce health disparities [69]. Since there are usually multiple interventions in one model, one can compare which intervention is most effective or cost-effective at reducing health disparities in chronic disease or understand under what conditions an intervention can achieve the highest effectiveness. Simulation modeling using a systems science approach can combine SDOH factors into one model and considers the interdependence and interactions of those factors at multiple levels [67]. By incorporating interdependence and feedback between SDOH and health disparities at multiple levels, the simulation model using a systems science approach can improve the understanding of complex causal pathways [69]. Although systems science approaches have been used to answer public health questions in the fields of infectious disease, obesity, tobacco control [68], and other chronic diseases [70, 71], limited research has focused on addressing health disparities particularly through the SDOH lens. There has been a growing call for using a complex systems science approach to address health disparities within the SDOH context [67, 72, 73].

Component C: Coordinating Center

The Coordinating Center is intended to facilitate the interaction, productivity, and communication of a network of investigators conducting research under Component A and B to maximize study quality and impact. The Coordinating Center is expected to facilitate linkages among Component A and B awardees and other partners and provide a coordinated forum for communication and transfer of methodological advances in study design and analyses of natural experiments.

The recipient of component C promotes collaboration among the awardees of Components A and B with the overall goal of accomplishing study goals, including planning and organizing a kick-off meeting for the network within two months of award, together with the CDC. Applicants are also expected to identify key partners and form or expand collaborations/partnerships that will facilitate accomplishment of study objectives.

Purpose

The purpose of this NOFO is to conduct applied research with rigorous study design (i.e., natural experiments, quasi-experimental design studies, economic evaluations, and system simulation

modeling) to evaluate the impact of existing programs, policies, or practices that address the structural social determinants to reduce health disparities in chronic disease. This research will build an evidence base of innovative, community-based, structural interventions across multiple SDOH to reduce health disparities in chronic disease outcomes. Specifically, the aim is to identify these programs, policies, or practices that address the structural social determinants and better understand whether they are effective in preventing chronic disease for all, improving health equity, and reducing disparities in chronic diseases between subpopulation groups. The overarching purpose of this NOFO is to:
(1) Assess the effectiveness of existing programs, policies, or practices that are being implemented in the real world and address NCCDPHP's five (5) SDOH priorities for reducing disparities in chronic disease.
(2) Conduct implementation and translational science and modeling approach to better understand the mechanisms such as processes and pathways through which these programs, policies, or practices lead to better outcomes in reducing health disparities in chronic diseases and their associated risk factors.
(3) Assess the effects of individual and combined SDOH factors on health disparities (at national, state, and local levels) in chronic disease outcomes using a simulation modeling approach.
(4) Assess cost and cost-effectiveness of programs, policies, or practices for reducing health disparities (improving health equity) in chronic disease outcomes (at national, state, and local levels) using a simulation modeling approach.
(5) Inform future public health practice, i.e., not just looking at which practices, programs, and policies work, but rather how they can be implemented in the most effective, cost-effective, sustainable, and equitable manner.

Healthy People 2030 and other National Strategic Priorities

This NOFO supports the US Department of Health and Human Services' Healthy People 2030 SDOH goal of addressing SDOH by including "social and physical environments that promote good health for all," specifically the following topic areas and objectives:

- Neighborhood and Built Environment
    - Increase the proportion of adults who walk or bike to get places — PA10
    - Increase the proportion of adolescents who walk or bike to get places — PA-11
- Reduce household food insecurity and hunger — NWS-01
- Eliminate very low food security in children — NWS-02
- Health Care Access and Quality
    - Increase the proportion of adults who get recommended evidence-based preventive health care — AHS-08
    - Reduce the proportion of people who can't get medical care when they need it — AHS-04
    - Increase the proportion of people with health insurance — AHS-01
- Tobacco Use
    - Increase Medicaid coverage of evidence-based treatment to help people quit using tobacco — TU-16

- Reduce current tobacco use in adults — TU-01
- Increase the proportion of smoke-free homes — TU-18
- Increase the number of states, territories, and DC that prohibit smoking in worksites, restaurants, and bars — TU-17
- Increase successful quit attempts in adults who smoke — TU-14

As an agency, CDC is transforming its public health research, surveillance, and implementation science efforts to shift from simply listing the markers of health inequities to identifying and addressing the drivers of these disparities. See CDC's CORE Health Equity Science and Intervention Strategy.

Measurable outcomes of this NOFO align with the following performance goal for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP): to monitor, prevent, delay, detect, and control chronic disease, to achieve health equity by eliminating health disparities and achieving optimal health for all Americans.

Public Health Impact

This NOFO will identify effective and cost-effective programs, policies, or practices that address SDOH factors and generate evidence that can guide public health decisions on how to improve health equity in chronic disease outcomes. Rigorous evaluation research will advance our understanding of what works, for whom, and why. This research will fill important gaps in knowledge about 1) the effectiveness and cost-effectiveness of SDOH-centered programs, policies, or practices aimed at reducing disparities in chronic disease outcomes, 2) the resources required for implementation and scaling [74, 75], and 3) the impact of existing novel jurisdictional policy levers and systems change approaches to reduce health inequities and improve chronic disease-related outcomes in economically or socially disadvantaged populations (i.e., people with lower incomes, lower educational attainment, those living in rural or hard-to-reach communities, racial and ethnic minority groups, and persons with disabilities). In addition, the evaluation research will contribute to an underlying theory of causation or reveal specific elements and strategies that contribute to intervention effectiveness and potential impact on health disparities.

Relevant Work

NCCDPHP's mission is to help people and communities prevent chronic diseases and promote health and wellness for all. Promoting equity and eliminating disparities in chronic disease and risk factors by addressing SDOH and systemic factors that drive inequity in chronic disease outcomes is a NCCDPHP's priority (Social Determinants of Health | CDC). NCCDPHP has been working with communities nationwide to reduce health disparities in chronic diseases and their risk factors. Examples of current efforts on SDOH and health equity can be reviewed here https://www.cdc.gov/chronicdisease/programs-impact/sdoh.htm. These efforts include:

- Racial and Ethnic Approaches to Community Health (REACH) https://www.cdc.gov/nccdphp/dnpao/state-local-programs/reach/index.htm;
- Healthy Tribes https://www.cdc.gov/healthytribes/index.htm;

- Well-Integrated Screening and Education for Women (WISEWOMAN) https://www.cdc.gov/wisewoman/index.htm;
- National Breast and Cervical Cancer Early Detection Program (NBCCEDP) https://www.cdc.gov/cancer/nbccedp/index.htm;
- National Tobacco Control Program (NTCP) https://www.cdc.gov/tobacco/stateandcommunity/tobacco-control/index.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Ftobacco%2Fstateandcommunity%2Ftobacco_control_programs%2Fntcp%2Findex.htm;
- Networking2Save: CDC's National Network Approach to Preventing and Controlling Tobacco-related Cancers in Special Populations

https://www.cdc.gov/tobacco/stateandcommunity/tobacco-control/coop-agreement/index.html

- Scaling the National Diabetes Prevention Program in Underserved Areas https://www.cdc.gov/diabetes/programs/stateandlocal/funded-programs/dp17-1705.html;
- Community Health Workers for COVID Response and Resilient Communities (CCR) https://www.cdc.gov/COVID-community-health-workers/index.html;
- Social Determinants of Health Accelerator Plans https://www.cdc.gov/chronicdisease/programs-impact/sdoh/accelerator-plans.htm;
- Improving Social Determinants of Health–Getting Further Faster (GFF) initiative https://www.cdc.gov/chronicdisease/programs-impact/sdoh/community-pilots.htm.

This NOFO is intended to complement and be fully nonredundant with the other programs.

2. Approach

Applicants may apply for Component A or Component B, not both. To be eligible to be funded for Component C, applicants must apply for and be funded for Component A or Component B.

This NOFO is intended to support rigorous evaluation of the effectiveness and cost-effectiveness of existing or imminently available programs, policies, or practices that address SDOH factors and how changes in SDOH improve health disparities related to chronic disease outcomes. It is not intended to fund studies with only individual-level exposure and outcomes, simple pre-post designs without an appropriate comparison or support the initiation and delivery of new programs.

There are three components of this NOFO:

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities
Applicants for Component A are encouraged to study more than one priority area, to be innovative, and to evaluate multisector and multilevel programs, policies, or practices that address SDOH factors and how changes in SDOH affect health disparities related to chronic disease outcomes.

Programs, policies, or practices to be evaluated should:

1. Be existing (naturally occurring without influence by the researcher) or imminently available (e.g., policy effective compliance date is imminent) and expected to affect health disparities related to chronic disease outcomes, either explicitly (by design) or implicitly (as a more secondary, passive health impact)
2. Address at least one of the following five priority areas: (1) Built environment, (2) Community-clinical linkages, (3) Food and nutrition security, (4) Social connectedness, and (5) Tobacco-free policy.

The research projects funded under this NOFO can assess one or more existing programs, policies, or practices and their impacts on reducing health disparities in chronic disease outcomes, risk factors, or health behaviors. Programs, policies, or practices examined should be naturally occurring without influence by the researcher. Examples of research topics of interest per priority area include but are not limited to:

Built Environment

1. Changes in disparities in access to healthy built environments (e.g., activity-friendly routes to everyday destinations) or disparities in unhealthy exposures by race/ethnicity, income, age, disability, or immigration status after implementation of new or improved:
    a. Transportation policies (e.g., Complete Streets, Safe Routes, Safe Systems, Vision Zero)
    b. Land-use policies (e.g., comprehensive, or master plans and zoning regulations)
    c. Policies to prevent or mitigate displacement in connection with transportation or land-use changes to increase physical activity (e.g., just-cause eviction, right to counsel, rent control)
2. Transportation and/or land-use policies (such as Complete Streets, zoning reforms, or park, trail, and greenway infrastructure interventions). Assess policy provisions, implementation practices and/or jurisdiction characteristics, correlated with equitable implementation, barriers to equitable implementation, and cost-effectiveness of equitable implementation.
3. Interventions to improve built environments for health or health equity (such as Complete Streets, zoning reforms, or park, trail, and greenway infrastructure interventions). Identify equity-related co-benefits, such as safety, social cohesion, or economic opportunity, and which co-benefits are most important to local decision-makers, including variation by jurisdiction characteristics.

Food and Nutrition Security

1. State, tribal, territory, or community food interventions (e.g., policies, programs, environmental improvements) to address food and nutrition security resulting directly or indirectly in improved healthy food access for those at greatest risk of food insecurity and chronic diseases (aimed at disparity reduction or equitable implementation). Examples of policies, programs, and environmental improvements include, but are not limited to:

- Federal & Tribal Nutrition Programs including Food Purchasing Policies and Programs (e.g., The Emergency Food Assistance Program (TEFAP), Local Food Purchase Assistance, Pandemic Electronic Benefits Transfer (EBT), food distribution programs on Indian reservations, innovations in the Summer Food Service Program, community eligibility waivers for School Meal Programs, state waivers for local food procurement within the Child and Adult Care Food Program, temporary waivers for college/higher education students for Supplemental Nutrition Assistance Program (SNAP))
- Jurisdictional health service policies for Food is Medicine (Medicaid waivers, state plan amendments, accountable care organizations (ACO) & managed care alternative models, dual eligible provisions, in lieu of service pilots, health-related services)
- Food banking system policies and standards and food procurement policies that meet purchasing standards and cultural food needs within the charitable food system network
- Federal, state, territory, and tribal social safety net policies (e.g., earned income tax credit, housing eviction policies, meal services for seniors & individuals with disabilities, paratransit initiatives)

Community-Clinical Linkages (CCL):

1. Evaluate the effectiveness and cost-effectiveness of CCL programs in reducing risk factors for chronic diseases and improving disease management and outcomes in populations disproportionately impacted by chronic diseases (e.g., racial/ethnic minorities, tribal populations, people with low income, rural residents).
2. Assess the impact of CCL programs to address food insecurity on distal outcomes, such as the impact on household food insecurity; improvements in healthy eating patterns; changes in clinical measures like BMI, A1c, and blood pressure; reduced health care utilization; improved chronic disease management; and medication adherence.
3. Assess the impact of Patient Navigation and Community Health Workers (CHWs) on cancer prevention and screening. That is, do patient navigators or CHWs improve smoking cessation? Do they help individuals receive the appropriate screening and follow-up in the community?
4. Assess the effectiveness of CCL programs in optimizing care (including medication initiation, medication adherence, and lifestyle change) for controlling hypertension, hyperlipidemia, and diabetes and related complications.
5. Investigate how CCL programs that address social needs (e.g., access to health care, food and housing insecurities, changes in childcare arrangements, financial and emotional stressors) reduce disparities in adverse maternal health outcomes (e.g., depression, substance use, gestational diabetes mellitus, hypertensive disorders during pregnancy, etc.).
6. Examine the effectiveness of CCL in reducing infant deaths and death of women during pregnancy, at delivery, or soon after delivery among those populations disproportionately affected.

Social Connectedness

1. Identify the population health strategies that are effective at increasing social connectedness particularly among populations at increased risk for loneliness and social isolation (e.g., older adults, persons with disabilities, people living in rural settings, LGBTQ persons, etc.).
2. Assess the effectiveness of a specific social connectedness program/practice/policy/system change on intermediate outcomes of behavior change or those pertaining to physical and mental health and wellness, including cognitive, emotional, and health outcomes; recovery; functioning; social outcomes (i.e., satisfaction, community tenure); quality of life; health care access and utilization, including Medicaid and Medicare service utilization; health care costs and cost shifts from spending on acute care to community-based services, etc.
3. Identify the key implementation factors that might drive the effectiveness of social connectedness program/practice/policy/system change.
4. Assess the associations between various factors of social connectedness, including those that can be objectively measured (e.g., biomeasures or data from health records, occurrence, or length of relationship disruption) and those that require self-report and more distal health outcomes (depending on the priority population), such as chronic disease incidence, burden of complications, poor maternal outcomes, and infant mortality.
5. Assess the associations between various factors of social connectedness, including those that can be objectively measured, particularly among low-income, underserved, and vulnerable subpopulations younger than 50 years.
6. Investigate the modifiable predictors of social isolation and loneliness that have the greatest impact on risk of chronic disease.
7. Investigate whether strategies that increase social connectedness contribute to improvements in increased physical activity, healthy eating, increased access to health care services and improved self-management of chronic diseases.
8. Assess how social connectedness impacts health-seeking behaviors related to chronic disease outcomes across the life course in priority populations.

Tobacco-Free policy

1. Examples of state, tribal, territory, or community tobacco control interventions (e.g., policies, programs, environmental improvements) of interest include but are not limited to:

- Licensing retailers who sell any types of tobacco products, to better understand who is selling menthol and other tobacco products and to aid with equitable implementation and enforcement of tobacco control policies.
- Prohibiting sales of menthol and other tobacco products. Raising the price of menthol and other tobacco products and prohibiting price discounts.
- Curbing the advertising and marketing of menthol and other tobacco products to young people.

- Ensuring that all people who use tobacco products have access to evidence-based quitting resources, including counseling and medication, to help them successfully quit, and tailoring of cessation messages to better reach people who use menthol products.
- Developing educational initiatives that describe targeted tobacco industry marketing tactics and warn about the risks of tobacco product use, including menthol products.

2. Specific research topics of interest include but are not limited to:

- Assess differential impacts of tobacco control policies on cancers and cardiovascular disease among US adults by population groups disproportionally impacted by tobacco use and secondhand exposure.
- Examine how the impact of state preemption of local tobacco control policies affect health outcomes and disparities.
- Examine the effects of the elimination of menthol/flavors overall, including helping people quit tobacco use, and by sociodemographic and other characteristics associated with health disparities (e.g., race/ethnicity, income, insurance status, sexual orientation/gender identity, behavioral health conditions, urbanicity).
- Examine the interactive relationship between people-based and place-based disparities, the effect of tobacco control policies on this interactive relationship and the implications of this people-place relationship on strategies for reducing socioeconomic disparity in tobacco use.
- Examine the health equity effect of the current tobacco prevention and control interventions which work at a population-level.
- Examine the effectiveness and cost-effectiveness of tobacco control policy and programs designed to reach population groups with high prevalence of tobacco use.

<u>For all priority areas examined, applicants are expected to</u>:

- Establish goals and objectives that are realistic, measurable, and time-oriented for all phases of the project.
- Develop a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project.
- Identify opportune, natural experiments wherein accessible, comparable control data can be assembled and confounders and biases can be limited through study design, sample selection, and, to a lesser extent, statistical analysis.
- Identify a priority population (minimum population size affected should be 10,000 individuals); The priority population should include subgroups among whom disparities exist or one or more subpopulation groups with high prevalence of chronic diseases or their risk factors such as historically socially disadvantaged subgroups (i.e. people with lower incomes, lower educational attainment, those living in rural or hard-to-reach communities, racial and ethnic minority groups, and people with disabilities).
- Engage community-level partners (including individuals with lived experience and patients, where applicable) in their research process (planning and execution) and ensure that partners support the selected study outcomes.

- Utilize essential data on exposure and outcomes at the outset of the funding period and assemble diverse sources of data, including but not limited to:
    - Public survey data
    - Medical information systems such as electronic medical records
    - Nontraditional sources (including big data)
    - Cohort and panel survey data (provided the data permit examination of study interventions that cover large segments of the population)
- Propose quasi-experimental studies such as pre-post intervention designs with concurrent control conditions where possible and historical trends or interrupted time series designs. Studies are expected to assess population-level policies as well as indicators of uptake (including use of community services, social services, health care) and health outcomes at the population level.
- If an applicant is proposing to evaluate a program, policy, or practice that is part of a broader, multi-level prevention effort, describe the broader effort and how the evaluation design will disentangle impacts that might be due to other prevention activities and allow conclusions to be drawn about how changes in two or more outcomes can be attributed independently to the program, practice, or policy.
- Consider suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Develop, design, and pilot research protocols and instruments; recruit participants; and conduct appropriate data management procedures when applicable.
- Analyze data and disseminate findings in peer-reviewed journals and presentations at scientific conferences and other meetings.
- Participate in a kickoff meeting and recurring meetings with CDC program staff.
- Participate in the Steering Committee, the primary governing body of the study comprised of PIs from each site.

Component B: SDOH Simulation Model Development
Applicant funded for Component B is expected to:

1. Apply a systems science approach to develop a simulation model of the interplay of SDOH factors and programs, policies, and interventions and their relationships with chronic diseases, their risk factors, and disparities by subpopulation group. Since SDOH are interconnected, applicants are expected to propose a single model that will cover all the SDOH in the five priority areas from Component A and all major chronic disease outcomes (Heart Disease, Cancer, Stroke, Alzheimer's Disease, Diabetes, and Chronic Kidney Disease). Examples of modeling methods include but are not limited to the following: microsimulation, agent-based modeling, network analysis, system dynamic modeling, Markov modeling, and discrete-time modeling. Applicants are required to include all SDOH priority areas into the simulation model. Applicants shall be able to demonstrate the interrelationship between SDOH factors and how programs, policies, and practices would influence SDOH factors and the relationship between SDOH factors and chronic diseases, their risk factors, and disparities in a single model system.

As the purpose of this Component is to apply a systems science approach to build a

simulation model of the interplay of SDOH and their relationship to chronic disease outcomes and related health disparities and be able to assess the long-term (e.g., 5, 10, 20, 30 years) effectiveness and cost-effectiveness of programs, policies, or practices, when completed, the simulation model should have the following structure and functionalities:

- Ability to show pathways through which SDOH affect health outcomes, including chronic diseases and their primary risk factors, mortality, and health-related quality of life and economic outcomes to include health and societal costs overall and by subpopulation group;
- Ability to quantify the individual and combined contributions of SDOH factors on health and economic outcomes overall and by subpopulation group;
- Ability to assess the long-term effectiveness and cost-effectiveness of programs, policies, and interventions that address SDOH as measured in costs for a unit of change in disparities by health outcome;
- Ability to quantify the uncertainty of all model produced estimates.
- Ability to evaluate the contribution of an individual SDOH factor and combined multiple SDOH factors on disparities in chronic disease.
- Ability to compare which intervention is most effective or cost-effective at reducing health disparities in chronic disease or understand under what conditions an intervention can achieve the highest effectiveness.
- Ability to be modified as needed for changes in CDC's IT environment after the end of the period of performance.

2. Specific activities should include:

- Conduct a literature review of chronic disease modeling/simulation methods focusing on SDOH with the key objectives focusing on the purpose, structure, strengths, and weakness of the models and the data sources used for developing modules/components.
- Identify state-of-the-art modeling methodologies that can be readily adopted for building the simulation models.
- Identify the most appropriate clinical and real-world data to use, both available publicly and not available publicly.
- Develop a set of mathematical equations for how programs, policies, and interventions affect SDOH factors and how SDOH factors affect risk factors of chronic diseases, chronic disease outcomes, all diseases-related mortality, quality-adjusted life years (QALY), and costs.
- Obtain the data needed for developing the mathematical equations.
- Specify an algorithm used to link all the mathematical equations in the model.
- Specify the programming language for the simulation model.
- Build a web-based simulation model that can be installed and operated on CDC's Microsoft Azure cloud environment for CDC to make available to researchers and to the public for research conducted for public benefit.
- Initiate installation of the web-based simulation model to CDC's development environment of Microsoft Azure 6 months before the end of the period of performance. Test the performance of the model, conduct vulerability security scans

within the CDC network, and resolve identified issues to ensure the model is fully operational and free of vulnerabilities at the end of the period of performance.

- Ensure the web-based platform meets the technical and security standards for the CDC platform.
- Ensure the model interface and any public-facing documents or webpages follow CDC branding guidelines and obtain all necessary permissions for any use of CDC name and logos.
- Provide a run book that includes written procedures for the IT administrators for installation and deployment.
- Ensure the model complies with HHS established Section 508 accessibility standards before deployment. Information about Section 508 is available at HTTP://www.hhd.gov/web/508.
- Document the model through technical reports and user manuals.
- Disseminate the findings from this research through peer-reviewed publications and meeting presentations.

3. Participate in a kickoff meeting and recurring meetings with CDC program staff.
4. Participate in the Steering Committee, the primary governing body of the study comprised of PIs from each site

Component C: Coordinating Center

1. Design and develop an approach for establishing an ongoing network structure of Component A and B Research Centers awardees and institutions, partner awardees and institutions, and the funding agency.
2. Develop and plan for maintenance of a governance and organizing structure for the network, including an executive committee, steering committee, communications committee, and a publications, presentation, and ancillary committee.
3. Coordinate collaborative activities that will optimize the ability of the network to develop and use state-of-the-art methodological approaches for conducting natural experiments.
4. The Steering Committee will coordinate one in-person meeting each year and regular teleconferences throughout the year. The Steering Committee may create sub-committees as appropriate to accomplish its goals.
5. Prepare meeting logistics for the study including agendas; securing meeting facilities such as negotiating and reserving hotel rooms; leasing of meeting rooms with meeting equipment for annual face-to-face meetings; and planning and preparing weekly and biweekly Executive and subcommittee meeting minutes, etc.
6. Arrange and conduct conference calls, webinars, and meetings for the network and committees.
7. Generate key points and action items from meetings and facilitate communication between groups.
8. Develop and maintain an internal and external website for the study in accordance with CDC IT standards. The project website must be password protected for Study Group members and include a publicly accessible section.
9. Coordinate communication and dissemination activities for the network, including tracking of study publications and presentations to maximize impact of study findings.

10. Applicants for component C should have sufficient staff available to plan, coordinate, and travel to in-person meetings, and to resolve day-to-day issues of the network; to maintain study-wide timeline management; and to facilitate the exchange of abstracts, manuscripts, presentations, fact sheets, and other scientific materials among the collaborating centers and the funding agency.

Objectives/Outcomes

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

Research Centers are expected to complete rigorous evaluation or comparative effectiveness research studies of naturally occurring, existing population-level, health system or non-health system-based programs, policies, or practices aimed at reducing health disparities in chronic diseases. Specific objectives are to:

1. Use a natural experiments approach to assess the effectiveness, comparative effectiveness, or cost-effectiveness of existing (naturally occurring) population-level programs, policies, or practices within the SDOH domains on health disparities.
2. Generate evidence regarding the impact of addressing discrimination (e.g., structural racism, classism, sexism, ableism, ageism) on the effectiveness of the program, policy, or practice focused on one or more disproportionately affected populations.
3. Investigate successes and challenges in program, practice, or policy implementation, utilization, and usability for one or more disproportionately affected groups and inform recommendations for strategies, resources, and/or technical support needed for successful implementation.
4. Determine the co-benefits, adverse effects, and unintentional consequences of programs, policies, or practices that may inform policy makers.

Component B: SDOH Simulation Model Development

Research funded under Component B is aimed at developing a simulation model to assess the effectiveness and cost-effectiveness of naturally occurring existing or hypothetical population-level, health system or non-health system-based programs, policies, or practices aimed at reducing health disparities in chronic diseases. Since the SDOH are interconnected, applicants are expected to propose a single model that will cover all the SDOH in the five priority areas from Component A and all major chronic disease outcomes (Heart Disease, Cancer, Stroke, Alzheimer's Disease, Diabetes, and Chronic Kidney Disease).

The primary outcome of component B is to design, develop, and test a new web-based SDOH simulation model that operates on the CDC Network for CDC to make available for researchers and to the public for public benefit. The model will be able to assess the long-term (≥5 years) effectiveness and cost-effectiveness of existing or hypothetical programs, policies, and interventions on reducing health disparities or promoting health equity by addressing SDOH. Since there are multiple interventions in one model, one can compare which intervention is most effective or cost-effective at reducing health disparities in chronic disease or understand under what conditions an intervention can achieve the highest effectiveness.

Outcomes generated by the model include both effectiveness and cost outcomes. The effectiveness outcome is measured in primary and secondary outcomes:

- The primary outcomes are disparities in the incidence rate of chronic diseases (diabetes, heart disease, cancer, etc.), related mortality rate, and their disparities (race and ethnicity, sex, urbanicity, etc.).
- The secondary outcomes include disparities in incidence of chronic disease risk factors (smoking, obesity, etc.), and quality-adjusted life-years (QALY).

The cost outcome includes disparities in both health sector cost and societal cost.
All the outcomes should be assessed by subpopulation groups (race and ethnicity, sex, education, income, and rural vs. urban).

Component C: Coordinating Center

The objective of this component is to facilitate the interaction, productivity, and communication of a network of investigators conducting research under Components A and B to maximize study quality and impact. The Coordinating Center is expected to facilitate linkages among Component A and B awardees and other partners and provide a coordinated forum for communication and transfer of methodological advances in study design and analyses of natural experiments.

Target Population

Components A and B

The programs, policies, or practices to be evaluated should include subpopulations where known disparities exist (e.g., people with lower incomes, people with lower educational attainment, those living in rural or hard-to-reach communities, racial and ethnic minority groups, sexual/gender minority groups, people with disabilities, etc.).

Component C

Not applicable

Collaboration/Partnerships

Components A and B

Investigators are encouraged to form or expand innovative scientific collaborations/partnerships with researchers or agencies (e.g., community-based organizations, local governments, employers, etc.) that have established interests in reducing the disparities in chronic disease or that do not have established interests but nonetheless may influence key levers in reducing these disparities (such as influencing food or physical activity patterns). Such relationships could be useful for planning and/or execution of their focused research plans. Where applicable, applicants are encouraged to also engage with research participants in their research process (including planning and execution). Recipients are encouraged to partner with a community or set of communities that experience disproportionately high rates of chronic disease risk factors or outcomes (i.e., those that are higher than the national rates). Through these partnerships, researchers can rigorously evaluate programs, policies, or practices to determine their effectiveness in reducing chronic disease disparities, build capacity of community organizations to prevent chronic disease, develop approaches that are scalable, and disseminate/translate effective community chronic

disease prevention approaches that can inform national prevention efforts.

Component C

The recipient of component C promotes collaboration among the awardees of Components A and B with the overall goal of accomplishing study goals, including planning and organizing a kick-off meeting for the network within two months of award, together with the CDC. Applicants are also expected to identify key partners and form or expand collaborations/partnerships that will facilitate accomplishment of study objectives.

Components A, B, and C

Applicants are strongly encouraged to partner with investigators from Historically Black Colleges and Universities, Hispanic-serving institutions, Tribal Colleges and Universities, or Alaska Native and Native Hawaiian Serving Institutions.

Evaluation/Performance Measurement

Components A and B

Applicants should provide a timeline of key milestones anticipated during each project year. During the first project year, evaluation will be based upon and measured by the refinements made to study design, analytic protocol, commitments made to professional staffing and potential collaborators, and updated reviews of existing data that are relevant to the selected program, policy, or environmental improvement strategy being evaluated.

In subsequent years, success should be measured by performance measures demonstrating the execution of the research plan, procurement and/or collection of key data, appropriate validation of data elements, timeliness of data analyses, dissemination of findings in the form of peer-reviewed publications and scientific presentations, and participation in the collaborative, multicenter research network. Evaluation should include assessment of the degree to which the research fills important research gaps and assesses outcomes of important health impacts, including chronic disease risk.

Component C

Applicants should provide a timeline of key milestones anticipated during each project year. Evaluation/performance should address measurements of quality of promoting and facilitating a multicenter and collaborative environment among the award recipients, coordination of network conference calls and in-person meetings, development and execution of a communication plan including development of a study website, distribution of meeting reports, and tracking and management of and coordination of committee activities.

Translation Plan

Components A and B

Study findings are expected to be presented at professional meetings and at formal briefings for health and policy makers. Results should be submitted to peer-reviewed journals and aspects of the work disseminated through diverse media such as a study website and policy briefs.

Component C
Develop and implement a detailed communication and dissemination plan and coordinating communication activities of the network, including a website and communication materials. This should occur within the first 3 months of year 1 funding.

OMB/PRA is not expected to apply.

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3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:
CA (Cooperative Agreement)

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:
New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding:
$28,500,000

The estimated total funding (direct and indirect) for the first 12-month budget period (September 30, 2023 – September 29, 2024) is $9,500,000. The estimated total funding (direct and indirect) for the 3-year period of performance, September 30, 2023 to September 29, 2026, is $28,500,000.

Anticipated Number of Awards:
12
Award Ceiling by Component

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities
Estimated number of Awards: Up to ten (10)

Award Ceiling (direct and indirect), by Tier:
Tier 1 (1 priority area): $600,000
Tier 2 (2 priority areas): $700,000
Tier 3 (3 priority areas): $800,000
Tier 4 (4 priority areas): $900,000
Tier 5 (5 priority areas): $1,000,000
This amount is for the first 12-month period of performance.

Component B: SDOH Simulation Model Development

Estimated number of awards: One (1)
Ceiling: $1,000,000 (direct and indirect)
This amount is for the first 12-month period of performance.

Component C: Coordinating Center

Anticipated number of awards: One (1)
Ceiling: $500,000 (direct and indirect)
This amount is for the first 12-month period of performance.

Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$1,000,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
3 year(s)

Throughout the Period of Performance, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC’s determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, 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.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC 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

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations

Regional Organizations

Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Additional Information on Eligibility

For an application to be considered, the application must be responsive to these Special Eligibility Requirements. If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

1. Applicants must have continuous access to data sets and/or data systems needed to accomplish study objectives and a minimum study sample size of 10,000 individuals for each priority area selected.
2. Applicants must have approval for unrestricted publication of the study findings, regardless of study outcomes.
3. Applicants may not request funding above the ceiling amount (direct and indirect) listed below:

    Tier 1: $600,000
    Tier 2: $700,000
    Tier 3: $800,000
    Tier 4: $900,000
    Tier 5: $1,000,000

Component B: SDOH Simulation Model Development

1. Applicants must have access to the clinical and real-world data that are needed to develop and validate the simulation model.
2. Applicants may not request funding above the ceiling amount of $1,000,000 (direct and indirect).

Component C: Coordinating Center

1. Applicants for Component C must apply for Component A or Component B.
2. Applicants may not request funding above the ceiling amount of $500,000 (direct and indirect).

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

1. Applicants must provide a letter of commitment, memorandum of understanding, or data use agreement that demonstrates continuous access to data sets and/or data systems needed to accomplish study objectives, and include documentation (in the form of a table) showing that

the data for the proposed study meets a minimum sample size of 10,000 individuals for each priority area selected. This evidence should be placed in Appendix A of the application.
2. Applicants must provide a letter or agreement from the institution(s) providing data sets or access to data systems that allows unrestricted publication of findings regardless of study outcomes, in Appendix A of the application.
3. Requested budget (direct and indirect) must not exceed the funding level for the selected Tier.

Tier 1: $600,000
Tier 2: $700,000
Tier 3: $800,000
Tier 4: $900,000
Tier 5: $1,000,000

Component B: SDOH Simulation Model Development

1. Applicants must provide a letter of commitment, memorandum of understanding, or a data use agreement that show evidence that they have access to the clinical and real-world data that are needed to develop and validate the systems science simulation model. This evidence should be placed in Appendix A of the application.
2. Requested budget (direct and indirect) may not exceed $1,000,000.

Component C: Coordinating Center

1. Provide a copy of the face page of the organization's Component A or Component B application in Appendix A of the Component C application.
2. Requested budget (direct and indirect) may not exceed $500,000.

If the application is incomplete or nonresponsive to these requirements, it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- Grants.gov
- eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The one-time registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later.

SAM.gov is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no

organization may receive a subaward under the grant unless the organization has provided its UEI number to the recipient organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.

If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide 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. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

Please use the form and instructions for SF 424 (R&R) FORMS-H for applications due on or after January 25, 2023.

3. Letter of Intent

Due Date for Letter Of Intent 01/10/2023

01/10/2023
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows CDC staff to plan for the review. Prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the applicant organization
- Name, address, and telephone number of the contact PD/PI
- Name of other key personnel
- Participating institutions
- Number and title of this notice of funding opportunity announcement (NOFO)
- Indicate the Component(s) and for Component A, also indicate the Tier and priority areas to be studied.

Email the LOI to Researchnofo@cdc.gov and include this announcement number, DP23-001, in the email subject line.

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide at How to Apply - Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

All instructions in the SF424 (R&R) Application Guide at How to Apply - Application Guide must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

RESEARCH PLAN

- Applicants should indicate at the beginning of the Specific Aims, the respective Component under which the application should be considered.
- Component A applicants must:

    1. Identify the Tier and priorities to be studied at the beginning of the Specific Aims
    2. For the selected Tier, provide one Staffing and Management Plan and Study Dissemination and Impact to support all priority areas to be studied. For each priority area, address the remaining categories (Study Setting and Context, Study Methods, etc.).

3. Follow the Research Strategy page length provided below.

Component A Research Strategy Length	
Tier	**Maximum Number of Pages**
Tier 1	18
Tier 2	24
Tier 3	30
Tier 4	36
Tier 5	42

4. To be funded for Component C: Coordinating Center, applicants must also apply for and be funded for either Component A or Component B.
5. A separate application must be submitted for each Component.

The applicant's research strategy should address activities that will be conducted over the entire 3-year period of performance and should include the following.

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

Study Setting and Context

- Identify the existing program(s), policies(s), or practice(s) that will be evaluated.
- Describe the geographic area(s), jurisdictions, or communities for the proposed research and the size and demographic characteristics of the populations included in the proposed research study. If the study includes subpopulation analyses, provide a description. Provide justification of the choice of the proposed program, policy or practice for a natural experiments study and justification of the anticipated effect on chronic disease outcomes or risk factors.
- Explain where evidence is lacking on the programs, policies, or practices to be evaluated.
- Describe the potential value of the proposed project for policy, environmental, or systems change to reduce health disparities in the population(s) of focus.
- Describe disparities in chronic disease outcomes or risk factors to be addressed, for example, which chronic disease or risk factors in which subgroups of the population are affected by the programs, policies, or practices.
- Describe how health disparities are impacted by the programs, policies, or practices to be evaluated. Describe previous efforts to address these outcomes or risks factors within the population of focus and the remaining knowledge gaps.
- Describe the aspects of inequity or discrimination (e.g., structural racism, classism, sexism, ableism, ageism) addressed by the intervention and use correlational data and historical information to describe how discrimination affects chronic disease disparities in the priority population.
- Discuss the potential generalizability of the findings.

- Describe existing relationships, if any, between the research team and key community partners including those serving the community where the program, policy, or practice is impacting, if appropriate.

Study Methods

For each priority, provide a separate description of the relevant study methods which includes the following:

- List research/study objectives and describe how they relate to current risks and outcomes of chronic diseases in the United States or jurisdiction impacted by the policy, practice, or program.
- Describe the specific outcomes and any risk or protective factors or other proposed moderators or mediators to be examined.
- Provide the hypotheses to be tested related to program, policy, or practice effectiveness to reduce health disparities in chronic disease outcomes in the United States.
- Describe key sources of data, specifically:
    - Existing data sets and data systems that permit the assessment of health impacts of the selected program, policy, or practice for populations of at least 10,000 people.
    - How the data are appropriate for documenting the effects of the program, policy, or practice and likely to show the expected changes in the time available.
- Provide a data analysis plan including statistical methods, sample sizes, and power calculations for evaluating the program, policy, or practice in the population of focus. The study should be powered to detect change in health disparities in chronic disease outcomes or risk factors.
- If the applicant is proposing to evaluate a program, policy, or practice that is part of a broader, multi-level prevention effort, describe how the evaluation design will disentangle impacts that might be due to other prevention activities and allow conclusions to be drawn about how changes in two or more outcomes can be attributed independently to the program, policy, or practice.

Study Dissemination and Impact

- Describe plans for disseminating study findings at professional meetings, at formal briefings for health and policy makers, and/or to the community residents where the program, policy, or intervention was implemented.
- Describe plans for the submission of findings for publication in peer-reviewed journals and other venues to inform future policy, environmental or systems change to reduce health disparities in chronic diseases.

Staffing and Management

- Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of the team and expected contributions of key/collaborative partners.

- Research Team: Describe the experience of the principal investigator and co-investigators in undertaking complex public health-related or policy studies that (1) make use of data from diverse data sources, (2) are multi-disciplinary (including, but not limited to food/agricultural, tobacco, and built environment policy research, implementation science, epidemiology, public policy, health communications, economics, individual and organizational behavioral science, statistics), and (3) result in peer-reviewed journal publications. Applicant's research team should include investigators with expertise in health equity and SDOH research.
- Principal Investigator: Describe the principal investigator's (1) expertise, (2) established leadership in designing and conducting complex studies that make use of multiple sources of data, (3) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences and policy forums, and (4) commitment to collaborate and contribute to a multi-center research network, including participating in study meetings as well as periodic teleconferences each year. Specify the percentage of time that will be committed to this research program by the PI.
- Other Researchers: For each proposed co-investigator and other members of the research team, describe the following:(1) the person's expertise, (2) previous experience and contributions to relevant complex studies, including their publications in peer-reviewed journals and presentations made at professional and scientific conferences, and (3) specify the percentage of time that will be committed to this research program.

- Provide a management plan, which describes:
  - The staffing plan for the 3-year period of performance. Include project organizational charts with key personnel.
  - How and by whom the quality oversight and supervision will be provided for the research team.
  - If a position is yet to be filled, the position description and proposed timeline to fill the position in an Appendix.

- Provide a detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
- Describe plans for producing technical reports, professional presentations, communications to community partners and others who may be interested in the study findings, and journal and other publications.

<u>Letters of Commitment</u>

- Provide a letter of commitment from partner organizations that will be involved in the activities proposed in the application. Letters should (1) describe prior collaborations with the applicant organization, if any, and (2) specify the contributions that the partner organization is committed to make to the proposed research, including the provision of necessary data. Letters of Commitment should be uploaded into an Appendix.

Budget

- Provide a separate, detailed budget and line-item justification broken down by priority area for the first year that is consistent with the stated objectives. Upload the budget(s) into Appendix B of the application. Applicants should also provide specific budget estimates broken down by priority area for each of the other Budget Periods.
- Include in the budget the cost of travel to attend the kickoff meeting and one in-person annual meeting of the study steering committee

Component B: SDOH Simulation Model Development

Applicants are expected to propose a single model that will cover all the SDOH in the five priority areas and all chronic disease outcomes (Heart Disease, Cancer, Stroke, Alzheimer's Disease, Diabetes, and Chronic Kidney Disease).

Study Setting and Context

- Indicate which SDOH factors, programs, policies, or practices will be simulated for the five priority areas.
- Describe disparities in chronic disease outcomes or risk factors to be addressed, for example, which chronic disease or risk factors in which subgroups of the population are affected by the SDOH factors and existing or hypothetical programs, policies, or practices. The model should aim to address all major chronic disease outcomes (Heart Disease, Cancer, Stroke, Alzheimer's Disease, Diabetes, and Chronic Kidney Disease). At minimum, the population subgroups examined should include people with lower incomes, people with lower levels of education, or racial and ethnic minority groups.
- Describe how health disparities are addressed by the SDOH factors and existing or hypothetical programs, policies, or practices. Describe previous efforts to address these outcomes or risks factors within the population of focus and remaining knowledge gaps.
- Describe previous efforts to conduct simulation studies using systems science approaches to model the relationship between SDOH factors and existing or hypothetical programs, policies, or practices and chronic disease outcomes, risk factors and their disparities, and remaining research gaps.
- Provide justification of the choice of the proposed SDOH factors and existing programs, policies or practices for the simulation model and justification of the anticipated effect on chronic disease outcomes or risk factors. Discuss the potential generalizability of the findings.
- Describe the geographic area(s), jurisdictions, or communities for the proposed simulation study and the size and demographic characteristics of the populations included in the proposed simulation study. If the study includes subpopulation analyses, provide a description.
- Describe the potential value of the proposed simulation study for policy, environmental, or systems change to reduce health disparities in the population of focus.

Study Methods

- List research/study objectives and describe how they relate to current risks and outcomes of chronic diseases in the United States.
- Provide the potential mechanisms and pathways through which SDOH factors and existing or hypothetical programs, policies, or practices affect chronic diseases, risk factors, and their disparities.
- Indicate which systems science approach is to be used for the simulation modeling to evaluate the effectiveness and cost-effectiveness of SDOH factors and existing or hypothetical programs, policies, or practices on chronic disease, risk factors, and their disparities. Provide justification of the choice of the proposed systems science approach(es) for the simulation modeling.
- Describe key sources of data used for building and validating the simulation model and how the proposed sources of data will be used to build and validate the simulation model.
- Specify the algorithm to link all the mathematical equations in the simulation model.
- Provide a plan for building, calibrating, and validating the simulation model including how uncertainty in estimates will be determined.
- Describe a plan for building a web-based platform on which the simulation model will be operated on the applicant's web server and a plan for installing the model on the CDC web platform so that it is fully operational at the end of the period of performance.
- Specify the programming language used for coding the simulation model and justify the programming language selection.

Study Dissemination and Impact

- Describe plans for disseminating study findings at professional meetings and formal briefings for health professionals and policy makers
- Describe plans for the submission of model design and methods, findings, and recommendations for translating, adapting, or scaling the programs, policies, or practices for publication in peer-reviewed journals and other venues to inform future policy, environmental, or systems change to reduce health disparities in chronic diseases.

Staffing and Management

- Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of the team and expected contributions of key/collaborative partners.
    - Research Team: Describe the experience of the principal investigator and co-investigators in undertaking complex simulation modeling and public health-related or policy studies that (1) design, validate, and program a simulation model using systems science approaches; (2) make use of data from diverse data sources; (3) are multi-disciplinary (including, but not limited to food/agricultural, tobacco, and built environment policy research, implementation science, epidemiology, public policy, health communications, economics, individual and organizational behavioral science, statistics, computer science); (4) result in peer-reviewed journal publications; and (5) provide decision support for public and private policy makers.

- Principal Investigator: Describe the principal investigator's (1) expertise; (2) track record of designing, building and applying complex simulation models using systems science approaches; (3) established leadership in designing and conducting complex studies that make use of multiple sources of data; (4) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences and policy forums; and (5) percentage of time committed to the research program.
- Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (1) describe the person's expertise; (2) describe previous experience and contributions to relevant complex studies, including their publications in peer-reviewed journals and presentations made at professional and scientific conferences; and (3) specify the percentage of time that will be committed to this research program.

- Provide a management plan, which describes:
  - The staffing plan for the 3-year period of performance. Include project organizational charts with key personnel.
  - How and by whom the quality oversight and supervision will be provided for the research team.
  - If a position is yet to be filled, provide the position description and proposed timeline to fill the position in an Appendix.
  - A detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
  - Plans for producing technical reports, professional presentations, communications to community partners and others who may be interested in the study findings, and journals and other publications.

Letters of Commitment

- Provide a letter of commitment from partner organizations that will be involved in the activities proposed in the application. Letters should (1) describe prior collaborations with the applicant organization, if any; and (2) specify the contributions that the partner organization is committed to make to the proposed research, including the provision of necessary data. Letters of Commitment should be uploaded into an Appendix.

Budget

- Provide a detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods.
- Include in the budget the cost of travel to attend the kickoff meeting and one in-person annual meeting of the study steering committee.

Component C: Coordinating Center
Describe the following:

- Experience in directing and operating a coordinating center for collaborative, population-based, large-scale epidemiological research projects that include coordination of multi-site studies and providing governance support and logistical support.
- Planned approach to optimize the dissemination and impact of the findings from the research site network.
- Planned approach to optimize the ability of the network to develop and use state-of-the-art methodological approaches for conducting natural experiments.
- Experience working with confidentiality and privacy issues.
- Experience in development and management of websites as well as approach and timeline for a study website.
- Physical facilities, data management and computer resources, and facilities for data retrieval and storage.
- Unique contribution to the multi-site study and plans for coordination with the study network.

Staffing and Management

- Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of the team and expected contributions of key/collaborative partners.
    - Research Team: Describe the experience of the principal investigator and co-investigators in undertaking complex public health-related or policy studies that (1) make use of data from diverse data sources; (2) are multi-disciplinary (including, but not limited to food/agricultural, tobacco, and built environment policy research, epidemiology, public policy, health communications, economics, individual and organizational behavioral science, statistics); (3) involve multi-center collaboration throughout the study process; (4) result in peer-reviewed journal publications; and (5) provide decision support for public and private policy makers. The team should include investigators with expertise in health equity and SDOH research.
    - Principal Investigator: Describe the principal investigator's (1) expertise; (2) established leadership in designing and conducting complex studies that make use of multiple sources of data; (3) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences and policy forums; and (4) his/her commitment to collaborate and contribute to a multi-center research network, including participating in study meetings as well as periodic teleconferences each year.
    - Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (1) describe the person's expertise; (2) describe previous experience and contributions to relevant complex studies, including publications in peer-reviewed journals and presentations made at professional and scientific conferences; and (3) specify the percentage of time that will be committed to this research program.

- Provide a management plan, which describes:
    - The staffing plan for the 3-year period of performance. Include project organizational charts with key personnel.

    - How and by whom the quality oversight and supervision will be provided for the research team.
    - If a position is yet to be filled, the position description and proposed timeline to fill the position in an Appendix.

- Provide a detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
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Budget

- Provide a detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods.
- Include in the budget the cost of travel to attend the kickoff meeting and one in-person annual meeting of the study steering committee.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 42 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 20 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide at .How to Apply - Application Guide.

Applicants must use FORMS-G application packages for due date on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

For this NOFO, use the SF424 (R&R) Application Guide Version H forms and instructions.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, the **applicant** must:

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 02/23/2023

02/23/2023
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

For more information on expanded authority and pre-award costs, go to https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

Public Health Data:

CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

Human Subjects:

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained. IRB approval letters must be dated and should specify the name of the NOFO, or title of the project covered and the expiration date or lack of need for continuation review. If and when new supplements are added to the protocol, dated IRB approval letters for protocol amendments are required.

If the amendment approval letter does not specify the content of the amendment, a summary of the amendment request that was submitted to the IRB is required.

- Awardee organizations that rely on other institutions for their IRB review responsibilities shall provide documentation of the reliance and the IRB approval.

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and UEI.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e., grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g.,

equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:
All Senior/Key Personnel (including any Program Directors/Principal Investigators (PD/PIs) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. 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 CDC.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the UEI number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (https://www.cdc.gov/about/organization/mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority 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? 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?

Component A and Component B

- Does the applicant adequately address the research objectives stated in the NOFO?
- Is there convincing rationale based on theory, conceptual models, or data presented in the application that suggests that the policy or program intervention focus of the study will plausibly lead to important change in individual and systems behaviors, outcomes, and mitigate health disparities related outcomes?
- Does the applicant describe the potential or actual impact of the research on public health in the US?

- To what extent will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- Does the proposed research address policy and system-level interventions that may be applied to broad segments of the population and are they potentially generalizable to diverse settings?

Investigator(s)
Are the PD/PIs, collaborators, and other researchers well suited to the project? 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?

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities
For each priority area addressed:

- To what extent do the PI and/or co-investigator or other members of the research team have experience in conducting research or rigorous evaluation of programs, policies, or practices in the specific SDOH priority areas being examined by the proposed research?
- To what extent is there evidence of past collaboration between the proposed research team and external partners, and inclusion of end users including those with lived experience to co-design the project, to support the success of the proposed research?
- To what extent does the application demonstrate that the research team has the skills, experience, and sufficiently devoted time to complete the proposed activities within the project period?

Component B: SDOH Simulation Model Development

- To what extent do the PI and/or co-investigator or other members of the research team have prior experience and knowledge in:
    - Developing a simulation model using systems science approaches, designing or building simulation models of SDOH?
    - Conducting research in chronic disease epidemiology?
    - Conducting cost-effectiveness studies related to public polices, especially to SDOH polices?
    - Programming a complex simulation model and designing computer software?

Component C: Coordinating Center

- Does the applicant have experience in directing and operating a coordinating center for collaborative, population-based, large-scale epidemiological research projects that included coordination of multi-site studies and providing governance support and logistical support?

- Does the applicant describe an approach to optimize the dissemination and impact of the findings from the Natural Experiments network? Does the applicant have experience in development and management of websites?

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?

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

- For each priority area addressed, does the research evaluate a program, policy, or intervention for which evidence of effectiveness in reducing health disparities in chronic disease outcomes, risk factors, or behaviors in the population of focus is lacking?

Component B: SDOH Simulation Model Development

- Does the application propose innovative methods for developing a simulation model?
- Does the application demonstrate the potential to increase efficiency in advancing methodology for evaluating the effectiveness and cost-effectiveness of SDOH programs, policies, or practices on reducing the disparities in chronic disease in a simulation model?

Component C: Coordinating Center

None

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? 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?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

- Does the applicant demonstrate the ability to access the necessary data for the evaluation of the selected programs, policies, or practices, including disaggregated subgroup data, to understand if disparities are lessened? Are these data appropriate for documenting the effects of the programs, policies, or practices and likely to show the expected changes in the time available? Are the outcomes and any risk or protective factors or other proposed moderators or mediators to be examined clearly described, validly measured, and appropriate?

- Does the applicant propose a study with adequate sample size to test the proposed hypotheses, and is the study adequately powered to measure changes in disparities between subgroups? To what extent does the application specify strategies to achieve the projected sample size? Are appropriate strategies proposed to assure sample retention and adequate statistical power over time?
- If an applicant is proposing to evaluate a program, policy, or practice that is part of broader, multi-level prevention effort, to what extent does the applicant describe the broader effort and how the evaluation design will disentangle impacts that might be due to other prevention activities and allow conclusions to be drawn about how changes in two or more outcomes can be attributed independently to the program, practice, or policy?
- If an applicant is proposing to evaluate multiple programs, interventions, or policies, to what extent does the applicant propose to evaluate each program, intervention, or policy for its impact on reducing chronic disease disparities?
- If an applicant is proposed to evaluate multiple programs, interventions, or policies, how well does the application describe how the evaluation design will be able to disentangle impacts that might be due to each of the selected programs, interventions, or policies and allow conclusions to be drawn about how changes in two or more outcomes can be attributed independently to each program, intervention, or policy?

Component B: SDOH Simulation Model Development

- To what extent does the proposed research describe the plan to develop the SDOH simulation model using the systems science approach including design and model structure; key mathematical equations/parameters for the models including, but not limited to the interaction of existing and hypothetical SDOH programs, policies, or practices with risk factors for chronic disease; chronic disease incidence and prevalence, and their disparities; and relationships between chronic disease and the related medical and societal cost?
- To what extent does the applicant propose a systems science simulation model that will incorporate multiple causal pathways of SDOH and chronic diseases and their disparities? To what extent does the applicant propose a systems science simulation model that will assess the effectiveness and cost-effectiveness of SDOH factors and existing and hypothetical SDOH programs, interventions, or policies on reducing the disparities in chronic disease?
- Are the proposed data sources appropriate for developing and validating the simulation model?
- To what extent does the proposed research describe the methods/approaches to handle different types of uncertainties, and statistical properties of simulated outcomes for formal post-simulation statistical testing.
- Which computer language will be used for programming the model and what are the advantages, disadvantages, and feasibility computational environments for running the model?

Component C: Coordinating Center

- Does the applicant describe an approach to optimize the ability of the network to develop and use state-of-the-art methodological approaches for conducting natural experiments?

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?

Component A: Research Studies to Assess the Impact of Programs, Policies, or Practices that Address SDOH on Chronic Disease-Related Health Disparities

For each priority area addressed:

- If the proposed research activities require the applicant to partner with an outside entity, are all the partnerships necessary to complete the proposed project supported by letters of support (LOS) or memoranda of understanding (MOU)?
- To what extent do the LOS or MOU clearly describe the working relationships between the research institution and all partner organizations? What is the anticipated extent of involvement and scope of work to which the partner is willing to commit to ensure the successful, implementation and evaluation of the proposed program, intervention, or policy evaluation, including directly providing or facilitating access to relevant implementation or outcome data?
- To what extent will the applicant's organizational support and proposed partnerships to carry out the research activities lead to potential success?

Component B: SDOH Simulation Model Development

- Does the applicant describe an institutional research infrastructure to carry out large, complex projects involving an infrastructure to develop and validate a complex systems science simulation model, program it in computer software, and transfer the model to the CDC web platform?
- If the proposed research activities require the applicant to partner with an outside entity, are all the partnerships necessary to complete the proposed project supported by letters of support (LOS) or memoranda of understanding (MOU)?
- To what extent do the LOS or MOU clearly describe the working relationships between the research institution and all partner organizations, and the anticipated extent of involvement and scope of work to which the partner is willing to commit to ensure the successful development and validation of the simulation model including directly providing or facilitating access to relevant data?
- To what extent does the described scientific environment reflect the necessary staffing, collaboration, and support to develop and validate the simulation model?

Component C: Coordinating Center

None

2. 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/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects
If the research involves human subjects but does not involve one of the six 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 six 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 HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additional-requirements/ar-1.html).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VASchecklist.pdf).

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.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. 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/priority score.

CDC requires awardees for projects that involve the collection or generation of public health data with federal funds to submit a Data Management Plan (DMP) prior to the initiation of generating or collecting public health data unless CDC will aggregate and disseminate the data. Public health data means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. In initial funding applications, the DMP should be addressed within the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application, either as a stand-alone DMP within this section or with a statement explaining why a DMP is not included. The DMP must be updated and submitted to CDC at least annually, or whenever plans for data collection or generation activities change. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements. The contents of the DMP are described in AR-25. Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for OMB approved template and guidance. Public health data are expected to be made freely available to the public (in a de-identified format) and archived long-term unless there are compelling reasons not to do so. When it is not feasible to make data freely available to the public, it may be possible to make data available to users on a restricted basis. The DMP should describe the expected level of public access, if any, and must justify the planned access level and describe how privacy and confidentiality will be protected. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data from ongoing surveillance systems which should be made accessible within 12 months of the end of a collection cycle. Awardees who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award. For data underlying scientific publications such as peer review journal articles, awardee should make the data available

concurrently with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set accompanying a scientific paper should consist of a machine-readable version of the data tables shown in the paper.

Applications from Foreign Organizations

N/A

Resource Sharing Plan(s)

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

Other examples of DMPs may be found here USGS, http://www.usgs.gov//products/data-and-

tools/data-management/data-management-plans

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. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/application-resources.html

The budget can include both direct costs and indirect costs as allowed.

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications:

- Will 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/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. 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. The following will be considered in making funding recommendations:

- 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.

Component A

- Balance and distribution of proposed research projects across the five stated priority areas. Specifically, to ensure that the portfolio of funded projects sufficiently represents research in all five priority areas, an application addressing a given priority area may be funded over another, similarly ranked application addressing a different priority area.
- Applications that address multiple NCCDPHD SDOH priority areas.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements

imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. 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) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the UEI, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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 grantee's business official.

Recipient must comply with any funding restrictions as described in Section IV.11. 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 allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: https://www.archives.gov/

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-36: Certificates of Confidentiality

AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020.

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

AR 23: Compliance with 45 C.F.R. Part 87

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75
To view brief descriptions of relevant CDC requirements visit: https://www.cdc.gov/grants/additionalrequirements/index.html

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider- obligations/index.html and https://www.hhs.gov/civil-rights/for- individuals/nondiscrimination/index.html.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and

Promoting Efficiency in Government (M-35-11). This policy applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274, was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: https://www.plainlanguage.gov/.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however, the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

> The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG-funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG-funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG-funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)

CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additional-requirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC-supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additional-requirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

- Complying with the Data Management and Access requirements https://www.cdc.gov/grants/additional-requirements/ar-25.html.
- Information collection consistent with OMB approval, as deemed necessary.
- Leading development of IRB packages.

Components A and B

- Maintaining an adequate management and staffing plan to support all project activities.
- Oversight of all management, administrative, and scientific aspects of the research project.
- Assuring and maintaining confidentiality of all relevant data and documents.
- Participating in the Steering Committee, the primary governing body of the study comprised of PIs from each site.
- Oversight of the design and conduct of research to address the described research objectives of this NOFO.
- Oversight of any data collection solely to meet the applicant's research needs. Retaining custody of and exercising primary rights to the data and software developed under these awards, subject to government rights of access consistent with current DHHS, PHS, and CDC policies.

- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented, detailing the nature and extent of involvement.
- Establishing goals and objectives that are realistic, measurable, and time-oriented for all phases of the project.
- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project.
- Assuring that IRB approvals are current for research involving human subjects for all participating sites.
- Considering suggestions from CDC, when requested, on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Oversight of the development design, piloting of research protocols and instruments, recruiting participants, and conducting appropriate data management procedures when applicable.
- Oversight of data analyses and dissemination of findings in peer-reviewed journals and presentations at scientific conferences and other meetings. Translating and disseminating research findings.
- Requesting consultation and technical assistance from CDC, as needed.
- Meeting with CDC program personnel on an ongoing basis.
- Participating in an initial kickoff meeting with CDC by phone or in person in Atlanta.

Component C

- Forming the Steering Committee consisting of a PI from each study site.
- Providing progress reports of the study to the Steering Committee meetings and facilitating communication among investigators including scheduling meetings and conference calls, developing agendas, documenting minutes, and maintaining membership rosters and committee lists.
- Maintaining an effective and adequate management and staffing plan.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to government rights of access consistent with current DHHS, PHS, and CDC policies and applicable regulations.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below for Components A, B, and C:

- Assisting the PI, as needed, in complying with Data Management and Access requirements https://www.cdc.gov/grants/additional-requirements/ar-25.html.
- NCCDPHP is a consultant with scientific and programmatic expertise, providing management oversight and scientific consultation as requested by Awardees.
- Appoint the Observational Study Monitoring Board.
- Provide consultation and technical assistance during regularly scheduled conference calls.

- Ensure adherence of human subject requirements and approval of study protocol by appropriate local IRB(s) for all cooperating institutions participating in the study.
- Serve as in an advisory capacity as a nonvoting member on the Steering Committee.
- Facilitate the process of obtaining Certificates of Confidentiality in the form of 301(d), as appropriate.
- Collaborate to produce technical reports and manuscripts for peer-reviewed publications on request.
- Provide assistance for joint analysis with aggregate data, on request from the recipient.
- For component B, work with the recipient throughout the period of performance to ensure the web-based platform meets the technical and security standards for installation on the CDC platform to ensure public health objectives of the award are met.

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

Additionally, an HHS/CDC agency Scientific Program Official (SPO) will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will:

- Be named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award.
- Monitor performance against approved project objectives.
- Assure assessment of the public health impact of the research conducted under this NOFO announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include:

- The Steering Committee, the main governing board of the study, will be comprised of the Principal Investigator from each study site from Component A and B and a NCCDPHP Project scientist(s) as nonvoting consultant. A chairperson will be selected from the nonfederal Steering Committee members. A Chairperson must have proven evidence of leadership ability and be able to make an adequate time commitment to the cooperative agreement.
- The Steering Committee will meet initially and throughout the year to develop common (where applicable) research designs, methods, measures, and protocols, for facilitating the conduct and monitoring of studies and reporting study results.
- Each member of the Steering Committee will have one vote, with the CDC NCCDPHP Project scientist(s) as a nonvoting member. Grantee members of the Steering Committee will be required to accept and implement policies approved by the Steering Committee. To promote the development of a collaborative program among awardees, Principal Investigators are expected to attend Steering Committee meetings and participate in conference calls on a regular basis.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually
(see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), 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.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is 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 CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

The Recipient Organization must submit:

1. **Yearly Non-Competing Grant Progress Report** is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR) SF 425 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through

the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:

    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
    - Research Aims: list each research aim/project

    a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

    b) Leadership/Partnership: list project collaborations and describe the role of external partners.

    - Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

    - How will the scientific findings be translated into public health practice or inform public health policy?
    - How will the project improve or effect the translation of research findings into public health practice or inform policy?
    - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?

- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contribute to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned

data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the period of performance. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified

portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

7. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

"Commodity" means any material, article, supplies, goods, or equipment;

"Foreign government" includes any foreign government entity;

"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

Section VII. Agency Contacts

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

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Scientific/Research Contacts

Sue Shaw, MPH
Scientific Program Official
Extramural Research Program Operations and Services (ERPOS), serving
National Center for Chronic Disease Prevention and Health Promotion &
National Center on Birth Defects and Developmental Disabilities
Telephone: 770.488.6142
Email: ResearchNOFO@cdc.gov
Note: When submitting questions, include the NOFO#, DP23-001 in the email subject line.

Peer Review Contact

Catherine Barrett, PhD
Scientific Review Official
Extramural Research Program Operations and Services (ERPOS), serving
National Center for Chronic Disease Prevention and Health Promotion &
National Center on Birth Defects and Developmental Disabilities

Telephone: 404.718.7664
Email: ohi6@cdc.gov

Financial/Grants Management Contact

Sharon Cassell
Grants Management Officer
Office of Grants Services (OGS)
Centers for Disease Control and Prevention (CDC)
Telephone: 770.488.2703
Email: zpr0@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.

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

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code of Federal Regulations.

Awards are made under the authorization of 317(k) (2) of the Public Health Service Act (PHS Act), 42 U.S.C. 247b(k)(2) and 301(a) of the PHS Act, 42 U.S.C. 241(a).