



Centers for Disease Control

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

Natural Experiments of Policy and Built Environment Impact on Diabetes Risk

RFA-DP-17-003

Application Due Date: 02/13/2017

Natural Experiments of Policy and Built Environment Impact on Diabetes Risk

RFA-DP-17-003

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Funding Opportunity Announcement (FOA) Title

Natural Experiments of Policy and Built Environment Impact on Diabetes Risk

Activity Code

Amendment 1. January 25, 2017

- Form D application package is to be used for this funding opportunity announcement (FOA). (Please disregard the reference to Form C in the "Executive Summary"; "Application Materials" of this FOA.) Form D can be downloaded from the "Package" tab on this announcement on www.grants.gov.
- Appendix A: "Questions from Potential Applicants and CDC Responses" added to Section VIII. "Other Information"

U18

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-17-003

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.945

Category of Funding Activity

Health

FOA Purpose

This FOA has two components, A and B.

Component A: To support a 5-year multi-center research network of innovative, non-health system-based, natural experiments approaches to alter the diabetogenic characteristics of US communities. 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 diabetes.

Component B: To fund a Central Coordinating Center (CCC) to provide organizational, logistic and communication support to enhance the efficiency, productivity, and 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-17-003, 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: 01/09/2017

Is a LOI: Recommended but not Required

Application Due Date: 02/13/2017

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: 04/01/2017

Secondary Review: 05/01/2017

Estimated Start Date: 09/30/2017

Expiration Date: 02/14/2017

Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) 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.

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

Executive Summary

- **Purpose. Component A:** To support a 5-year multi-center research network of innovative, non-health system-based, natural experiments approaches to alter the diabetogenic characteristics of US communities. 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 diabetes. **Component B:** To fund a Central Coordinating Center (CCC) to provide organizational, logistic and communication support to enhance the efficiency, productivity, and 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.** It is anticipated up to 4 awards will be issued under Component A and one award under Component B in response to this FOA. For Component A, an applicant may request up to \$675,000 per year for up to five years. For Component B, an applicant may request up to \$300,000 per year for up to five years. These estimates include direct and indirect costs. Awards issued under this FOA 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 Project Period.** The estimated total funding (direct and indirect for Component A and B)

for the first budget period, September 30, 2017 to September 29, 2018, will be **\$3,000,000**. For Component A, the estimated funding per award in the first year is \$675,000. For Component B, the estimated funding per award in the first year is \$300,000. The estimated total funding (direct and indirect) for the entire project period will be **\$15,000,000**. The entire 5 year project period will run from **September 30, 2017 to September 29, 2022**.

- **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, 1.A.](#) 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.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) per component is allowed. Eligible applicants may apply for Component A or both components (A and B). If an applicant organization intends to apply to more than one component in this FOA, the applicant must submit separate applications for each component. Applicants must submit an eligible application under Component A in order to apply under Component B. The PI for Component A may be different than 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 C is to be used when downloading the application package. <http://grants.nih.gov/grants/funding/424/index.htm#inst>
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

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

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 decline in the rates of diabetes-related complications, there remains a considerable preventable burden of diabetes complications and continued high rates of diabetes prevalence nationally. Altering the course of the diabetes epidemic will require a diverse armamentarium of effective changes in policies as well as 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.

While prevention of type 2 diabetes 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. In particular, diet and physical activity play major roles in the

development, and thus the potential prevention of type 2 diabetes and its complications. As such, food and agricultural policies and programs, as well as legislative and community-based approaches that alter the environment to promote active living and enhance physical activity levels, may play a large role in affecting diabetes risk at the individual and population levels. Many innovative approaches to change the availability of healthy foods through incentives and taxation, and efforts to improve food and physical activity environments through neighborhood and urban planning, have not been rigorously examined. For example, 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 will all benefit from rigorous evaluation of the behavioral, economic, health impact, or unintended consequences.

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 initiative by the Department of Housing and Urban Development (HUD)¹, whereby women with children living in public housing in high-poverty urban census tracts (in which $\geq 40\%$ 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.

The lack of evidence for the health impact of such population-targeted policies is in part due to the types of research that have been traditionally employed in public health sciences. Observational epidemiologic studies are not optimal, 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 diverse data sources, including surveys, administrative, and non-traditional data sources that may be useful in assessing the impact of health policies – 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. Rigorous scientific evaluation of such policies or programs can help build an evidence base to better inform public policy approaches to prevent type 2 diabetes by encouraging healthier diets and increased physical activity, and ultimately improving diabetes-related health outcomes. This FOA is designed to promote rigorous study of high impact programs or policy interventions for prioritization in the public health response to prevent type 2 diabetes and its complications.

This FOA is designed to stimulate and support natural experiments of population-targeted policies and large-scale interventions to prevent type 2 diabetes and its complications. Specifically, the purposes of this FOA are to: (1) Component A: support a 5-year multi-center research network of innovative, non-health system-based, natural experiment approaches to alter the diabetogenic characteristics of US communities; and (2) Component B: improve the methods and infrastructure for natural experiments in public health.

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. The overall goal is 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, community organizations, or businesses.

Policies to be evaluated 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, worksites or school districts. Examples include, but are not limited to, the development of supermarkets in underserved areas (or the development of poorer neighborhoods in general), calorie labeling requirements, taxes on foods

and/or beverages, modification/improvements to environments that promote active living, such as zoning/laws that include cycling paths/lanes, parks, or sidewalks, or incentives – either financial or otherwise – to encourage people to use active transport (walking and cycling) over cars. Programs are defined as a set of activities initiated by governmental or other organizational bodies, with the potential to contribute to diabetes prevention and control. Examples might include programs implemented in communities that can be expected to improve diet- and physical activity- related type 2 diabetes prevention behaviors. This FOA is not intended to support the initiation and delivery of new programs; rather, it is intended to support evaluation of the effectiveness of programs and/or policies that are being or will be implemented regardless of CDC grant funding. In addition, this FOA is not intended to support the evaluation of policies implemented in health-care systems.

There are two components to this FOA. Component A will fund a network of independent research centers to conduct novel non-health system-based natural experiments. Component B 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.

Healthy People 2020 and other National Strategic Priorities

Component A and B:

This FOA supports or addresses at least four topics outlined in the program of “Healthy People 2020” (<http://www.healthypeople.gov/2020/topics-objectives>):

- **Determinants of Health:** Identify aspects of social and physical environments that can be improved to promote good health for all.
- **Nutrition and Weight Status:** Promote health and reduce chronic disease risk through the consumption of healthful diets and achievement and maintenance of healthier body weights and distributions of body fat.
- **Diabetes:** Reduce the disease and economic burden of diabetes mellitus (DM) and improve the quality of life for all persons who have, or are at risk for, DM.
- **Heart Disease and Stroke:** Improve cardiovascular health and quality of life through identifying and modifying contextual factors associated with county-level rates of heart attack and stroke.

The FOA also responds to an objective of CDC Winnable battles:

- Nutrition, Physical Activity, and Obesity

The FOA is aligned with at least three priorities of the CDC Division of Diabetes Translation:

- **Prevent type 2 diabetes:** Conduct surveillance and applied research to identify and prioritize effective approaches and targeted sub-populations for diabetes prevention.
- **Prevent complication, disabilities and burden associated with diabetes:** Conduct surveillance and applied research to identify and prioritize effective approaches and targeted sub-populations for diabetes.
- **Promote health equity by reducing disparities that affect diabetes and its burden.**

It is also aligned with the following performance goal for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP):

- Monitor, prevent, delay, detect and control chronic disease, to achieve health equity by eliminating health disparities and achieving optimal health for all Americans.

Public Health Impact

This activity is designed to impact population health by identifying and prioritizing large-scale diet- and physical activity-related strategies to reduce type 2 diabetes risk factors and 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 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 FOA builds on prior work funded by CDC and NIH (FOA #DP10-002), including the Natural Experiments in Translation for Diabetes (NEXT-D), a multi-center network of natural experiments, and its follow-up network (FOA #DP15-001). The former network has published a manuscript on this work. However, these two focused mainly on natural experiments within health care settings, and thus major gaps remain in how natural experiments outside of health care settings might impact health behaviors and diabetes-related health outcomes. This FOA aims to fill those gaps by focusing on natural experiments that occur outside of the health sector (e.g., in the food/agricultural policy and built environment policy arena).

2. Approach

This FOA is comprised of two components. Component A (Natural Experiment Research Centers): Supports Natural Experiments Research Centers to design and conduct rigorous longitudinal studies of naturally occurring, population-targeted, non-health system-based policies and large scale interventions on the risk of diabetes, its complications, and economic impact. Component B (Coordinating Center): supports a Coordinating Center to provide logistic and communications support to the full network of Natural Experiments Research Centers funded through this FOA. Applicants may apply for Component A alone or both Components A and B. For those who apply for both, a separate application is required for each submission. In addition, applicants for Component B must have an eligible application under Component A in order to apply for and be awarded under Component B. In order for an institution to be awarded funds for Component B, it must also have been successfully awarded funding for Component A.

For Component A, studies should focus on ongoing, naturally occurring, or imminently available policy or population-level interventions or on quasi-experimental designed studies that target large populations (minimum population size affected should be 10,000 individuals). Policies or interventions may include 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. 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. Investigators are particularly encouraged to identify opportunistic, 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 and impact of 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. Innovative scientific partnerships between researchers and public or private partners (e.g., community based organizations, local governments, employers) are also encouraged.

Examples of research topics may include, but are not limited to:

- Economic incentives and disincentives, such as subsidies, taxes, and vouchers, to promote healthy lifestyle and community programs.

- Policies expected to influence available options and purchasing, such as calorie labeling in restaurants, menu or food product reformulation, and supermarket layout or pricing strategies;
- Laws aimed at consumer information such as citywide menu labeling statutes.
- 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 retailers offering healthier food options in underserved areas.
- Population-level approaches undertaken by large employers and institutions to promote healthy eating and/or active living.
- Laws, policies, and interventions that shape the built environment (e.g., urban planning, land use, and transportation-related laws) to increase physical activity.
- Public policies or initiatives that seek to improve neighborhood environments and conditions through economic, environmental, or other approaches.
- Improvements or modifications in housing and urban development policies, either those that explicitly seek to improve health behaviors and 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.
- Zoning/laws to include parks or walking and cycling paths/lanes in new construction developments.
- Incentive-schemes (either financial or otherwise) to encourage active transport, such as walking or cycling, over motorized transport.

Investigators are encouraged to assemble diverse sources of data, including those available from public survey data. Applicants should have ready access to essential data on exposure and outcomes at the outset of the funding period. Interventions to be evaluated should be assessed at multiple levels where possible: e.g., system-wide, communities, or clusters of individuals. Studies are expected to assess population-targeted policies as well as indicators of uptake and health at the population-level. Studies should also examine the costs, adverse effects, and unintentional consequences of policies. 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, usage statistics on public structures to promote physical activity (e.g., sidewalk, bicycle paths, bicycle lanes). Cohort and panel survey data may be employed, provided they permit examination of study interventions that are applied and targeted at large segments of the population. Applicants are also strongly encouraged to incorporate data from non-traditional sources.

Component A of this FOA 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, nor intended to fund the implementation of new programs or interventions.

Objectives/Outcomes

This announcement will fund and support a 5-year multi-center research network of innovative, non-health system-based, natural experiment approaches to alter the diabetogenic characteristics of US communities. 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.

Component A (Natural Experiments Research Centers)

Specific objectives are to:

1. design and develop studies to test the effectiveness of an identified policy or population-level intervention.
2. identify a target population
3. evaluate/test the effectiveness of policy/system change, focusing on diabetes and cardiometabolic risk

factors or intermediate outcomes of behavior change.

4. analyze and disseminate study findings

Studies should investigate the effects of policies on systems changes, changes in uptake on the intervention (for example, increased population use of a newly designed bike/walking path); behavioral changes; physiological risk factors; and the risk of type 2 diabetes and its complications, including the effects on morbidity, age of onset, and quality of life.

Component B: (Coordinating Center)

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 between collaborating centers 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 grantees 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 grantees and the funding agency 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. Generate key points and action items from meetings; and facilitate communication between groups.
6. 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 public access section to the website.
7. 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: Proposals should examine exposures and outcomes across broad populations, 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. Similarly, the impact of natural experiments on diabetes, its risk factors, and complications, should be expressed at the community or population level. Applicants are encouraged to aim for a minimum impacted population size of 10,000 individuals.

Component B: Not applicable.

Collaboration/Partnerships

Component A: Evaluation/performance measurements should include quality and completeness of study design approaches, study and analytic protocol, procurement and/or collection of key data, timely conduct of analyses, and dissemination of data in the form of peer-reviewed publications and scientific presentations. Evaluation should include assessment of degree to which the research fills important research gaps and assess outcomes of important health impact, including risk of diabetes, its complications, and cardiovascular disease.

Specifically, research should focus on approaches to reduce type 2 diabetes and cardiometabolic risk factors (e.g., reduced HbA1c, blood pressure, cholesterol levels, weight/BMI) 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 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 methods such as the International Physical Activity Questionnaire, 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.

Component B: Evaluation/performance should address measurements of quality of the coordination of network meetings, conference calls, 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 shall have sufficient staff available to plan, coordinate, travel to face to face meetings, and resolve day-to-day issues of the network and to maintain study-wide timeline management. Facilitate the exchange of abstracts, manuscripts, presentations, fact sheets, and other scientific materials among the collaborating centers and the funding agency.

Evaluation/Performance Measurement

Translation Plan

Component A: Applicants for Component A will be expected to publish findings in peer-reviewed publications, present findings at scientific meetings, formal briefings for health and public policy makers, and use diverse methods, including the study website, policy briefs, and social media to disseminate findings widely to diverse policy makers. The rigorous scientific evaluation of food policies and built environment interventions will provide an evidence base to better inform public health policy approaches to prevent type 2 diabetes and its complications.

Component B: 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.

OMB/PRA is not expected to apply.

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: \$15,000,000

The estimated total funding (direct and indirect costs) for the first budget period is \$3,000,000, and the estimated total funding (direct and indirect) for the entire 5 year project period is \$15,000,000.

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

Anticipated Number of Awards: 5

Component A: It is anticipated that each budget year up to 4 award(s) of approximately \$675,000 per recipient (direct and indirect costs) will be made under this RFA-DP-17-003.

Component B: It is anticipated that each budget year up to 1 award of approximately \$300,000 will be made to a single grantee (direct and indirect costs).

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

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

Award Ceiling: \$675,000 Per Budget Period

The ceiling amounts for the first 12-month budget period are (including both direct and indirect costs):

Component A: \$675,000

Component B: \$300,000

Applications with budget requests greater than the ceiling will be considered non-responsive and will not be reviewed. This ceiling is only for the first 12-month project period.

Award Floor: \$0 Per Budget Period

There is no floor amount for this funding opportunity announcement.

Total Project Period Length: 5 year(s)

The project period for this FOA is 5 years and will run from **September 30, 2017** to **September 29, 2022**.

Throughout the project period, 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 FOA.

Section III. Eligibility Information

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

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:

- Native American tribal organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

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. Special Eligibility Requirements

Component A: Applicants must have letters of commitment from partners to show continuous access to datasets and/or data systems proposed for the study), or access to other data sources or populations needed to accomplish study objectives (i.e. data use agreements) for ready access to data in order to assess the uptake/usage, behaviors, and health status impact for populations of at least 10,000 individuals. Agreements must also be in place that allow for unrestricted publication of findings regardless of study outcomes.

Component B: Applicants must have an eligible application under Component A to apply for Component B, and must be awarded under Component A in order to be awarded under Component B.

Evidence of these Special Eligibility Requirements should be placed in Appendix A of the application.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Component A: Applicants should show evidence of a data use agreement (in the form of a letter of commitment or memorandum of understanding) that demonstrates continuous access to datasets and/or data systems needed to accomplish study objectives.

Applicants must also provide verification (in the form of a table) that the data for the proposed study meets minimum sample size (i.e., 10,000 individuals).

Component B: Applicants must provide a statement of submission of application for Component A under the current RFA and include the principal investigator (PI) name and title of the application.

Evidence of these Special Eligibility Requirements should be placed in Appendix A of the application.

Applications with budgets exceeding the ceiling will be deemed non-responsive and not entered into the review process.

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%20for%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/#1>.

- [Grants.gov](https://www.Grants.gov)
- [eRA Commons](https://www.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 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 registration process at least four (4) weeks prior to the application due date.

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 grantee 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 grantee 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, (<http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement 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

FOA 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) per component is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide

<http://grants.nih.gov/grants/how-to-apply-application-guide.htm> and here:

<http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf>, except where instructed in this Funding Opportunity Announcement 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 forms package associated with this FOA includes all applicable components, mandatory and optional.

Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from <http://grants.nih.gov/grants/forms.htm>

3. Letter of Intent

Due Date for Letter of Intent: **01/09/2017**

Is a LOI: Recommended but not Required

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 (**include the Component applying to**)

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

The letter of intent should be sent electronically to:

Natalie J Darling

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: (770)-488-5740

Email: ndh6@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

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 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide <http://grants.nih.gov/grants/how-to-apply-application-guide.htm> and here: <http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf> for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, 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 FOA.
- 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 timeline.
- 4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY)
- 5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

- 6. Protection of Human Subjects**
- 7. Inclusion of Women and Minorities**
- 8. Targeted/Planned Enrollment Table** (for New Application ONLY)
- 9. Inclusion of Children**

Other Research Plan Sections

- 10. Vertebrate Animals**
- 11. Select Agent Research**
- 12. Multiple PD/PI Leadership Plan.**
- 13. Consortium/Contractual Arrangements**
- 14. Letters of Support**
- 15. Resource Sharing Plan(s)**
- 16. Appendix**

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the [SF 424 \(R&R\) Application Guide](#) unless otherwise specified in the FOA. All instructions in the SF424 (R&R) Application Guide

<http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf> must be followed along with any additional instructions provided in the FOA.

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:

- Descriptions of the data to be produced in the proposed project
- How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
- 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
- Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified

Examples of DMPs may be found here: University of California <https://dmp.cdlib.org/>, or USGS, <http://www.usgs.gov/datamanagement/plan/dmplans.php>

Research Plan

The applicant's research plan should address activities that will be conducted over the entire 5-year project period. The Research Plan narrative is comprised of components 2 (specific aims) and 3 (research strategy) above. NOTE: that the research Strategy is divided into three parts: 1) Significance, 2) Innovation, and 3) Approach.

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

Component A

1. Include a brief assessment of the specific problem to be addressed; for example, which aspect of diabetes and its complications in the United States will be addressed by the project.
2. Provide justification of the choice of the proposed policy or intervention for a natural experiments study, and justification or evidence submitted should be about the anticipated effect of the intervention/policy change on diabetes.

3. Describe the geographic area(s) or jurisdictions and the size of the sub-populations included in the proposed research/study, with special emphasis on underserved and at-risk populations.
4. Provide evidence of availability of and access to key sources of data, specifically:
 - a. Description of existing datasets and data systems that permit the assessment of health impact of changes in food/agricultural, built environment, or public policies for populations of at least 10,000 people.
 - b. Evidence of continuous data access and use in the form of letters of commitment or memorandum of understanding.
 - c. Summaries of existing data 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 diabetes and its complications; risk factors associated with diabetes and its complications; changes in food/agricultural, built environment, or public policies.
- Analysis plan, including methods, sample sizes and power calculations.
 - Potential generalizability of findings.
 - Human subjects protection considerations that may exist.
5. List research/study objectives and how they relate to current risks and complications of diabetes in the United States.
6. State hypotheses to be tested.
7. Clearly state the potential value from the proposed research/study for policy, systems changes, community changes, and individual/population behavioral changes related to type 2 diabetes risk and its complications, with a focus on high-risk, underserved populations.
8. Provide an analysis plan as well as a plan for disseminating study findings, particularly with individuals who may use the findings to inform future programs/policies.

Component B

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 an approach to optimize the dissemination and impact of the findings from the Natural Experiments network.
3. Describe an approach to optimize the ability of the network to develop and use state-of-the-art methodological approaches for conducting natural experiments.
4. Describe experience working with confidentiality and privacy issues.
5. Describe 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 unique contribution to the multi-site study and plans for coordination with the study network.
8. Propose a process for, and experience with, developing a common protocol with other grantees for a core set of common variables and hypotheses.

Component A and Component B

1. Provide a staffing plan that defines the roles, responsibilities, and qualifications of team and expected contributions of key/collaborative partners.
 - a. **The Research Team:** The applicant should provide evidence of 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 and provide evidence of the principal investigator's (a) expertise; (b) established leadership in designing and conducting complex studies that make use of multiple sources of data, (c) strong 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 serve on the Research Network Committee (the governing body of the network), including participating in up to two face-to-face meetings as well as periodic televideo 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) provide evidence of their 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.

2. Provide a management plan, which specifies:

- a. The role to be played by the principal investigator in the center-specific primary research/study, and potential ancillary studies.
- b. The roles of the co-investigators and other members of the research team in each of the proposed studies.
- c. The roles in an organizational chart.
- d. Who and how quality oversight and supervision will be provided for the research team.
- e. A timeline for all proposed center study activities and outcomes. The timeline should also clarify the contributions of individuals to each activity.
- f. If a position is yet to be filled, provide a position description in the appendix.
- g. Include the percentage of time each will devote to the project.

3. Provide 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. A letter of support from partner organizations, if applicable, should be provided, especially as related to accessing datasets and data systems proposed in the application. Letters should (a) describe prior collaborations with the applicant organization; (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 Committee.

6. 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.

Supporting materials may be attached and shall show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

Awardees upon acceptance of Notice of Award (NoA), must agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI. "Award Administration Information".

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. If submitting electronically, use and PDF version of the agreement, attach in Grants.gov under "Other Attachments", and title it appropriately.

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 FOA must be followed. For this specific FOA, 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.

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 <http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf>.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

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

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date 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).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.

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. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

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

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states “*rejected*,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/13/2017**

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](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.

For more information on expanded authority and pre-award costs, go

to: (<http://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).

Awardees 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: <http://www.cdc.gov/grants/additionalrequirements/index.html> for revised AR-25.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained.
- Human Subjects Education Requirement documentation is provided for any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects.
- Reimbursement of pre-award costs is not allowed.

OMB/PRA is not expected to apply. 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.)

12. Other Submission Requirements and Information

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 or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

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](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).

b. Scored Review Criteria

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

Significance

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

Component A and B

- Does the applicant address the research objectives stated in the FOA?
- 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?
- What is the potential or actual impact of the research on public health in the US and/or globally?
- Do the proposed studies 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

- 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?

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

- Does the applicant provide documentation of direct, committed and continuous access to large datasets that permit the assessment of health impact of changes in policies or practices on communities' health, for populations of at least 10,000 residents? Does the documentation include appropriate letters of commitment or memorandum of understanding?
- 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 study design involve assessment of a policy or intervention that targets large populations, communities, or employers of at least 10,000 individuals?
- 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)?

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

- Does the applicant have appropriate access to the target communities and systems?
- Have adequate partnerships been assembled to carry out the proposed research?
- Does the project utilize critical partnerships or collaborations?
- Does the project support key stakeholder involvement throughout the research process?

Component B

- 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 an approach to optimize the ability of the network to develop and use state-of-the-art methodological approaches for conducting natural experiments?
- Does the applicant describe experience in development and management of websites?
- Does the applicant describe experience in developing a common protocol for a core set of common variables and hypotheses?

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

(<http://www.cdc.gov/grants/additionalrequirements/index.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 (http://www.cdc.gov/maso/Policy/Policy_women.pdf) and <http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf> #page=1) and the policy on the Inclusion of Persons Under 21 in Research (<http://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 five 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) adequacy of veterinary care; 4) 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 5) 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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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: <http://www.cdc.gov/grants/additionalrequirements/index.html>

New additional requirement: CDC requires awardees 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 funding opportunity announcement 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:

- Type of data to be produced in the proposed project;
- Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
- 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.

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>

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 FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Diversity of population being studied.
- Diversity of policies 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 Awardee 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 funding opportunity announcement.

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 FOA 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 (<http://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.

Awardees 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

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award

(<http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

[AR-1: Human Subjects Requirements](#)

[AR-2: 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 2010](#)

[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 –;new requirement](#)

[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: Distinguishing Public Health Research and Public Health Nonresearch](#)

[AR-32: FY 2015 Enacted General Provisions](#)

[AR-8: Public Health System Reporting Requirements](#)

[AR-15: Proof of Non-profit Status](#)

[AR-23: Compliance with 45 C.F.R. Part 87](#)

[AR-25: Data Management and Access](#)

CDC requires awardees for projects that involve the collection or generation of data with federal funds to develop, submit and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data.

Data Management Plan

Consistent with the terms of and activities expected under the funding opportunity announcement (FOA), awardees must develop and submit a DMP generally during the project planning phase, but in any event, prior to the initiation of generating or collecting public health data. Accordingly, the DMP may be evaluated during the application, study proposal, or project review process or during other times in the project period. For FOAs that involve already defined projects which include data collection or generation at the time of application, applications submitted without the required DMP may be deemed non-responsive for award. For FOAs where CDC specifies that submission of the DMP is deferred to a later period, funding restrictions may be imposed pending submission and evaluation of the DMP. For awards where data collection or generation activities may become necessary during the project period, DMPs will be required to be submitted and evaluated during the project period of the award. These DMPs also will be required to comply with this

AR. In all instances described above, the reviewing officials have to approve an acceptable DMP. 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.

A DMP for each collection and/or generation of public health data funded by this award should include the following information:

- 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 (see below for additional information about access);
- 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 (see below for additional information regarding archiving).

Access to and Archiving of the Data

Awardees whose terms of award do not include submitting data to CDC are expected to plan and prepare for access to and archiving/long-term preservation of collected and/or generated data within the funding period, as set forth below. 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 which should be made accessible within a year of the end of a collection cycle. In addition, awardees should ensure the quality of data they make accessible and seek to provide the data in a nonproprietary format. 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 public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be provided on request under a data-use agreement.

Awardees will be required to inform the appropriate CDC point-of-contact identified in the award via an update to their DMP of the location of the deposited data. The DMP is a living document that should be updated throughout the life cycle of data.

For data underlying scientific publication, 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 should consist of a machine-readable version of the data tables shown in the paper.

Requirements set forth in this policy are not intended to conflict with or supersede applicable grants regulations related to agency access to awardee data and records.

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: <http://www.archives.gov/>.

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Either refer to the current Releasing and Sharing Data Policy AR-25 here (<http://www.cdc.gov/grants/additionalrequirements/index.html#ar25>) and/or replace it on the PGO website

with the Data Access and Management policy and add the link above as an AR.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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: <http://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.fsrcs.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>.

Tobacco and Nutrition Policies The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- [http://www.gsa.gov/graphics/pbs/Guidelines for Federal Concessions and Vending Operations.pdf](http://www.gsa.gov/graphics/pbs/Guidelines%20for%20Federal%20Concessions%20and%20Vending%20Operations.pdf)
- http://www.cdc.gov/tobacco/basic_information/healthy_people/toolkit/index.htm
- <http://www.cdc.gov/obesity/strategies/food-serv-guide.html>

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

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 <http://www.cdc.gov/grants/additionalrequirements/index.html> outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officer are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The Principal Investigators and Co-Investigators will have the primary responsibility for the following:

Components A and B

1. Establishing goals and objectives that are realistic, measurable, and time-oriented for the project.
2. Participating in Research Network Committee and subcommittee, CDC-sponsored meetings as scheduled by the Research Network Committee and CDC.
3. Make use of local analytic support, center-specific and shared datasets.
4. The Principal Investigator will attend in-person and televideo conference call Research Network Committee meetings per year, as scheduled by the Committee in consultation with CDC.
5. Other members of the research team will participate in appropriate subcommittee and CDC-sponsored meetings.
6. Ensure adequate staffing, oversight, and mentoring in support of the research team and its activities.

Component A

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, including Research Network 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.

Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access and consistent with current HHS/CDC policies.

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 described below:

Components A and B

1. As requested by the awardee, CDC will provide consultation and provide assistance on the project.
2. Serve as consultants on the Research Network Committee and subcommittees.

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:

Components A and B

- 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 director from Component B (the Coordinating Center), and a NCCDPHP Project scientist as a 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.
- To promote the development of a collaborative program among awardees, Principal Investigators are expected to attend Steering Committee meetings and participate in conference calls on a regular basis.

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually 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 awardees 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 awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees 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 (<http://www.hhs.gov/sites/default/files/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**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at [http:// grants.nih.gov/grants/ funding/2590/ 2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm), **is due 90 to 120 days prior to the end of the current budget period.** 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 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 project period.**

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 PHS 2590 ([http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm](http://grants1.nih.gov/grants/funding/2590/2590.htm)) [http:// grants.nih.gov/grants/ funding/2590/2590.htm](http://grants.nih.gov/grants/funding/2590/2590.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:**

N/A

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. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends.** Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees 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 grantees are now available at [http:// grants.nih.gov/ grants/forms.htm](http://grants.nih.gov/grants/forms.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://era.nih.gov/registration_accounts.cfm

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) ([https:// commons. era.nih.gov/ 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/ registration/ registration Instructions. jsp](https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp) 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: <http://era.nih.gov/commons/index.cfm>.

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 project period. 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

CDC Technical Information Management Section (TIMS)

Telephone 770-488-2700 Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)

Natalie Darling

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention (CDC)

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5740

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Peer Review Contact(s)

Jaya Raman, Ph.D

Scientific Review Official

Extramural Research Program Operations and Services

CDC

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-6511

Email: kva@cdc.gov

Financial/Grants Management Contact(s)

Natasha Grant

Grants Management Specialist (GMS)

Office of Financial Resources (OFR), Office of Grants Services (OGS)

CDC

2920 Brandywine Road, M/S K-69

Atlanta, GA 30341

Telephone: 770-488-1649

Email: mgz2@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements 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. 241.(a) and 247(b).

Appendix A: Questions from Potential Applicants and CDC Responses

Question (1.A). I was recently forwarded the CDC RFA-DP-17-003, and I am wondering if a proposal that I've been working on would be eligible to submit. I wonder if you could advise on whether you think this proposal would be responsive or not responsive to the RFA?

Response (1.A). We cannot determine responsiveness of proposals from potential applicants nor make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We have highlighted some sections of the FOA that may be helpful in clarifying the FOA's intent, approach, objectives and outcomes which also address your questions.

Section 1 "Funding Opportunity Description", "Relevant Work", clarifies this FOA's intent. RFA DP17-003 "builds on prior work funded by CDC and NIH (FOA #DP10-002)and its follow-up network (FOA #DP15-001)." Since these two previous cooperative agreements concentrate on natural experiments within health care settings, gaps remain on how health behaviors and diabetes-related health outcomes might be impacted by natural experiments conducted outside of health care settings. RFA DP17-003 "aims to fill those gaps by focusing on natural experiments that occur outside of the health sector (e.g., in the food/agricultural policy and built environment policy arena)." It is up to each applicant to determine whether their proposed natural experiment aligns with the FOA's intent of addressing these data gaps.

This FOA is comprised of 2 components (A and B). The purpose of Component A is "to support a 5-year multi-center research network of innovative, non-health system-based, natural experiments approaches to alter the diabetogenic characteristics of US communities. 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 diabetes."

The purpose of Component B is "to fund a Central Coordinating Center (CCC) to provide organizational, logistic and communication support to enhance the efficiency, productivity, and impact of the Natural Experiments research centers that are funded as part of Component A. "

In Section I. "Funding Opportunity Description", 2. "Approach", under "Objectives/Outcomes" of Component A, under "Study Design, Data Sources, and Approach", the FOA lists what types of study designs ("longitudinal, quasi-experimental study designs using concurrent control conditions, historical trends or interrupted time series designs"), interventions (" e.g., system-wide, communities, or clusters of individuals) and data applicants should employ ("cohort and panel survey data" that "permit[s] examination of study interventions"). The FOA also states that proposals "should not be based on cross-sectional studies, cohort studies with only individual level exposure and outcomes, or simple pre-post designs without an appropriate comparison".

Question (1.B). Would it be okay to use electronic medical records as the source of health data? <Would health clinic data> qualify as being evaluated at the population-level?

Response (1.B). In Section 1, under "Approach" the FOA provides example of data sources which "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, usage statistics

on public structures to promote physical activity (e.g., sidewalk, bicycle paths, bicycle lanes). Cohort and panel survey data may be employed, provided they permit examination of study interventions that are applied and targeted at large segments of the population. Applicants are also strongly encouraged to incorporate data from non-traditional sources.”

The FOA does not preclude obtaining data from health clinics as long as the study’s targeted intervention and population evaluation is performed outside of a health care setting.

The minimum population level is 10,000 individuals.

Question (2). My colleagues and I are planning to apply for the RFA-DP-17-003, Component A. We plan to partner with other investigators, so we can conduct studies on 2-3 natural experiments within unique underserved communities. Does this “multiple-project” plan fit within the expectations of the RFA? What is the source of funds for this project? Is the money tied to the Prevention Fund?

Response (2). In Section 1 of FOA under executive summary and 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.” In addition, the FOA encourages partnerships with other investigators to expand innovation. Specifically in Section 1, “collaboration and partnerships” for component A, the FOA states “investigators are encouraged to form or expand innovative scientific partnerships among researchers and public or private partners (e.g., community based organizations, local governments, employers). Where possible, applicants should provide letters of support from the proposed partners that indicate their full cooperation with the research team.”

The FOA does not specify nor preclude multiple projects.

Funding is provided by the Centers for Disease Control and Prevention’s (CDC) National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). These funds are not associated with the Affordable Care Act or Prevention and Public Health Fund.

Question (3). I have a question regarding an application to the RFA titled “Natural Experiments of Policy and Built Environment Impact on Diabetes Risk”. Specifically, I am interested in applying to component B (coordinating center). On page 5, it states “Applicants must submit an eligible application under Component A in order to apply under Component B.” There is an application going in from another university for Component A, with <name of institution> as the subcontractor. Is this sufficient to merit allowance for <name of institution> to apply for Component B? Or must the prime applications both be from <name of institution>?

Response (3). In Part. 1 Overview, under “Executive Summary” of the FOA it states “Only one application per institution (normally identified by having a unique DUNS number) per component is allowed. Eligible applicants may apply for Component A or both components (A and B). If an applicant organization intends to apply to more than one component in this FOA, the applicant must submit separate applications for each component. Applicants must submit an eligible application under Component A in order to apply under Component B. The PI for Component A may be different than the PI for Component B.”

The interpretation of this paragraph is the applicant must have the same DUNS number when applying for Component A and Component B and must submit separate applications for each component. In other words the same institution would need to apply as prime for both components (can have different PIs but must be same institution).

Question (4). My team and I are putting in a proposal for this RFA, and we have a question about the required components for the Research Plan. On page 17 of the RFA, item 4c says we need to provide:

"Summaries of existing data 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 diabetes and its complications; risk factors associated with diabetes and its complications; changes in food/agricultural, built environment, or public policies."

Do we need to present data on all of these factors? I'm having a hard time imagining what we would present in a table format that summarizes "changes in food/agricultural, built environment, or public policies" across the cities/areas where we'll be doing data collection. Would it be ok if we omitted "changes in food/agricultural, built environment, or public policies" from our table?

Response (4). Each applicant must determine their research topic or approach and demonstrate how their research topic fits within the intent of the FOA. We have highlighted the FOA's intent, purpose and objectives/outcomes below which may be helpful in addressing your questions.

Section 1 "Funding Opportunity Description", "Relevant Work", clarifies the FOA's intent. RFA DP17-003 "builds on prior work funded by CDC and NIH (FOA #DP10-002)and its follow-up network (FOA #DP15-001)." Since these two previous cooperative agreements concentrate on natural experiments within health care settings, gaps remain on how health behaviors and diabetes-related health outcomes might be impacted by natural experiments conducted outside of health care settings. RFA DP17-003 "aims to fill those gaps by focusing on natural experiments that occur outside of the health sector (e.g., in the food/agricultural policy and built environment policy arena)." Each applicant can determine how their research aligns with the FOA's intent.

The purpose of Component A is "to support a 5-year multi-center research network of innovative, non-health system-based, natural experiments approaches to alter the diabetogenic characteristics of US communities. 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 diabetes."

On page 12 of FOA under "Special Eligibility Requirements" it states what is required to meet responsiveness for Component A including "letters of commitment from partners to show continuous access to datasets, and/or data systems proposed for the study, or access to other data sources or populations needed to accomplish study objectives (data use agreements) for ready access to data in order to assess the uptake/usage, behaviors, and health status impact for populations of at least 10,000 individuals."

The research plan (beginning on page 16) outlines what activities applications should describe, and each applicant should address these criteria/activities as they see appropriate for their proposal. If data is not available for factors that will not be impacted by an applicant's planned intervention, then the applicant is not expected to provide that data in their application.

Question (5). For this RFA, I am preparing an application for component A as PI and component B as co-PI. The RFA states that "only one application per institution (normally identified by having a unique DUNS number) per component is allowed." A colleague at another university is also preparing an application for component A and would like to include me and my staff on her project through a sub-contract. Is this allowed?

Response (5). As referenced in the FOA, applicants may apply for Component A alone or both Components A and B. For those who apply for both, a separate application is required for each submission. In addition, applicants for Component B must have an eligible application under Component A in order to apply for and be awarded under Component B. Regarding your question, each application will be reviewed individually, and the level of effort will be taken into consideration.

Question (6). We are planning to submit a proposal for this opportunity. You have received a letter of

intent from <Institution A>. We are edging toward the idea of switching the prime to <Institution B> with PI and Co-PIs <from Institution A>, so that we can also submit a Coordinating Center (CC) proposal <Application for Component B> with <PIs and co-PIs from Institution B> in leadership roles. We have a few questions for you based on this:

(6.A). Can we propose the Coordinating Center would handle the data management and analysis for the <study site>? We would cover the cost of this in the <study site> in the event <Component B> was not funded.

(6.B). The RFA specifies the following committees: executive committee, steering committee, communications committee, and a publications, presentation and ancillary committee. Can you say more about what is intended for the communications committee, and are we free to propose additional committees, or working groups within them? For example based on past experience with CCs we are thinking of proposing a measurement committee/working group as well as a Project Managers committee/WG.

(6.C). Will the Coordinating Center be responsible for covering the cost of leasing meeting rooms and other facilities for face to face meetings? We understand that the CC will be in charge of the logistics for these meetings, but we were not sure about the cost of facilities.

Response (6.A). If you plan to apply to both Component A and B, they are two separate applications (two complete SF424s and PHS 398s), so each application would require a separate plan for data management and analysis. Applicants can describe their preferred approach to accomplish the work in their applications. If there would be overlap in the staff completing these activities for the CC in Component B and the study site in Component A, and your institution were funded for both Comp A and B, the award amounts would be adjusted to eliminate any overlap in staff time.

(6.B). The FOA doesn't specify the purpose of the communications committee; however, it is envisioned that the committee would be aimed at communicating with a wider audience (ie, the public) about the natural experiments network and study findings, once they are available. Applicants may propose additional committees/working groups if desired.

(6.C). The coordinating center (CC) is expected to handle the logistics for study meetings, thus leasing costs for any required facilities should be included in Component B budget.

Question (7). In terms of <Question 6.A>, our question was whether there was any concern about keeping staff independent between the <Components> B and A?. We are writing the two proposals, so that <Component> A could stand alone with data/analytic support provided by the same staff as <Component> B, but the <Component> B proposal budget only covers the responsibilities related to the Coordinating Center, so there would be no staff overlap in terms of the funding.

Response (7). Yes, staff may perform on both Components A and B given that there is no overlap in the time or activities.

Question (8). I have a follow-up question for you regarding RFA-DP-17-003. On page 17, item 4c the RFA requests: *"Summaries of existing data 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 diabetes and its complications; risk factors associated with diabetes and its complications; changes in food/agricultural, built environment, or public policies."* Do we need to provide numerical summaries of these data (i.e., numerically quantify risk factor prevalence for all the various race/sex/age sub-groups in the population)? Or do we just need to summarize in words what the data include, how they were collected, etc?

Response (8). The FOA references the summaries of existing data in the Research Plan for Component A and in the Review Criteria under "Approach." However, the FOA does not specify a particular format other than what is stated, so an applicant may provide data summaries as appropriate for their proposal.

