

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

Natural Experiments of the Impact of Population-targeted Policies to Prevent Type 2 Diabetes and Diabetes Complications

RFA-DP-20-002

Application Due Date: 02/04/2020

Natural Experiments of the Impact of Population-targeted Policies to Prevent Type 2 Diabetes and Diabetes Complications

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Natural Experiments of the Impact of Population-targeted Policies to Prevent Type 2 Diabetes and Diabetes Complications

Activity Code

U18

Amendment I. made January 16, 2020

Section VIII. Other Information - Added Appendix A. Questions from Potential Applicants and CDC Responses

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-20-002

Assistance Listings (CFDA) Number(s)

93.945

Category of Funding Activity:

Health

NOFO Purpose

- **Component A: Natural Experiment Research Centers** to support a 5-year multi-center network of independent research centers to evaluate innovative, health system and non-health system-based natural experimental approaches that alter the diabetogenic characteristics of US communities. Applicants must select only one of the following two tracks:
  - Track 1 Evaluation of population-level programs or policies that affect population-level risk factors for type 2 diabetes (such as diet or physical activity, as well as other health behaviors; glucose; prediabetes), or
  - Track 2 Evaluation of programs or policies aimed at improving care and management of diabetes, and the risk for diabetes complications.
- **Component B: Coordinating Center** to provide organizational, logistic and communication support to enhance the efficiency, productivity, and public health impact of the Natural Experiments research centers that are funded as part of Component A.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-20-002, 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:	**01/06/2020**
Application Due Date:	**02/04/2020**

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 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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:	**03/31/2020**
Secondary Review:	**05/12/2020**
Estimated Start Date:	**09/30/2020**
Expiration Date:	**02/05/2020**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) 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.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

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

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

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

Executive Summary

- **Purpose.**
  - **Component A: Natural Experiment Research Centers** to support a 5-year multi-center network of independent research centers to evaluate innovative, health system and non-health system-based natural experimental approaches that alter the diabetogenic characteristics of US communities. Applicants must select only one of the following two tracks: Track 1 Evaluation of population-level programs or policies that affect population-level risk factors for type 2 diabetes (such as diet or physical activity, as well as other health behaviors; glucose; prediabetes), or Track 2 Evaluation of programs or policies aimed at improving care and management of diabetes, and the risk for diabetes complications.
  - **Component B: Coordinating Center** to provide organizational, logistic and communication support to enhance the efficiency, productivity, and public health impact of the Natural Experiments research centers that are funded as part of Component A.
- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total funding (direct and indirect) for the 5-year period of performance, September 30, 2020 to September 29, 2025, is $12,500,000 to fund up to six (6) awards in two Components:
  - Component A: Natural Experiment Research Centers
    - Number of Awards - Up to five (5), however, there is the possibility of more awards, should additional funding becoming available.
    - Estimated total funding: $11,250,000
  - Component B: Coordinating
    - Number of Awards - One (1)
    - Estimated total funding: $ 1,250,000

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 also 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 Period of Performance.** For Component A: Natural Experiment Research Centers, the estimated funding per award in the first budget year is $450,000 (direct and indirect). For Component B: Coordinating Center, the estimated funding per award in the first budget year is $250,000 (direct and indirect). The estimated total funding (direct and indirect) for the 5-year period of performance, September 30, 2020 to September 29, 2025, is $12,500,000.
- **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. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application will be the "contact PI" for all correspondence. Any additional 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 DUNS number) per component is allowed. If an applicant organization intends to apply to more than one component in this NOFO, the applicant must submit separate applications for each component. To be funded for Component B, applicants must apply for and be funded for Component A. The PI for Component A may be different from the PI for Component B.
- **Application Type.** New
- **Special Date(s).** N/A
- **Application Materials**. See Section IV.1 for application materials. Please note that Form E is to be used when downloading the application package.

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

The link to this NOFO is available at https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under Section 317(k)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 247b(k)(2) and Section 301(a) of the PHS Act, 42 U.S.C. 241(a).

1. Background and Purpose

Diabetes is one of the nation's leading public health threats and a key target of public health interventions and policy reform. Despite improvements in clinical care and the rates of diabetes-related complications, there remains a considerable preventable burden of diabetes and its complications. Altering the course of the diabetes epidemic will require a diverse array of effective changes in policies and the environments in which people live, work, and play. Such changes may be achieved via population health promotion, improving community resources, enabling access and delivery of preventive services, or policies to change the diabetogenic aspects of U.S. communities, and policies and practices to improve care and management of diabetes.

In particular, diet and physical activity play major roles in the development and potential prevention of type 2 diabetes and diabetes complications. Food and agricultural policies and programs, as well as public policy, planning, legislative, and community-based initiatives that alter the built environment to enhance physical activity levels, may play a large role in affecting diabetes risk at the individual and population levels. However, while prevention of type 2 diabetes and diabetes complications is a critical public health goal, relatively little is known about the effectiveness of large-scale policies and programs that could help achieve this goal at the population level, or any differential effects on sub-populations. Rigorous scientific evaluation of such policies and programs can help build an evidence base to inform public policy approaches to prevent type 2 diabetes and diabetes complications by encouraging healthier diets and increased physical activity.

To date, studies evaluating innovative policy approaches to change the availability of healthy foods through incentives and taxation, or efforts to improve food and physical activity environments through neighborhood and urban planning, have been limited, and relatively scattered across the landscape. For example, sugar-sweetened beverage taxes have received a relatively large evaluation focus in recent years, from US cities like Berkeley and Philadelphia, to Mexico – while recent legislation for menu or front-of-package calorie and nutrition labelling, school food programs (including school fruit and vegetable gardens), and changes to foods eligible for Supplemental Nutritional Assistance Program (SNAP) benefits, such as Wholesome Wave, have all proceeded with little empirical evaluation of the behavioral, economic, and health impact, or unintended consequences.

The Community Preventive Services Task Force recommends built environment strategies that combine one or more interventions to improve pedestrian or bicycle transportation systems with one or more land use and environmental design interventions to increase physical activity. There are several evidence gaps however that remain to be filled through longitudinal assessments of policy, systems, and environmental intervention approaches. Studies describing both the implementation and evaluation of coordinated built environment approaches, such as Complete Streets, would strengthen the evidence base and provide direct guidance and support to help community, urban, and regional planners. More studies are needed to evaluate combinations of micro-scale interventions in different settings and populations. Additional research is needed to assess intervention effectiveness among different populations including racial and ethnic minorities and people with lower socioeconomic status, and in different

settings that may lack activity-supportive environments and services.

Additionally, public policy approaches that may not have the primary goal of changing health behaviors nor health outcomes, but that nonetheless have implicit health-related impacts, are important to consider as potentially large levers in impacting individual and population health behaviors and outcomes. One such example is the 1994-1998 Moving to Opportunity for Fair Housing (MTO) initiative by the Department of Housing and Urban Development (HUD), a designed experiment whereby women with children living in public housing in high-poverty urban census tracts (in which 40% of residents had incomes below the federal poverty threshold) were randomly assigned to one of three groups: (1) received housing vouchers, which were redeemable only if they moved to a low-poverty census tract (where <10% of residents were poor), and counseling on moving; (2) received unrestricted, traditional vouchers, with no special counseling on moving; and (3) offered neither of these opportunities. Although health was not the primary motivation for the initiative, results showed that the opportunity to move from a neighborhood with a high level of poverty to one with a lower level of poverty was associated with significant reductions in the prevalence of extreme obesity and diabetes. [1]

The lack of evidence for the health impact of population-targeted policies and changes to the built environment is in part due to the types of research that have been traditionally employed in public health sciences. Observational epidemiological studies are not optimal, and randomized controlled trials and cluster-randomized trials are not feasible to study the impact of large-scale health policy interventions. However, novel methods — particularly those employing the use of 'big data' — exist to rigorously examine the impact of naturally occurring interventions through elements of the study design, sample selection, evaluation and control for bias and confounding, and statistical analyses.

This NOFO is designed to promote rigorous study of high impact programs and policy interventions for prioritization in the public health response to prevent type 2 diabetes and diabetes complications. This NOFO builds upon previous work from the Division of Diabetes Translation (RFA #DP-15-001) using the Natural Experiments approach, which focused on healthcare and health sector policies such as Medicaid expansion and Health Homes, new models of coordinated health care, high deductible health plans, obesity counseling in primary care settings, and State Innovation Models for healthcare payment and delivery systems. This NOFO will fill the gap in evaluation of non-health sector policies, with an emphasis on community-based, upstream policies and approaches, while continuing to build evidence for clinical care improvement practices to reduce complications in people with diabetes.

This NOFO aims to promote and provide a platform and framework for the rigorous study of the health impact of new and imminently available population-targeted diabetes-related programs and policy innovations by federal, state, local governments, healthcare organizations, community organizations, or businesses. A major goal is to construct an optimal multi-sectoral approach to preventing type 2 diabetes and diabetes complications – whether in the form of a set of multi-sectoral evidence-based strategies and interventions, or a toolkit for integrated approaches for population-wide policies – that is guided by key organizations or multi-sectoral entities that might be motivated to act. A secondary goal is to reduce disparities in diabetes-related risk factors, as well as type 2 diabetes itself and diabetes complications.

Healthy People 2020 and other National Strategic Priorities

This NOFO supports the Diabetes Healthy People 2020 objectives D1: "To reduce the number of new cases of diabetes in the population by 10%" to D-16: "Increase prevention behaviors in persons at high risk for diabetes with prediabetes by 10%."

The NOFO supports the CDC strategic framework to reduce the number of new diabetes diagnoses from 1.4M in 2018 to 1.1M cases per year by 2025 (https://www.cdc.gov/about/organization/strategic-framework/index.html)

Public Health Impact

This NOFO is designed to impact population health by identifying and prioritizing large-scale strategies that reduce type 2 diabetes-related risk in the population (including diet and physical activity), and policies to improve care and management of diabetes, and to reduce the risk for diabetes-related complications. Specifically, results from this work could point to key interventions that have the impact to shift entire populations towards healthier diet- and physical activity-related behaviors, and subsequent diabetes-related health outcomes. The focus of Track 1 on policies and interventions that lay outside of health systems will provide the opportunity for learning how communities and societies might improve health behaviors and outcomes through non-traditional pathways.

Relevant Work

This NOFO builds upon previous NOFOs sponsored by the CDC's Division of Diabetes Translation using the Natural Experiments approach, which focused on healthcare and health sector policies such as Medicaid expansion and Health Homes, new models of coordinated health care, high deductible health plans, obesity counseling in primary care settings, and State Innovation Models for healthcare payment and delivery systems. Specifically, this work was part of the Natural Experiments in Translation for Diabetes (NEXT-D) , RFA #DP10-002 and NEXT-D2 (RFA #DP15-001) multi-center research networks, funded by CDC in partnership with National Institutes of Health/National Institute of Diabetes, Digestive, and Kidney Diseases (NIH/NIDDK) and Patient-Centered Outcomes Research Institute (PCORI; NEXT-D2 only). This new NOFO will fill the gap in evaluation of non-health sector policies, with an emphasis on community-based, upstream policies and approaches, along with clinical care improvement practices to reduce complications in people with diabetes. A major goal for this NOFO is to construct an optimal multi-sectoral approach to preventing type 2 diabetes, as well to address disparities in type 2 diabetes and risk factors, and to reduce diabetes-related complications. This particular NOFO is intended to complement but be fully non-redundant with the other program while taking advantage of the experience in organization and methodology gained by NEXT-D and NEXT-D2.

2. Approach

There are two components to this NOFO.

Component A: Natural Experiment Research Centers will fund a network of independent research centers to conduct novel health system and non-health system-based natural experiments through the rigorous health and economic evaluation of ongoing, new, or imminently available population-targeted diabetes-related programs and policies by federal, state, local governments, healthcare organizations, community organizations, or businesses.

Component B: Coordinating Center will fund a coordinating center to provide logistical and communications support to the network to enhance the methodological quality and public health impact of the natural experiments. Awardees for both Component A: Natural Experiment Research Centers and Component B: Coordinating Center will actively participate in the research network, including the Network Steering Committee and network subcommittees.

Applicants may apply for Component A alone or both Component A and Component B. If applicants choose to apply for both Component A and B, a separate application must be submitted for each Component. To be funded for Component B, applicants must apply for and be funded for Component A.

Component A: Natural Experiment Research Centers

Independent Natural Experiments Research Centers will design and conduct rigorous evaluation or comparative effectiveness research studies of naturally-occurring ongoing, new, or imminently available population-level, health system or non-health system-based policies and large-scale intervention programs on the risk of diabetes and its complications. Each applicant for Component A must select only one program or policy to evaluate. Alternatively, applicants may choose to focus on comparative effectiveness research, by designing their evaluation to compare the implementation of different programs or policies.

Policies may include both formal public policies at local, state and federal levels of government, and organizational level policies, such as those implemented by large organizations (including companies or businesses), worksites, or school districts. Program is defined as a set of activities initiated by governmental or other organizational bodies, with the potential to contribute to type 2 diabetes prevention and/or diabetes control. The policy or program to be evaluated should be ongoing (naturally occurring), new, or imminently available, and expected to reasonably affect behaviors relevant to type 2 diabetes prevention and/or prevention of diabetes-related complications, either explicitly (by design) or implicitly (as a more secondary, passive health impact).

Specific objectives are to:

1. design and develop evaluation or comparative effectiveness research studies to test the effectiveness of an ongoing (naturally occurring), new, or imminently available population-level policy or program
2. identify a target population (minimum population size affected should be 10,000 individuals)
3. evaluate/test the effectiveness of policy/system change at multiple levels where possible (e.g., system-wide, communities, or clusters of individuals), focusing on diabetes and cardiometabolic risk factors or intermediate outcomes of behavior change
4. analyze and disseminate study findings

Applicants are encouraged to 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. Studies should employ rigorous designs that provide inferences about the effectiveness/comparative effectiveness and impact of health sector policies, food/agricultural policies or changes to the built environment, or public policies that may not explicitly intend to improve health behaviors and diabetes-

related health outcomes. Investigators are encouraged to propose both quasi-experimental studies such as pre-post intervention designs with concurrent control conditions where possible, historical trends or interrupted time series designs. Studies are expected to assess population-level policies as well as indicators of uptake (including health care) and health at the population-level. Studies should also examine the costs, adverse effects, and unintentional consequences of policies. Applicants should plan to engage stakeholders (including patients, where applicable) in their research process (planning and execution) and to ensure that stakeholders support the selected study outcomes.

Applicants should have ready access to essential data on exposure and outcomes at the outset of the funding period, and are encouraged to assemble diverse sources of data, including but not limited to:

- public survey data
- medical information systems such as electronic medical records
- non-traditional sources (including big data)
- cohort and panel survey data (provided the data permit examination of study interventions that are applied and targeted at large segments of the population)

This NOFO is not intended to fund cross-sectional studies, cohort studies with only individual-level exposure and outcomes, simple pre-post designs without an appropriate comparison. This NOFO is not intended to support the initiation and delivery of new programs; rather, it is intended to support rigorous evaluation of the effectiveness of programs and/or policies that are being or will be implemented regardless of CDC grant funding.

Component A: Natural Experiment Research Centers is divided into two tracks: Track 1 will be focused on programs or policies that affect type 2 diabetes-related risk in the population (including diet or physical activity or other health behaviors; glucose; prediabetes) and Track 2 will be focused on programs or policies aimed at improving care and management of diabetes, and the risk for diabetes complications. Applicants must focus their research plans on only <u>one</u> of these two tracks.

Track 1:

Applicants under Track 1 should target policies and interventions that are <u>outside</u> of the health sector. Priority areas include population-level approaches to the promotion of healthy eating and active living by evaluating the impact of environmental and policy interventions on population-level risk factors for type 2 diabetes.

Policies or programs may include public policy, planning, legislative, and community-based initiatives that are aimed at influencing overall health promotion, type 2 diabetes prevention behaviors, and the health of broad segments of the population. Examples of programs might include those implemented in communities that can be expected to improve diet- and physical activity-related type 2 diabetes prevention behaviors. Public policies that do not have the primary purpose of improving health may also be studied. However, the policy or program to be evaluated should reasonably be expected to affect behaviors relevant to type 2 diabetes prevention (i.e., diet/nutrition and physical activity).

Examples of Track 1 programs and policies may include, but are not limited to:

- Economic incentives and disincentives, such as pricing strategies (e.g., increasing the price of unhealthy foods/beverages/ultra-processed foods or decreasing the price of healthy foods like fruits and vegetables) or other price changes/incentives (e.g. vouchers or subsidies) to promote healthy lifestyle and community programs;
- Policies expected to influence available options and purchasing, such as menu or food product reformulation, and supermarket layout or pricing strategies;
- Laws aimed at consumer information and labeling (e.g., menu labeling, calorie labeling, warning labels, the upcoming added sugars label on the nutrition facts panel);
- Federal and state policies, regulations, and licensing fees on agricultural production, packaging, marketing, and availability of fruits and vegetables and the dietary practices of high-risk individuals;
- Infrastructure initiatives (such as the development of farmers markets or food co-ops) to offer healthier food options in underserved areas;
- Population-level approaches undertaken by large employers and institutions to promote healthy eating and/or active living;
- Incentive-schemes (either financial or otherwise) to encourage active transport, such as walking or cycling, over motorized transport;
- Laws, policies, and interventions that modify the built environment to encourage walking or cycling for transportation or leisure (such as the implementation of bike lanes in urban areas, multi-use trails, subsidies for public transit, upgrades of sidewalks, improved access to parks and recreation facilities, or housing and urban development policies);
- Zoning/laws to include parks or walking and cycling paths/lanes in new construction developments;
- Improvements or modifications in housing and urban development policies, either those that explicitly seek to improve health behaviors and type 2 diabetes-related health outcomes (such as the implementation of bike lanes in urban areas, multi-use trails, subsidies for public transit, upgrades of sidewalks, improved access to parks and recreation facilities) or those that seek to improve neighborhood environments independent of health behaviors and outcomes;
- Public policies or initiatives that seek to improve neighborhood environments and conditions through economic, environmental, or other approaches.

Studies should focus on approaches to reduce type 2 diabetes and cardiometabolic risk factors (e.g., reduced HbA1c, blood pressure, cholesterol levels, weight, body mass index) or improve intermediate outcomes of behavioral changes (e.g., decreased purchases of sugar-sweetened beverages; increased purchases of healthier foods like fruit and vegetables, or whole grains; increased use of resources intended for physical activity), and/or improved individual- or population-level food consumption and physical activity (e.g., improved nutritional status or, where appropriate, reduced energy intake; activity changes such as reduced sedentary behavior or increased physical activity). Furthermore, proposed research should demonstrate that measures collected and evaluated will allow for meaningful and scientifically valid conclusions to be made about the effects of the policy or program on nutrition/physical activity and type 2 diabetes indicators. In the case of dietary intake, standardized and comprehensive methods

(such as 24-hour recalls or food frequency questionnaires, for example) should be used as the primary measure of the outcome.

In the case of physical activity, standardized methodologies such as the recently-developed ACT24 web-based physical activity instrument or wearable activity monitors (i.e., accelerometers or pedometers) should be employed. Additional measures that provide information about the mechanism of effect, such as increased enrollment in fitness classes or increased number of fitness facilities, as well as evidence of the potential sustainability of the effects of the policies or programs, may also be used as secondary measures.

Data sources may include, but are not limited to, publicly available population survey data and special population surveys adapted for this project, sales data from large-scale chain supermarkets or other food outlets, and usage statistics on public structures to promote physical activity (e.g., sidewalk, bicycle paths, bicycle lanes).

Track 2

Applicants under Track 2 may target policies and interventions that are outside of the health sector or may involve interventions that are directly aimed at health systems and health care practices. Priority areas include population-level approaches to improving diabetes care and management, as well as prevention of complications, in either health care or community-based settings.

Policies or interventions may include legislative, health system-based, and community-based initiatives that are likely to influence health care practices that impact individuals with diabetes, management of diabetes and its complications. Applicants for Track 2 may choose to focus on public policy approaches (such as reimbursement policies by Centers for Medicare and Medicaid Services (CMS) and Medicaid aimed at screening, behavioral change for individuals with diabetes, or other aspects of diabetes care and complications) or on health system-community partnerships, defined as formal partnerships between clinical settings and community organizations, including employers (such as health system policies to reimburse for diabetes care services provided in communities, referral programs to community programs, and partnerships to improve diabetes care and management in communities).

Examples of Track 2 programs or policies may include, but are not limited to:

- Novel managed care and employer-based disease management approaches
- Statutory and regulatory laws at all levels of government on access, delivery, outcomes, and cost of diabetes care
- Insurance reimbursement policies and benefit designs on adoption, adherence, and effectiveness of health behavior improvement programs among those with diabetes
- Changes in Medicare and Medicaid reimbursement policies on care and outcomes to manage diabetes and prevent complications
- Economic incentives (such as subsidies or vouchers) to promote healthy lifestyle and community programs among the diabetes population
- Population screening approaches implemented in health systems, employers, and community settings on changes in behavior, risk, and morbidity for individuals with diabetes
- Complications prevention-focused quality improvement and disease management

programs
- Employer-based policies and incentives on health promotion, including 4-day work weeks, health club vouchers, etc.
- Population disease stratification, management and feedback tools, including laboratory-based registries and electronic health records
- Management-focused quality improvement and disease management programs

Studies should investigate the effects of policies on systems changes; changes in health promotion for individuals with diabetes; care/management practices (quality, levels of implementation and coverage, costs); changes in uptake on the intervention; physiological risk factors; the risk of complications, including the effects on morbidity and age of onset; and/or quality of life. Although not required, applicants for Track 2 are encouraged to include patient-reported outcomes (physical and emotional).

Data sources may include health plan-based registries, administrative outcomes databases such as Medicare and Medicaid, and Healthcare Management Organizations (HMO) databases.

Component B: Coordinating Center will provide logistic and communications support to the full network of Natural Experiments Research Centers funded under Component A of this NOFO.

Objectives/Outcomes

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

1. Design and develop an approach for establishing an ongoing network structure of Component A: Natural Experiment 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. Work with the full network of cooperative agreement awardees, partner awardees, and the CDC to 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 sub-committee meeting minutes, etc.
5. Arrange and conduct conference calls, webinars, and meetings for the network and committees.
6. Generate key points and action items from meetings; and facilitate communication between groups.
7. Develop and maintain an internal and external website for the study in accordance with

CDC IT standards. Project website must be password protected for Study Group members and include a publicly accessible section.

8. Coordinate communication and dissemination activities for the network, including tracking of study publications and presentations, to maximize impact of study findings.

Target Population

Component A: Natural Experiment Research Centers: Proposals under Track 1 and 2 should examine exposures and outcomes across broad populations of at least 10,000 individuals, including communities, states, or regions, and present background, pilot data on the characteristics of denominators, and where possible, levels of exposure to the policy interventions being examined. The impact of the natural experiment on type 2 diabetes risk factors and diabetes complications should be expressed at the community or population level. Applicants are also encouraged to examine sub-populations of interest where known disparities exist, so that outcomes in these vulnerable populations may be compared to the population changes as a whole.

Component B: Coordinating Center: Not applicable.

Collaboration/Partnerships

Component A: Natural Experiment Research Centers: Investigators are encouraged to form or expand innovative scientific collaborations/partnerships with researchers or agencies (e.g., community based organizations, local governments, employers) that have established interests in reducing the diabetes burden, or that do not have established interests but nonetheless may influence key levers in reducing the diabetes burden (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 patients in their research process (including planning and execution).

Component B: Coordinating Center: As described throughout this NOFO, Component B will establish a Coordinating Center to promote collaboration among the awardees of Component A 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.

Evaluation/Performance Measurement

Component A: Natural Experiment Research Centers: For both Tracks 1 and 2, internal evaluation during the first project year should be measured by the refinements made to its 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 or policy being evaluated.

In subsequent funded years, success should be measured by execution of the research plan, procurement and/or collection of key data, appropriate validation of data elements, timeliness of epidemiologic analyses, dissemination of data in the form of peer-reviewed publications and scientific presentations, and participation in the collaborative, multi-center research network. Evaluation should include assessment of the degree to which the research fills important

research gaps and assesses outcomes of important health impact, including risk of type 2 diabetes (Track 1) and diabetes complications (Track 2).

Component B: Coordinating Center: Evaluation/performance should address measurements of quality of promoting and facilitating a multi-center 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, tracking and management of and coordination of committee activities.

Applicants for Component B: Coordinating Center shall have sufficient staff available to plan, coordinate, and travel to face-to-face 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.

Translation Plan

Component A: Natural Experiment Research Centers: Applicants for Component A (Tracks 1 and 2) will be expected to present findings at professional meetings and at formal briefings for health and policy makers. They should submit results to peer-reviewed journals, and also disseminate aspects of their work through diverse media such as a study website and policy briefs.

Component B: Coordinating Center: Applicants for Component B will be responsible for developing a detailed communication and dissemination plan and coordinate communication activities of the work group, including a web-site and communication materials.

Section II. Award Information

Funding Instrument Type:	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: $12,500,000

The estimated total funding (direct and indirect) for the first budget period is $2,500,000, and the estimated total funding (direct and indirect) for the 5-year period of performance is $12,500,000. The total estimated funding for Component A is $11,250,000 ($2,250,000 per budget period) and the estimated funding for Component B is $1,250,000 ($250,000 per budget period).

Anticipated Number of Awards: 6

Component A
Anticipated Number of Awards: Five (5)
Award ceiling: $450,000
Award floor: $0

Component B
Anticipated Number of Awards: One (1)
Award ceiling: $250,000
Award floor: $0

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

Award ceiling and floor are for the first 12-month budget period only.

Award Ceiling:	$450,000 Per Budget Period
Award Floor:	$0 Per Budget Period
Total Period of Performance Length:	5 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 (http://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.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments County governments City or township governments Special district governments Independent school districts Public and State controlled institutions of higher education Native American tribal governments (Federally recognized) Public housing authorities/Indian housing authorities Native American tribal organizations (other than Federally recognized tribal governments) Nonprofits having a 501(c)(3) status with the IRS, other than institutions of

higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
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."
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR

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

Special Eligibility

Component A: Natural Experiment Research Centers

1. Applicants must have continuous access to datasets and/or data systems needed to accomplish the study objectives, including verification that the data for the proposed study meets the minimum sample size of 10,000 individuals.

2. Applicants must have approval for unrestricted publication of the study findings,

regardless of study outcomes.

Component B: Coordinating Center

1. Applicants for Component B must submit an application for Component A: Natural Experiment Research Centers.

If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter the review process.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Component A: Natural Experiment Research Centers (Tracks 1 and 2)

1. Provide a letter of commitment, memorandum of understanding, or a data use agreement that demonstrates continuous access to data sets and/or data systems needed to accomplish study objectives, including verification (in the form of a table) that the data for the proposed study meets minimum sample size of 10,000 individuals. This evidence should be placed in Appendix A of the application.
2. Provide a letter or agreement that allows unrestricted publication of findings regardless of study outcomes, in Appendix A of the application.

Component B: Coordinating Center

1. Provide a copy of the face page of the organization's Component A application in Appendix A of the Component B application.

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 Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/ Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- 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 Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle 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 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 DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. 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 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 the SAM internet site at https://www.sam.gov/index.html.
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 DUNS 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 FOA 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.

Only one application per institution (normally identified by having a unique DUNS number) is allowed per Component.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist 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:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, 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.

3. Letter of Intent

Due Date for Letter of Intent: **01/06/2020**

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

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

- Name of the Applicant
- Descriptive title of proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity
- Component(s) being applied for

The letter of intent should be sent to:

Dionne Godette-Greer, PhD
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: 404.498.3213
Email: DGodette@cdc.gov

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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and http://grants.nih.gov/grants/how-to-apply-application-guide.htm 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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm 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).
Examples of DMPs may be found here: USGS, http://www.usgs.gov/products/data-and-tools/data-management/data-management-plans

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. The DMP may be presented in a table, a narrative format, or as a checklist.

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 coincident 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.

Research Plan

The applicant's research plan should address activities that will be conducted over the entire 5-year period of performance and should include the following items:

Component A: Natural Experiment Research Centers (Tracks 1 and 2)

1. Clearly indicate which track the applicant is applying for, and the specific program or policy to be evaluated.
2. Identify and provide an assessment of the specific problem to be addressed; for example, which aspect of type 2 diabetes prevention or diabetes complications in the United States will be addressed by the project.
3. Provide justification of the choice of the proposed policy or program for a natural experiments study, and justification of the anticipated effect of the intervention/policy change on diabetes and its complications. Discuss the potential generalizability of the findings.
4. Describe the geographic area(s) or jurisdictions for the proposed research and the size of the sub-populations included in the proposed research/study. If the study includes sub-population analyses, provide a description.
5. Describe key sources of data, specifically:
    a. Existing datasets and data systems that permit the assessment of health impact of the selected program or policy change for populations of at least 10,000 people.
    b. Summaries of existing data (either public or private) collected in the last five years, which show for geopolitical units of at least 10,000 residents, by race, sex, and age, the incidence and prevalence of type 2 diabetes or diabetes complications; risk factors associated with type 2 diabetes or diabetes complications; changes in programs or policies.
6. List research/study objectives and describe how they relate to current risks and complications of diabetes in the United States.
7. Provide the hypotheses to be tested.
8. Describe the potential value of the proposed research/study for policy, systems changes, community changes, and individual/population behavioral changes related to type 2 diabetes risk or diabetes complications, including for any sub-populations of interest.
9. Provide a data analysis plan including methods, sample sizes and power calculations.
10. Describe plans for disseminating study findings, particularly the generalizability of findings and where the findings may help to inform future programs/policies.

Component B: Coordinating Center

1. Describe experience in directing and operating a coordinating center for collaborative, population based large-scale epidemiological research projects that include coordination of multi-site studies, providing governance support, and logistical support.
2. Describe the planned approach to optimize the dissemination and impact of the findings from the Natural Experiments network.
3. Describe the planned approach to optimize the ability of the network to develop and use state-of-the-art methodological approaches for conducting natural experiments.
4. Describe the applicant's experience working with confidentiality and privacy issues.
5. Describe the applicant's experience in development and management of websites; describe approach and timeline for a study website.
6. Describe applicant's physical facilities, data management and computer resources, and facilities for data retrieval and storage.
7. Describe the applicant's unique contribution to the multi-site study and plans for

coordination with the study network.
8. Propose the planning approach/process for, and experience with, developing a common protocol with other awardees for a core set of common variables and hypotheses.

Component A: Natural Experiment Research Centers and Component B: Coordinating Center

Staffing and Management

1. Provide a staffing and management plan that defines the roles, responsibilities, and qualifications of team and expected contributions of key/collaborative partners.
    a. The Research Team: The applicant should describe the experience of the principal investigator and co-investigators in undertaking complex public health-related or policy studies that (a) make use of data from diverse data sources; (b) are multi-disciplinary (including, but not limited to food/agricultural and built environment policy research, epidemiology, public policy, health communications, economics, individual and organizational behavioral science, statistics); (c) involve multi-center collaboration throughout the study process; (d) result in peer-reviewed journal publications; and (e) provide decision-support for public and private policy makers.
    b. The Principal Investigator: The applicant should describe the principal investigator's (a) expertise; (b) established leadership in designing and conducting complex studies that make use of multiple sources of data, (c) track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences, and policy forums; (d) his/her commitment to collaborate and contribute to a multi-center research network, including participating in up to two face-to-face meetings as well as periodic tele-video conferences each year; and (e) the percentage of time allocated by the PI to this research program.
    c. Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (a) describe the person's expertise; (b) 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 (c) specify the percentage of time that will be committed to this research program. If a position is yet to be filled, provide the position description in an appendix.
2. Provide a management plan, which describes:
    a. the staffing plan for the 5-year period of performance. Include project organizational chart(s) with key personnel.
    b. how and by whom the quality oversight and supervision will be provided for the research team.
    c. the percentage of time each person will devote to the project
3. 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.
4. Describe plans for producing reports: interim progress reports and a final report, as well as technical reports, professional presentations, and publications.

5. Provide a letter of support from partner organizations, if applicable. Letters should (a) describe prior collaborations with the applicant organization, if any; (b) specify the contributions that the partner organization is committed to making to the proposed research; (c) commit to providing continuous access and use of datasets or data systems as applicable; and (d) commit to adhering to decisions of the research network.
6. 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. Travel costs for up to three people, including the PI, for annual meetings with CDC and the Research Network Committee and subcommittees should be included in the budget of the first Budget Period and in annual continuation plans and budgets.

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 publically 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 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 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** https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf.

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.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application 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 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: **02/04/2020**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 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.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
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.
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. 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/additionalrequirements/ar-25.html for revised AR-25.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained.

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request).

Reimbursement of pre-award costs is not allowed. All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement.

12. 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. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. 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 DUNS.

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 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.

The applicant organization must ensure that the DUNS 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 (http:// 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: Natural Experiment Research Centers (Tracks 1 and 2) and Component

B: Coordinating Center

- 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 intervention focus of the study will plausibly lead to important change in individual and systems behaviors and outcomes?
- Does the applicant describe the potential or actual impact of the research on public health in the US and/or globally?
- Does the proposed evaluation 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: Natural Experiment Research Centers (Tracks 1 and 2)

- Do the investigators have a successful track record in natural experiments research?
- Does the applicant have a diverse multi-disciplinary team with expertise in the areas of public health, public health policy, public policy, epidemiology, statistics, and economics?
- Does the principal investigator (PI) have extensive experience leading major epidemiologic and policy studies assessing population impact?
- Do the PI and other members of the research team have documented (1) expertise in health policy research, public policy research, epidemiology, behavioral and organizational change, and economics; (2) experience in designing, implementing, and documenting research findings for complex, multi-site studies; (3) strong records of peer-reviewed scientific publications; and (4) a documented record of working with partners in translating study recommendations into innovative policies and systems changes that are taken under advisement by public and private sector policy makers, examined, and (best case scenario) adopted?
- Has the PI previously conducted (or is currently conducting) policy-focused food and/or built environment research, or does he/she have experience designing or evaluating natural experiments?

Component B: Coordinating Center

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

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: Natural Experiment Research Centers (Tracks 1 and 2)

- Does the applicant provide sample summaries of existing data collected in the last 5 years, which show for geopolitical units of at least 10,000 individuals, by race/ethnicity, gender, and age, the incidence and prevalence of diabetes and its complications; risk factors associated with diabetes and its complications; changes in policies; and changes in behaviors? Does the applicant show readiness to initiate work using the data once the funding is in place?
- Does the proposed study address the impact of policies or systems-changes at multiple levels at different stages of implementation?
- Is the study design adequate to rigorously test the effectiveness of the policy or intervention; i.e., will the findings lead to a clear answer as to whether the policy or systems-change intervention can lead to changes in individuals behaviors and outcomes (as opposed to whether the intervention was merely associated with changes in health)?

Component B: 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: Natural Experiment Research Centers (Tracks 1 and 2)

- Does the applicant have the appropriate level of access to the target communities and systems?
- Does the applicant have adequate partnerships to carry out the proposed research?
- Does the project utilize critical partnerships or collaborations to achieve study objectives?
- Does the project support key stakeholder involvement throughout the research process?

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/additionalrequirements/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.

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/additionalrequirements/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.

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/applicationresources.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 all responsive applications 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.

- Geographic diversity of population being studied.
- Diversity of program and policies (including similar distribution of studies across Tracks 1 and 2) being studied.

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 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 subpart F 45 CFR 75 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 DUNS, 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).

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: http://www.access.gpo.gov/nara/cfr/cfr-table- search.html.

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-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

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-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-34: Language Access for Persons with Limited English Proficiency

AR-36: ; Certificates of Confidentiality ;

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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 apply 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: http://www.plainlanguage.gov/plLaw/index.cfm.

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 the 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/additionalrequirements/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/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

Component A: Natural Experiment Research Centers and Component B: Coordinating Center

1. Establishing goals and objectives that are realistic, measurable, and time-oriented for the project.
2. Participating in research network and subcommittees, CDC-sponsored meetings as scheduled by the Research Network Committee and CDC.
3. Making use of local analytic support, center-specific and shared datasets.
4. Attending in-person and tele-video conference call and Research Network Committee meetings, as scheduled by the Committee in consultation with CDC.
5. Ensuring adequate staffing, oversight, and mentoring in support of the research team and its activities.
6. Promoting 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.
7. Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research; and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Component A: Natural Experiment Research Centers

1. Designing and conducting research to address the described research objectives of this cooperative agreement.
2. Obtaining the appropriate Institutional Review Board approvals for research involving human subjects.
3. Conducting studies agreed upon in Year 1 for implementation beginning in Year 2, and disseminating findings in peer-reviewed journals, technical reports, research and policy briefs, presentations at professional and scientific conferences and policy forums, as appropriate, and contributing scientific findings to appropriate Web sites or other channels for sharing findings.

Recipients 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.

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

1. Component A: Natural Experiment Research Centers and Component B: Coordinating Center

- As requested by the awardee, CDC will provide consultation and provide assistance on the project.
- Serve as consultants on the Executive Committee and subcommittees.
- Assist the PI with complying with the responsibilities for the Extramural Investigators as

described in the Policy on Public Health Research; and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

2. 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.

3. Additionally, an HHS/CDC agency Program Official 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; and
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include:

Component A: Natural Experiment Research Centers and Component B: Coordinating Center

- The Steering Committee, the main governing board of the study, will be comprised of the Principal Investigator and/or co-principal investigators from each study site from Component A, the Principal Investigator or project direct from Component B (the Coordinating Center), and a NCCDPHP Project scientist as a non-voting consultant, to answer questions and provide scientific guidance. A chairperson will be selected from the non-Federal Steering Committee members. A Chairperson must have proven evidence of leadership ability and be able to make adequate time commitment to the Steering committee network.
- The Steering Committee will meet initially to develop the protocol and throughout the year to discuss study progress. It will have primary responsibility for developing common research designs, protocols, manual of operations, facilitating the conduct and monitoring of studies, and reporting study results. The Steering Committee must approve the protocol, changes to the protocol and manuals of operation. The Principal Investigator of each study site will be responsible for the execution of the protocol and provide progress reports to the Steering Committee. The Steering Committee will also develop policies relating to access to data. It will establish guidelines for presentations at scientific meetings and for writing and publishing manuscripts on the findings of the study.

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 provide HHS/CDC with an original, plus one hard copy of the following reports:

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** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which 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 contributed 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:

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the

calendar quarter in which the budget period ends. 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.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
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 end of grant period. 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).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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.

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 Contact

Dionne Godette-Greer, PhD
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: 404.498.3213
Email: DGodette@cdc.gov

Peer Review Contact

Jaya Raman, PhD
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: (770).488.6511
Email: kva@cdc.gov

Financial/Grants Management Contact

Sharon Cassell
Grants Management Specialist
Centers for Disease Control and Prevention
Office of Financial Resources
Office of Grants Services
Global Health Security Branch
Telephone: 770.488.2703
Email: scassell@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 Federal Regulations.

This program is authorized under Section 317(k)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 247b(k)(2) and Section 301(a) of the PHS Act, 42 U.S.C. 241(a).

Appendix A. Questions from Potential Applicants and CDC Responses

1. On pages 11 and 12 in the discussion of Component A, Track 2 it gives examples of programs and policies that might be evaluated. Those include things like "management and feedback tools" and "management-focused quality improvement and disease management programs". Much of the NOFO suggests that the research centers are to evaluate existing policies and programs. However, would it be acceptable for the Center to implement a "management-focused quality improvement and disease management program" as part of the Center activity and then evaluate it?

   Response
   There is guidance related to this question under the following sections:

   - Approach: Component A: Natural Experiment Research Centers, Specific Objectives: "Specific objectives are to:
     design and develop evaluation or comparative effectiveness research studies to test the effectiveness of an ongoing (naturally occurring), new, or imminently available"
   - Approach: Component A: Natural Experiment Research Centers, This NOFO is not intended… "This NOFO is not intended to support the initiation and delivery of new programs; rather, it is intended to support rigorous evaluation of the effectiveness of programs and/or policies that are being or will be implemented regardless of CDC grant funding."

2. Do you know if we would need to use a local IRB or can you use a central?

   Response
   There is a hyperlink within the RFA-20-002 NOFO with guidance related to this this question under the following section:

   - Additional Review Criteria:
     https://www.cdc.gov/grants/additionalrequirements/ar-1.html

     Additional Requirement - 1: Human Subjects Requirements
     If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects, unless that research is exempt as specified in the regulation. All

awardees of CDC grants and cooperative agreements and their performance sites engaged in research involving human subjects must obtain (1) an assurance of compliance with the Regulations, and (2) initial and continuing approval of the research by an appropriately constituted and registered institutional review board.

3. Do we include a "facilities and environment" section?

   Response
   There is a hyperlink within the RFA-20-002 NOFO with guidance related to this this question under the following section:

   - Section IV. Application and Submission Information, #2 Content and Form of Application
     https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf

     Please refer to page 72 of the document in the hyperlink above.
     Project/Performance Site Primary Location
     Generally, the primary location should be that of the applicant organization or identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the budget form of the application.
     Provide an explanation of resources available from each project/performance site on the "Facilities and Resources" attachment of the G.220 - R&R Other Project Information Form.

4. Do we include NIH style biosketches of all key personnel?

   Response
   There is a hyperlink within the RFA-20-002 NOFO with guidance related to this this question under the following section:

   - Section IV. Application and Submission Information, #2 Content and Form of Application
     https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf

   Please refer to page 82 of the document in the hyperlink above.

   Who must complete the "Biographical Sketch" section: All senior/key personnel and other significant contributors (OSCs) must include biographical sketches (biosketches).

   Format: Use the sample format on the Biographical Sketch Format Page to prepare this section for all grant applications.
   Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).
   The biosketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.
   Attach this information as a PDF file. See the Format Attachments page.

5. How does it work with evaluation of "effectiveness of programs and/or policies that are

being **or will be implemented**"? What is the difference between a "new program" and one that "will be implemented"?

Response
Approach: Component A: Natural Experiment Research Centers, This NOFO is not intended… "This NOFO is not intended to support the initiation and delivery of new programs; rather, it is intended to support rigorous evaluation of the effectiveness of programs and/or policies that are being or will be implemented regardless of CDC grant funding."

CDC funds will not support initiation or implementation of a new program. If the new program will be implemented regardless of/without CDC funds, this funding mechanism will support the evaluation.

6. Is the CDC expecting institutions to use research or programmatic indirect rates?

Response
You can find information about how indirect costs are defined at the following link: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.300-r&;r-budget-form.htm#H

Indirect costs (Facilities & Administrative [F&A] costs) are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. See the NIH Glossary's definition of Indirect Costs.

7. There is some confusion regarding what is included. Is there a clear list of what is in the 25-page Research Plan and 35 pages for all appendices?

Response
Information about what should be included can be found on pages 21 and 22 of the Notice of Funding Opportunity.

- Research Plan Section
- Specific Aims
- Research Strategy
- Progress Report Publication List
- Other Research Plan Section
- Vertebrate Animals
- Select Agent Research
- Multiple PD/PI Leadership Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan(s)
- Authentication of Key Biological and/or Chemical Resources

8. Page 11 of the RFA reads (emphasis added): "Data sources may include, but are not limited to, publicly available population survey data and special population surveys adapted for this project, sales data from large-scale chain supermarkets or other food outlets, and usage statistics on public structures to promote physical activity (e.g., sidewalk, bicycle paths, bicycle lanes)."

I just want to clarify that we may propose to collect primary data, using a population-representative sample phone survey. If so, am I reading it correctly that we should use items from a population survey that is commonly used, such as the BRFSS?

Response
While RFA DP-20-002 does not specifically prohibit primary data collection, applicants are asked to describe the existing data sources they will use for the project under the following section: Research Plan, Component A, Page 24, #5.

Describe key sources of data, specifically:

a. Existing datasets and data Existing datasets and data systems that permit the assessment of health impact of the selected program or policy change for populations of at least 10,000 people.

b. Summaries of existing data (either public or private) collected in the last five years, which show for geopolitical units of at least 10,000 residents, by race, sex, and age, the incidence and prevalence of type 2 diabetes or diabetes complications; risk factors associated with type 2 diabetes or diabetes complications; changes in programs or policies."

Under Track 1, applicants are asked to target policies and interventions that are outside of the health sector. Priority areas include population-level approaches to the promotion of healthy eating and active living by evaluating the impact of environmental and policy interventions on population-level risk factors for type 2 diabetes.

On page 33 under Section V. Application Review Information, under Approach, there is information about what reviewers will be using to evaluate applications submitted in response to Component A. Please use the information in this section to evaluate whether a primary data collection would meet the review criteria mentioned below:

"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: Natural Experiment Research Centers (Tracks 1 and 2)
Does the applicant provide sample summaries of existing data collected in the last 5 years, which show for geopolitical units of at least 10,000 individuals, by race/ethnicity, gender, and age, the incidence and prevalence of diabetes and its complications; risk factors associated with diabetes and its complications; changes in policies; and changes in behaviors? Does the applicant show readiness to initiate work using the data once the funding is in place?"

9. Do the following sections count against the 35 - page limit?

Response
In section 2. Content and Form of Application Submission, there are two links https://grant

s.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf ;and http ://grants.nih.gov/grants/how-to-apply-application-guide.htm with useful information about page limits and required application content. Specifically, see the table in the link https ://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm. The table for R01, R03, R21, and all other Applications includes information on the page limits.

9a. Does the budget narrative counts towards the 35 pages?

Response
Not included in table of page limits. Page 26, section 7, Page limitations, the Notice of Funding Opportunity states: "the Research Strategy component of the Research Plan narrative is limited to 25 pages Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 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." https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write /page-limits.htm

9b. Are bio sketches required and do they count towards the 35 pages?

Response
Limited to 5 pages. Please refer to table for R01, R03, R21, and all other Applications https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm

9c. Do references count towards the 35 pages?

Response
Not included in table of page limits. Please refer to table for R01, R03, R21, and all other Applications https://grants.nih.gov/grants/how-to-apply-application-guide/format -and-write/page-limits.htm

9d. Does the human subjects and inclusion of women and children sections count towards the 35 pages?

Response
The CDC Administrative Requirements Section of the Notice of Funding Opportunity provides guidance indicating that this information must be included in your application, AR-28 Inclusion of Persons Under the Age of 21 in Research. This is not included in the table of page limitations. Please refer to table for R01, R03, R21, and all other Applications https://grants.nih.gov/grants/how-to-apply-application-guide /format-and-write/page-limits.htm