

Centers for Disease Control and Prevention

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

Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications

RFA-DP-15-001

Application Due Date: 03/24/2015

Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications

RFA-DP-15-001

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

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

Funding Opportunity Announcement (FOA) Title

Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications

Activity Code

Amendment 2. March 10, 2015

- **Appendix A: "Questions from Potential Applicants and CDC Responses" added to Section VIII. "Other Information"**
- **"Eligible applicant institutions may submit more than one application to a component, provided that each application is scientifically distinct" added under Executive Summary, Number of Applications**

Amendment 1. February 19, 2015.

- **Correction for eligibility of foreign organizations made in Section III. "Eligiblity Information", 2. "Foreign Organizations"**

National Institutes of Health, National Institute for Diabetes, Digestive and Kidney Diseases (NIDDK)

U18

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-15-001

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

93.945

Category of Funding Activity:

Health

FOA Purpose

Component A: To fund rigorous natural experiments of impact of population-targeted health policies and large scale interventions on risk and complications of diabetes, and reducing disparities in these risks and complications. Specific goals of the research program are to: 1) Test the health impact of naturally occurring health policies and interventions, including public health policies, clinical-community partnerships, and health system-wide strategies; and 2) Improve the methods and research infrastructure for natural experiments in public health. Findings could be used to inform the prioritization of policies and interventions for policy-makers, health plan directors, and community leaders.

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-15-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**

Letter of Intent Due Date: **02/24/2015**

January 20, 2015

Application Due Date: **03/24/2015**

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: **06/01/2015**

Secondary Review: **06/01/2015**

Estimated Start Date: **09/30/2015**

Expiration Date: **03/25/2015**

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 fund rigorous natural experiments of impact of population-targeted health policies and large scale interventions on risk and complications of diabetes, and reducing disparities in these risks and complications.Specific goals of the research program are to: 1) Test the health impact of naturally occurring health policies and interventions, including public health policies, clinical-community partnerships, and health system-wide strategies; and 2) Improve the methods and research infrastructure for natural experiments in public health. Findings could be used to inform the prioritization of policies and interventions for policy-makers, health plan directors, and community leaders. **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.** The participating organizations, NCCDPHP and NIDDK, intend to commit approximately $2,500,000 in FY 2015 to fund up to five awards under component A and one award under component B in response to this FOA. An applicant under Component A may request a project period of up to five years and a total budget of up to $450,000 including direct and indirect costs each year. An applicant under Component B may request a project period of up to five years and a total budget of up to $250,000 direct and indirect costs each year. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications.
- **Funding Source:** This FOA is funded by CDC/NCCDPHP and NIDDK. Specifically, grantees will be supported by $2,000,000 from CDC/NCCDPHP and $500,000 from NIDDK. For Component A, five awards of up to $450,000 each ($350,000 from CDC/NCCDPHP and $100,000 from NIDDK) are supported by both the CDC/NCCDPHP and NIDDK in FY2015. Specifically, under Component A, grantees will be awarded CDC/NCCDPHP funds of up to $350,000 (direct and indirect costs) to support the design, conduct, analysis, and dissemination of the health impact of the natural experiment of study and NIDDK funds of up to $100,000 (direct and indirect costs) to support the design, conduct, analyses and dissemination of the economic impact analyses. For Component B, one award of up to $250,000 is supported by CDC/NCCDPHP.
- **Budget and Project Period.** The project period will run from 09/30/2015 to 9/29/2020. The estimated total funding for this FOA in the first year is $2,500,000 (direct and indirect), including $2,000,000 from CDC and $500,000 from NIDDK. For Component A, the estimated total funding in the first year is $2,250,000 ($1,750,000 funded by CDC/NCCDPHP and $500,000 funded by the NIDDK). For Component B, the estimated total funding in the first year is $250,000 provided by CDC/NCCDPHP. The estimated total funding for the entire project is $12,500,000.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1 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 must designate a PI. Applications may designate co-PIs, however, the first PI listed will be the designated PI and official "contact PI" for all correspondence.
- **Number of Applications.** Eligible applicant institutions may submit one application for Component A and a separate application for Component B, if applying to both components. For component A, the applicants must select one of the two tracks. Eligible applicant institutions may submit more than one application to a component, provided that each application is scientifically distinct.
- **Application Type.** New
- **Special Date(s).** Not Applicable.

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

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 Sections 301, 317(k)(2), 405, and 426 of the Public Health Service Act (42 USC §§ 241, 247b(k)(2), 284, and 285c).

1. Background and Purpose

Diabetes is one of the nation's leading public health threats and a key target of public health interventions and health care reform because of the high prevalence, diverse comorbidities and extensive need for health services that follow. Despite improvements in clinical care and the rates of diabetes-related complications, there remains a considerable preventable burden of diabetes complications and continued increases in diabetes prevalence. Randomized controlled trials and observational cohorts have established a diverse evidence base for clinical and behavioral interventions, including lifestyle interventions, glycemic and cardiovascular disease risk factors control, and early screening to reduce diabetes and its complications. However, reducing the incidence of diabetes, and further reducing its complications, will depend upon population-targeted strategies, or health policies, to alter the health systems, communities, and behaviors in the population.

Policy-level innovations may come from private or public sectors and may work through health systems, business and community organizations, and through laws, ordinances, regulations, and enforcement. Policies are frequently aimed at expanding, changing, re-organizing services or increasing or redirecting resources to change health by affecting the health care people receive, the behaviors they engage in, or the social factors underlying their condition. For example, legislation at state and local levels frequently affect the coverage of services for diabetes care and prevention, incentives and availability of healthy foods and programs for physical activity and positive lifestyle changes. Similarly, large employers and health plans implement policies that affect the provision of preventive care, wellness programs, and the connection to community services. Policies outside the health sector, including changes to education, employment, and housing, may also have important effects on health status. Despite the diversity of innovative policies, there has been little rigorous empirical examination of such approaches.

The Need for Rigorously Evaluated Natural Experiments:

The lack of evidence for population-targeted policies is in part due to the types of research that have been traditionally employed in public health sciences. Neither traditional cohort studies nor randomized controlled trials are practical to test large scale policies and often not flexible enough to test the continual innovation in strategies employed by health systems and communities. However,

methods 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. Along these lines, natural experiments have been defined as studies of the impact of population-wide interventions or policies on health or health care that make use of naturally occurring events and compare the effects of variation in exposure to interventions without manipulation by the experimenter (Craig et al., 2012). Similarly, the Medical Research Council has defined natural experiments as experimental studies that exploit natural or unplanned variation in exposure (variation that is not manipulated for the purposes of research) using a combination of design and analytical features that are meant to allow causal inferences to be drawn. (Medical Research Council, 2012)

This FOA is designed to stimulate and support natural experiments of population-targeted policies and large-scale interventions to prevent diabetes and its complications. Specific goals of the research program are to: 1) Test the health and economic impact of naturally occurring health policies and interventions, including public health policies, clinical-community partnerships, and health system-wide strategies; and 2) Improve the methods and research infrastructure for natural experiments in public health It is designed to promote efficient, rigorous examination of naturally occurring interventions using the strongest data sources available and state-of-the art analytic and statistical designs. Findings from the network should lead to a prioritization of policies and interventions for policy-makers, health plan directors, and community leaders. This FOA is also intended to strengthen methods for longitudinal experiments on health policies.

There are two components to this FOA. Component A will fund a network of independent research centers to conduct novel 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

- This FOA will support the full spectrum of Diabetes Healthy People 2020 objectives D-1: “To reduce the number of new cases of diabetes in the population” to D-16: “Increase prevention behaviors in persons at high risk for diabetes with pre-diabetes.”

Public Health Impact

The research supported by this FOA is designed to enhance public health by improving and refining the evidence base whereby public health policy makers, including legislators, health plan directors, and community leaders and their constituents are better informed about what public health policies work to reduce (or improve) risk of diabetes and its chronic morbidities. Similarly, better prioritization of major population approaches may reduce risk factors and incidence, and improve quality of life. This research program is also designed to improve the methods for natural experiments of health policies, and thereby improve the quality of public health research for future public health impact.

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) manuscript by (Gregg et al., Prev Chronic Disease), a multi-center network of natural experiments.

It also builds upon the NIDDK PAR-13-365, the Evaluating Natural Experiments in Healthcare to Improve Diabetes Prevention and Treatment (R18) PAR-13-365.

2. Approach

This FOA is comprised of two components. Component A (Natural Experiment Sites): Supports Natural Experiments Research Centers to design and conduct rigorous longitudinal studies of naturally occurring, population-targeted health 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.

Because awardees, under Component A, will be funded with two sources or funds, applicants are expected to submit a single budget, but that budget must delineate and distinguish funds devoted to health impact and economic impact aspects of the study. Throughout the study period, the CDC/NCCDPHP funds are expected to support the design, conduct, analysis, and dissemination of the health impact of the natural experiment of study under Component A whereas the NIDDK funds are expected to support the design, conduct, analyses and dissemination of the economic impact analyses under Component A.

In order to ensure a diversity of policies being examined, Component A supports applications for natural experiments from two research tracks. Applicants will be asked to select from one of the tracks. 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 to apply and be awarded under Component B.

Objectives/Outcomes

The goal of this FOA is to fund rigorous natural experiments of the impact of population-targeted health policies on risk of diabetes and its complications. This will be achieved by supporting the assessment of the health policy and economic impacts from a portfolio of contemporary natural experiments and assembling a research network aimed at strengthening methods for conducting and evaluating natural experiments and promoting collaborative studies.

Component A (Natural Experiments Research Centers)

The objective of this component is to design and conduct rigorous tests of the impact of one or more population-targeted health policies on diabetes risk, care, complications, and economic outcomes. Investigators will be expected to:

1) Design natural experiments of the health impact of ongoing health or public policy interventions and available data;

2) Identify, assemble, analyze and interpret data from appropriate sources to test

natural experiments;

3) Publish and disseminate findings to inform policy-makers about effective and cost effective approaches to prevent diabetes and its complications;

4) Participate in a network of natural experiments to maximize quality of study designs and dissemination and impact of study findings and improve methods of conducting natural experiments.

Characteristics of Policies and Interventions for Examination:

Policies studied by the network may include legislative, health system-based, and community-based initiatives that are likely to influence health promotion, preventive care and the health of broad segments of the population. Studies should focus on ongoing, naturally occurring, or imminently available policy or systems-level interventions or on quasi-experimental designed studies that target large populations. Interventions of study may also be non-health related (i.e., educational, housing) but should have a strong rationale for why the policy would be expected to improve health status.

Applicants for component A will be expected to propose a natural experiment from one of two tracks:

1. *Public policy approaches*: involves legislative or other public approaches that could affect, whether beneficially or adversely, diabetes risk and health status in large segments of the community. This may involve changes to the food or built environment or nutritional or physical activity practices of large communities that in turn, affect the diabetes risk of populations. This may also include reimbursement policies by CMS and Medicaid aimed at screening, behavioral change, or other aspects of diabetes risk. In some cases, the principal goal of the policy may be non-health related (e.g., education, urban planning, economic development).
2. Health system-community partnerships: are formal partnerships between clinical settings and community organizations, including employers. For example, this may include health system policies to reimburse for services provided in communities, referral programs to community programs, and partnerships to change the health context of communities.

Examples of *Public Policy Interventions* include:

- Statutory and regulatory laws at all levels of government on access, delivery, outcomes, and cost of diabetes care.
- Economic incentives and disincentives, such as subsidies, taxes, and vouchers, to promote healthy lifestyle and community programs.
- Food taxation and subsidies on diabetes-related health outcomes.
- Laws aimed at consumer information such as the recent citywide menu labeling statutes.
- Laws, policies, and interventions that shape the built environment (e.g., urban planning, land use, and transportation-related laws) on physical activity.
- 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.
- Policies focusing on the economic or environmental characteristics of communities.
- Laws, policies, and interventions aimed at improving the levels of education, living conditions, and economic well-being of large segments of the population.

Examples of *health system-community partnerships* include, but are not limited to:

- Novel managed care and employer-based disease management and health promotion

approaches.

- Insurance reimbursement policies and benefit designs on adoption, adherence, and effectiveness of preventive health behavior programs.
- Changes in Medicare and Medicaid reimbursement policies on preventive care and outcomes.
- Population screening approaches implemented in health systems, employers, and community settings on changes in behavior, risk, and morbidity.
- Prevention-focused quality improvement and disease management programs.
- Employer-based policies and incentives on health promotion, including 4 day work weeks, health club vouchers, etc.
- Population disease stratification, management and feedback tools, including laboratory based registries and electronic health records

Study Outcomes:

Studies should investigate the effects of policies on systems changes, changes in health promotion and care practices (quality, levels of implementation and coverage, costs); behavioral risk factors; physiological risk factors; and the risk of diabetes and its complications, including the effects on morbidity, age of onset, and quality of life. Studies may target policies and interventions that are directly aimed at health systems and behaviors, or may involve interventions outside the health sector. Studies should also examine the costs, adverse effects, and unintentional consequences of policies.

Study Design, Data Sources, and Approach:

Studies should employ rigorous designs that can provide causal inferences about the effectiveness and health and economic impact of policies. Investigators should identify opportunistic, natural experiments that make use of longitudinal, quasi-experimental study designs using concurrent control conditions, historical trends or interrupted time series designs. Interventions should be assessed at multiple levels where possible: e.g., system-wide, communities, or clusters of individuals. Cohort and panel survey data may also be employed but should permit examination of study interventions that are applied and targeted at large segments of the population by health system or public policies. 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.

Investigators are encouraged to assemble diverse sources of data, including those available from public survey data and/or medical information systems such as electronic medical records. Applicants should have ready access to essential data on exposure and outcomes at the outset of the funding period. Studies are expected to assess population-targeted policies as well as indicators of care and health at the population-level. Data sources may include, among others, health plan based registries, administrative outcomes data bases such as Medicare and Medicaid, HMO databases, publicly available population survey data and special population surveys adapted for this project. Applicants are also strongly encouraged to incorporate data sources from non-traditional sources.

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 funding agencies.
2. Assists in the development of and 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 agencies to prepare meeting logistics for the study including i.e. agendas, securing meeting facilities such as negotiating and reserving hotel guests rooms; leasing of meeting rooms with meeting equipment for annual face to face meetings, preparing meeting minutes from the annual study group 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 web-site 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; health plans, 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, care, and complications, should be expressed at the community or population level.

Component B: Not applicable.

Collaboration/Partnerships

Component A: Investigators are encouraged to form or expand innovative scientific partnerships between researchers and public or private partners (e.g., community based organizations, local governments, employers). Applicants that have established data-sharing agreements and can demonstrate population level pilot data of baseline exposure and health status of target populations is desired.

Component B: The project director or principal investigator of this component shall establish partnerships with the study investigators and study partners under Component A to accomplish study goals; i.e. by first planning and organizing with the funding partners a kick-off meeting for the network within two weeks of award.

Evaluation/Performance Measurement

Component A: Evaluation/performance measurements should include quality and completeness of study designapproaches for case ascertainment, validation, and classification of diabetes type, 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 assesses outcomes of important health impact, including risk of diabetes and its morbidities, including cardiovascular disease.

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, 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 agencies.

Translation Plan

Component A: Applicants for components 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.

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

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

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

Application Types Allowed:

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

Estimated Total Funding: $2,500,000

The estimated total funding (direct and indirect costs) for the first year (12 month budget period) is $2,500,000, including up to $2,000,000 from CDC/NCCDPHP and $500,000 from NIDDK. The estimated total funding for the entire project is $12,500,000.

Component A: Average award size will be $450,000 per year with up to five awards to five different grantees. CDC/NCCDPHP will award $350,000 per year, and NIDDK will award $100,000 per year.

Component B: Average award size will be $250,000 per year for up to one award to a single grantee. CDC/NCCDPHP will award the $250,000 per year.

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: 6

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

Component A: $450,000

Component B: $250,000

Applications with budget requests greater than the ceiling will be considered non-responsive and will not be reviewed.

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

Component A: $350,000

Component B: $200,000

Applications with budget requests less than the floor amount will be considered non-responsive and will not be reviewed.

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

Award Ceiling: $0 Per Project Period

Award Floor: $0 Per Project Period

Total Project Period Length: 5 year(s)

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/asfr/ogapa/aboutog/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)

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 (i.e. data use agreements) for ready access to data in order to assess the health care, behaviors, and health status impact for populations of at least 10,000 individuals.

Applicants must provide a written acknowledgement of receipt of funds from the two funding sources, (CDC and NIDDK) and commitment to adhere to budget requirements to delineate budget and expenditures by funding source. Evidence should be provided in the form of a letter from the applicant institution and should be included in Appendix A of the application.

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

4. Justification for Less than Maximum Competition

1. **Not applicable**

5. Responsiveness

Component A: Applicants must provide evidence in the form of background/preliminary data from the last 5 years related to the primary exposure data and characteristics of the population of at least 10,000 individuals.

Applicants should show evidence of ready access to data sets and systems necessary for execution of the study design, in the form of letters of commitment, memorandum of understanding, or other documents indicating data access exists prior to or at the time of the outset of the funding period.

Applicants must provide a written acknowledgement of receipt of funds from the two funding sources, (CDC and NIDDK) and commitment to adhere to budget requirements to delineate budget and expenditures by funding source. Evidence should be provided in the form of a letter from the applicant institution and should be included in Appendix A of the application.

Component B: Applicants must provide a statement of submission of application for Component A under RFA DP15-001 to include the principal investigator (PI) name and title of the application.

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

Incomplete applications, applications submitted after 5:00 PM on the listed application due date or non-responsive applications with budgets that exceed the ceiling or with budgets that are below the floor of the award will not be 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%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

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

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing 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/ asfr/ ogapa/ aboutog/ hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (http://www.hhs.gov/asfr/ogapa/aboutog/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.

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 Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard 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/funding/ 424/SF424_RR_Guide_General_VerC.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.

3. Letter of Intent

Due Date for Letter of Intent: **02/24/2015**

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 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 (List 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, MPH
National Center for Chronic Disease and Health Promotion (NCCDPHP) and NCBDDD

Extramural Research Program Operations and Services (ERPOS)

Centers for Disease Control and Prevention

4770 Buford Highway, NE M/S F-80

Atlanta, GA 30341

Telephone: (770) 488-5740
Email: ndarling@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 Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.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 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Research Plan

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:

Both 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.
2. Provide detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
3. Describe plans for producing reports: interim progress reports and a final report, as well as technical reports, professional presentations, and publications that will be produced

collaboratively with CDC.

Component A:

1. Describe the scope, target population, and intended mechanism and impact of the health policy to be studied.
2. Provide evidence of access to key data using pilot or baseline descriptive data.
3. Describe the study design and methodological approach for testing the effectiveness of the policy of interest.
4. Provide evidence of demonstrated partnerships, access to data and data use agreements for the proposed or existing collaborations to address the goals, objectives, and intent of the FOA.
5. Describe access to existing and new data sources and patient populations.
6. Describe the key data and variables to be used to assess the exposure to the policy of interest and the intermediate and long-term outcomes to be examined.
7. Describe the infrastructure and work environment to be used to access existing data sources or to create new data sources to accomplish the research goals and objectives in this funding opportunity announcement.
8. Describe the existing or new data sources that will be used in the proposed research activities.
9. Describe the project team's expertise related to: a) health policies to influence risk for diabetes and its complications; b) methodological approaches for conducting natural experiments.
10. Describe plans to evaluate funded activities and report on findings, including how you plan to:
    a. Track process, outcome, and the impact of supported activities, focusing on outcomes and stated goals;
    b. Report process and outcome data on activities and evaluation findings using written report(s), and peer-reviewed journals.
    c. Provide evaluation plan on monitoring outcomes of proposed activities.

Component B:

1. 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.
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.

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 (Part I, Section 2) (http://grants.nih.gov/ grants/funding/424/ SF424_RR_Guide_General_VerC.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), 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 CDC PGO TIMS at 770-488-2700; www.pgotim@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: **03/24/2015**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, 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/asfr/ogapa/aboutog/hhsgps107.pdf.

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

Recipients may not use funds for any kind of lobbying activity designed to influence proposed or pending legislative matters. These restrictions include grass roots lobbying efforts and direct lobbying. Certain activities within the normal and recognized executive-legislative relationships within the executive branch

of that government are permissible. See Additional Requirement (AR) 12 in Section VI. "Award Administration Information", Part2. "CDC Administrative Requirements" for further guidance on this prohibition.

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/ Electronic Receipt /avoiding_ errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit_ app.htm

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

Section V. Application Review Information

1. Criteria

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

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

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

Significance

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

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

- Does the applicant have a diverse multi-disciplinary team with expertise in the areas of health services research, public health policy, epidemiology, statistics, and economics?
- Does the principal investigator (PI) have extensive experience leading major epidemiologic, health services research and policy studies assessing population impact?
- Do the PI and other members of the research team have documented (1) expertise in health policy research, health services research, epidemiology, behavioral and organizational change, and economics; (2) experience in designing, implementing, and documenting research findings for complex, multi-site studies; and (3) strong records of peer-reviewed scientific publications.

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 health-related policies, health systems, and practices on communities' health, for population of at least 10,000 individuals? 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 five 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; access and utilization of services; changes in health-related policies; and changes in heathcare systems and practices?
- Does the study design involve assessment of a policy or intervention that targets large populations, communities, employers, or health systems of at least 10,000 individuals?
- Does the proposed study (ies) 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 interventions; i.e, will the findings lead to a clear answer as to whether the policy or systems change intervention can lead to changes in health care, individual 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 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 experiment?
- Does the applicant describe experience in development and management of websites?

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/od/pgo/funding/grants/additional_req.shtm#ar1).

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.

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.

Data collected must be released to the public no later than two years after the end of the budget period as specified in the application's Data Release Plan and in accordance with CDC policy on Releasing and Sharing Data.

Resource Sharing Plans
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/od/pgo/funding/grants/additional_req.shtm#ar25. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

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/od/pgo/funding/budgetguide.htm.

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.
- Readiness to initiate study (availability of established data-sharing agreements, availability of population level pilot data of baseline exposure and health status of target populations

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/ asfr/ogapa/aboutog/ 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/ asfr/ogapa/ aboutog/ hhsgps107.pdf).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

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 2012 Enacted General Provisions

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

ARs applicable to ATSDR Awards:

AR-18: Cost Recovery –; ATSDR

AR-19: Third Party Agreements –; ATSDR (AR-19)

ARs applicable to Conference Awards:

AR-20: Conference Support

AR-27: Conference Disclaimer and Use of Logos

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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.

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/ asfr/ogapa/acquisition/ effspendpol_ memo.html)

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), 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 Web site, www.USASpending.gov (http:// www.usaspending. gov/). For the full text of the requirements, please review the following website: https:// www.fsrs.gov/.

Plain Writing Act

The Plain Writing Act of 2010 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.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm

  - http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm

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.

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 Scientific Collaborators and 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/ Project Director will have the primary responsibility to:

Components A and B

1. Establish goals and objectives that are realistic, measurable, and time-oriented for the project.
2. Participate in the Research Network Committee and subcommittee meetings, as well as CDC-sponsored meetings; as scheduled by the Research Network Committee and CDC.
3. Invite other members of the research team to participate in appropriate subcommittee and CDC-sponsored meetings.
4. Ensure adequate staffing and oversight of the research activities.
5. Mentor junior investigators and fellows, including individuals from underrepresented racial and ethnic groups as well as individuals with disabilities in support of the research team and its activities.

Component A:

1. Design and conduct research to address the described research objectives of this cooperative agreement.
2. Submittals for approval to local Institutional Review Board (s) (IRB).
3. Conduct studies and disseminate 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.

There are two separate roles – Scientific Collaborator and the Scientific Program Official (SPO).

In this cooperative agreement, a CDC Scientist (Scientific Collaborator) within the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) is involved with all aspects of the scientific and programmatic matters of the project through technical assistance, advice and coordination. It is expected that CDC's Project Scientists will have substantial programmatic involvement in this cooperative agreement.

Components A and B:

CDC Scientific Collaborators will:

- Serve as technical advisor and scientific consultant for the project activities related to this cooperative agreement overall and monitor its progress, including conducting site visits to recipient institutions.
- Serve as a technical consultant and advisors to the Steering Committee and study workgroups.
- Provide scientific and technical assistance advice as needed to assist the investigator in achieving the study objectives.
- Facilitate distribution and dissemination of results.
- Contribute to analyses, publications, technical reports and other products as co-authors within

the CDC authorship guidelines.
- Obtain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.

Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

CDC Extramural Research Program Operations and Services (ERPOS) will appoint a Scientific Program Official (SPO), apart from the NCCDPHP Scientific Collaborator. The CDC SPO will be responsible for the normal scientific and programmatic stewardship of the award.

The SPO will:

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

Additionally, an HHS/CDC NCCCDPHP project officer will provide day-to-day programmatic, administrative, and fiscal management in support of this project

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 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 an adequate time commitment to the cooperative agreement.
- 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 patient data and specimens and ancillary studies. 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/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

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.

1. Interim progress report, (use form PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application and must contain the following elements:
    a) Current Budget Period Activities Objectives.
    b) Current Budget Period Financial Progress.
    c) New Budget Period Program Proposed Activity Objectives.
    d) Budget.
    e) Measures of Effectiveness.
    f) Additional Requested Information.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.
4. Data collected must be released to the public no later than two years after the end of the budget period as specified in the application's Data Release Plan and in accordance with CDC policy on Releasing and Sharing Data .

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 Central Contractor Registry; 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://dhhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf) for additional information on this reporting requirement.

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, **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 report 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:// 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.

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. 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: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

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

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: http://era.nih.gov/commons/. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. 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.

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)
Procurement and Grants Office
Telephone 770-488-2700
Email: PGOTIM@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)
Natalie J. Darling, MPH
NCCDPHP and NCBDDD

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE M/S F-80

Atlanta, GA 30341

Telephone: (770) 488-5740
Email: ndarling@cdc.gov

Peer Review Contact(s)

Moises (Chris) Langub, PhD
NCCDPHP and NCBDDD

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE M/S F-80

Atlanta, GA 30341

Telephone: (770) 488-3585
Email: eeo6@cdc.gov

Financial/Grants Management Contact(s)
Charles Denard

NCCDPHP and NCBDDD

Grants Management Specialist (GMS)

Procurements and Grants Office (PGO)

Centers for Disease Control and Prevention

2920 Brandywine Rd., MS E-09
Atlanta, GA 30341
Telephone: (770) 488-2932
Email: xyg9@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.

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 Sections 301, 317(k)(2), 405, and 426 of the Public Health Service Act (42 USC §§ 241, 247b(k)(2), 284, and 285c).

Appendix A: Questions from Potential Applicants and CDC Responses

Q1: If I read the Eligibility information correct we would be allowed to submit one proposal by a PI to

Component A, and one proposal to Component B. Is this correct? What if we just wanted to submit to Component A… would we be allowed just 1 submission to Component A.

A1: Yes, eligible applicant institutions may submit one application for Component A and a separate application for Component B (2 separate applications if applying to both components). PIs would be listed on each application.

Applicants can choose to submit an applicant for Component A only. An applicant does not have to submit an application for Component B. However, in order for an applicant to apply for Component B, the applicant must first have an eligible application submitted under Component A.

Q2. I am writing to request a clarification in the RFA-DP-15-001, entitled, "Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications." In Section IV - Application and Submission Information, subsection 7. Page Limitations is the Research Strategy component of the Research Plan narrative limited to 25 pages ***single-spaced?*** In addition, I would like to confirm that the margins for the submission are 1/2 inch on all sides of the Research Plan narrative.

A2: Section IV of the FOA provides the following link to the "SF424 Application Guide (version C)" http ://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf which contains detailed instructions for applicants. Section 2.6 of the referenced guide (page 35) provides information on font, paper size/page margins, and page formatting. The SF424 application guide states "at least one-half inch margins" on all sides should be used for PDF documents/attachments. The FOA and the referenced guide do not specify a line spacing requirement for the Research Strategy component; however, the referenced guide encourages applicants to use a "standard, single-column format" for text. I have reprinted the information from section 2.6 below.

> **Font**
>
> Prepare the application using Arial, Helvetica, Palatino Linotype, or Georgia typeface in black font color. After text attachments are converted to PDF, font size in each final PDF document must be at least 11 points (or larger). (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.) Since some PDF converters may reduce font sizes, it is important to confirm that type density in each final PDF document, including both characters and spaces, is no more than 15 characters+spaces per linear inch and no more than six lines per vertical inch.
>
> **Paper Size and Page Margins**
>
> Final PDF documents should be formatted to be no larger than *standard paper size (8 ½" x 11)*. The final PDF document should have at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI's name and page numbers.
>
> **Page Formatting**
>
> Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically. Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Q3. Can you please help clarify the number of applications allowed for "Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications" (RFA-DP-15-001)? From Page 2 of the RFA: "**Number of Applications**. Eligible applicant institutions may submit one application for Component A and a separate application for Component B, if applying to both components. For component A, the applicants must select one of the two tracks."

- Is an institution allowed to submit more than one application for Component A?
- Is an institution allowed to submit more than one application for Component B (with at least one separate application for A)?
- If an institution submits an application for Component B, may it submit multiple Component A applications?

A3. Yes, eligible applicants may submit more than 1 application to each component if each application is scientifically distinct. This statement will be added to the amended FOA approximately 2 weeks before the due date. Please note: each submission must be a separate and complete application using the SF424 (R&R) application package.

Q4. We propose to understand the influence of this "natural experiment" on diabetes prevalence and complications, data on which will come from the [applicant's dataset]. [Is this idea consistent with the intent/goals/objectives of the FOA?]

A4. We cannot comment on specific topics or approaches or 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 can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question.

The FOA is comprised of 2 components (A and B). The purpose of Component A is "to fund rigorous longitudinal studies of naturally occurring, population-targeted health policies and large scale interventions on the risk of diabetes and its complications. Findings should inform policy-makers, health plan directors, and community leaders to prioritize population-wide interventions for diabetes prevention and control." Component A has 2 tracks, and Applicants for component A will be expected to propose a natural experiment from one of two tracks: (1) Public Policy approaches or (2) Health system-community partnerships (see Objectives/Outcomes in Section 1., 2. Approach).

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

Q5. My question is whether you thought (based on the brief description) if our application sounds like a good fit for the RFA? There are aspects of the RFA which seem to suggest a focus on health care systems or delivery—which our application will not address. I am also interested in finding out if the following aims are aligned with the goals of the economic impact aspect of the RFA:

1. Evaluate the overall health impact of those neighborhood changes in terms of Quality of Life Years.

2. Conduct a cost-effectiveness/cost-utility analysis for the overall revitalization program and its components.

A5. We cannot comment on specific topics or approaches or 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 can highlight the purpose of the

FOA and highlight some sections of the FOA that may be relevant for your question.

The purpose of Component A is "to fund rigorous longitudinal studies of naturally occurring, population-targeted health policies and large scale interventions on the risk of diabetes and its complications. Findings should inform policy-makers, health plan directors, and community leaders to prioritize population-wide interventions for diabetes prevention and control." Component A has 2 tracks, and Applicants for component A will be expected to propose a natural experiment from one of two tracks: (1) Public Policy approaches or (2) Health system-community partnerships (see Objectives/Outcomes in Section 1., 2. Approach).

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".

In addition, for Component A, the FOA's intent is to test the health and economic impact of naturally occurring health policies and interventions, including public health policies, clinical-community partnerships, and health system-wide strategies.

Q6. I am writing about the above-referenced RFA with special reference to the eligibility of foreign entities as applicants or as participating sites. In particular, we have been working with one of the large HMO's in [name of foreign country], collaborating on data analyses and papers.

Based on the comments in the RFA, page 12, about foreign organizations, we have been thinking about responding to this RFA. However, we wanted to get a better sense of whether there is a preference for US entities since this preference might influence our decision to apply.

A6. In Section III "Eligibility Information" part 2. "Foreign Organizations", the FOA should state the following: "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."

We will amend the FOA to reflect this correction.

Q7. I have a PI who is submitting a proposal to the referenced RFA. Do you, by chance, have the RFA guidelines available in *word* format? We are only able to locate it in pdf, which does not allow us to copy/paste info out of it (when we try, everything shows up as little squares – so odd).

A7. After discussing with technical support, their suggestion was to use Adobe Acrobat XI Pro Version 11.0 to convert the FOA from PDF to MS Word format. Unfortunately, the copy and paste function as well as the search function do not work properly for the PDF format of this FOA on www.grants.gov.

Q8. When preparing the LOI, should the "Name of the Applicant" be the PI's name **OR** the name of the submitting institution? For the "Participating Institutions" section, would we enter our institution's (applicant) name *again* OR is this an area where we are to list if there are additional (subcontracts) institutions?

A8. For Letter of Intent (LOI), "Name of Applicant" refers to name or institution or organization. You may place the principal investigator's (PI) name on a separate line. "Participating Institutions" would include both –list the name of the primary organization/institution again and any additional institutions that will be participating.

Q9. We have two questions regarding this RFA on the Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and Its Complications.

- If an applicant submits as a prime for Component A can they submit as a subcontractor to another prime for Component B?
- Is there a minimum percentage requirement of the proposal cost that needs to be bid by a prime applicant?

A9. In Section III. "Eligibility Information", 3. "Special Eligibility Requirements" for Component B, the FOA states: "Applicants must have an eligible application under Component A to apply and be awarded under Component B". The announcement does not specify the role of applicants as subcontractors in one or more applications. However, the announcement does address the number of applications from one applicant In Part 1. "Overview Information", "Executive Summary", under "Number of Applications" which states "eligible applicant institutions may submit one application for Component A and a separate application for Component B, if applying to both components. For component A, the applicants must select one of the two tracks."

The FOA does not specify a minimum percentage of the proposal costs for the prime grantee as this is not normally placed in CDC FOAs. However, standard policy is that a substantial amount, typically in excess of 49% of the awarded funds, should not be "pass through" from the prime grantee to a subcontractor/consultant to perform the work.

Q10. For Component A [Applicant's Institution Name] will be the prime and most likely will have 85% of the work with [contractor's Name] having about 15%. For Component B [Contractor's Name] will be the prime and most likely will have 85% of the work with [Applicant's Institution Name] having about 15%. On page 6 of the RFP the last sentence of the second paragraph says "In addition applicants for Component B must have an eligible application under Component A to apply and be awarded under Component B." Please confirm our team with [Applicant's Institution Name] and [Contractor's Name] and our plan on how we will bid these two components meets your criteria for applying.

A10. We cannot comment on specific topics or approaches or 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 can highlight some sections of the FOA that may be relevant for your question. Section III. "Eligibility Information", 3. "Special Eligibility Requirements" for Component B) states that "Applicants must have an eligible application under Component A in order to apply and be awarded under Component B. Also in Section III, under 5. "Responsiveness", it states **"**Component B:Applicants must provide a statement of submission of application forComponent A under RFA DP15-001 to include the principal investigator (PI) name and title of the application."

Further, In Section I. "Funding Opportunity Description", 2. Approach, it states that "Applicants may apply for Component A alone or both Components A and B. For those applicants who apply to both components, a separate application is required for each submission. In addition, applicants for Component B must have an eligible application under Component A to apply and be awarded under Component B." This means an applicant cannot just apply for Component B, but if applying for B, must also apply for A. It also means to be awarded under Component B, the applicant must have applied (and been eligible) for Component A. "Applicant" refers to the primary applicant: the institution (identified by a unique DUNS) submitting the application.

Q11. We are submitting an application under Component A. Will preparation of an expanded budget justification to support the budget and provide detail on the delineation of costs devoted to the health impact and economic impact aspects of the study and their distinct funding sources, provide sufficient detail for review of the application? If not, is there a preferred format or method that the CDC would recommend to provide the required detail?

A11. In Part I. "Overview Information", under "Executive Summary", "Budget and Project Period" of the Funding Opportunity Announcement the FOA states: "Because awardees, under Component A, will be funded with two sources or funds applicants are expected to submit a single budget, but that budget must delineate and distinguish funds devoted to health impact and economic impact."

In Section III. “Eligibility Information”, under 3. “Special Eligibility for Component A, the FOA states “Applicants must provide a written acknowledgement of receipt of funds from the two funding sources, (CDC and NIDDK) and commitment to adhere to budget requirements to delineate budget and expenditures by funding source. Evidence should be provided in the form of a letter from the applicant institution and should be included in Appendix A of the application.” The FOA does not specify the exact approach to use to delineate and distinguish the different activities and expenditures; the approach can be determined by the applicant.

Q12. I had a specific question about the language in RFA-DP-15-001 under “Special Eligibility Requirements” and “Responsiveness”. Specifically, there is language in these sections (though not in the other sections you describe below) that refers to having access to “data from the last 5 years…on populations of at least 10,000” (p.12 of FOA). Can you clarify what this means? (e.g., do we need to have a sample size of at least 10,000?) We would very much appreciate this clarification as soon as possible, so that we can determine if our proposed study will be eligible and responsive.

A12. In Section III. “Eligibility Information” 3. “Special Eligibility”, under Component A, the FOA states “Applicants must have letters of commitment from partners to show continuous access to datasets and/or data systems proposed for the study (i.e. data use agreements) for ready access to data in order to assess the health care, behaviors, and health status impact for populations of at least 10,000 individuals.” In Section III, under 5. “Responsiveness” the FOA states "Applicants must provide evidence in the form of background/preliminary data from the last 5 years related to the primary exposure data and characteristics of the population of at least 10,000 individuals. Applicants should show evidence of ready access to data sets and systems necessary for execution of the study design, in the form of letters of commitment, memorandum of understanding, or other documents indicating data access exists prior to or at the time of the outset of the funding period."

The 10,000 refers to the minimum sample size of the applicant’s dataset.