

Centers for Disease Control

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

Community Characteristics Associated with Geographic Disparities in Diabetes and Cardiometabolic Health
RFA-DP-17-001
Application Due Date: 02/14/2017

Community Characteristics Associated with Geographic Disparities in Diabetes and Cardiometabolic Health

RFA-DP-17-001

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

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

Funding Opportunity Announcement (FOA) Title

Community Characteristics Associated with Geographic Disparities in Diabetes and Cardiometabolic Health

Activity Code

Amendment 1. February 7, 2017

- Form D application package is to be used for this funding opportunity announcement (FOA). (Please disregard the reference to Form C in the "Executive Summary"; "Application Materials" of this FOA.) Form D can be downloaded from the “Package” tab on this announcement on www.grants.gov .

Appendix A: "Questions from Potential Applicants and CDC Responses" added to Section VIII. "Other Information"

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Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-17-001

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

93.068

Category of Funding Activity:

Health

FOA Purpose

This FOA has two components, A and B.

Component A supports applications aimed at examination of county-level disparities in type 2 diabetes and cardiometabolic conditions to enhance understanding of disease determinants. Applicants will test hypotheses aimed at clarifying the contribution of environmental or socioeconomic circumstances to diabetes geographic disparities. As part of this initiative, Component A awardees will also be asked to form a common protocol for a selected subset of variables to permit multi-center analyses.

Component B of this FOA solicits applications for a study Coordinating Center (CC) to provide logistics, data management, and analysis support to the multi-center research study.

Key Dates

Publication Date: **To receive notification of any changes to RFA-DP-17-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**

Letter of Intent Due Date: **01/13/2017**

01/13/17

Application Due Date: **02/14/2017**

02/14/17

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

Scientific Merit Review: **04/03/2017**

Secondary Review: **05/15/2017**

Estimated Start Date: **09/29/2017**

Expiration Date: **02/15/2017**

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

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

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

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

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

Executive Summary

- **Purpose.** This FOA has two components, A and B. Component A supports applications aimed at examination of the modifiable characteristics at the community, environmental, and individual level that explain large disparities in type 2 diabetes and related chronic conditions across counties in the United States. Following the award, grantees will collaborate to establish a common protocol and data management plan for the collection of a core set of exposure and outcome variables to permit multi-center analyses.

  Component B of this FOA solicits applications for a study Coordinating Center (CC) to provide logistics, data management and analysis support to the multi-center research study funded under component A.

- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total level of funding (direct and indirect for entire project period in dollars) that is available for the FOA for the entire project period,9/30/2017 - 09/29/2022, is $20,000,000. It is estimated that 5 awards will be made under this FOA, four under component A and one under component B. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first budget period, 9/30/2017 - 09/29/2018, is $4,000,000. The estimated total funding (direct and indirect) for the entire project period,9/30/2017 - 09/29/2022, is $20,000,000. Under both component A and B, the estimated average award for year 1 will be $800,000.
- **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.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs:** Applications may include more than one PI; however, the first PI listed on the application will be the "contact PI" for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** An institution (normally identified by having a unique DUNS number) may submit no more than one application for Component A and no more than one for Component B. However, no institution will receive more than one award under this funding announcement. That is, the awardee for Component B will not also receive an award for Component A.
- **Application Type.** New
- **Special Date(s)**
- **Application Materials.** See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf

- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

Comprehensive public health programs may be improved by incorporating measures that address socioeconomic factors and community contexts, as well as individual counseling or clinical interventions (1, 2). This comprehensive balance may be especially important in settings where poverty, low educational attainment and social deprivation are common. To maximize a program's population impact, it may help to identify which environmental or socioeconomic circumstances (contexts) could have the greatest influence on health outcomes. A related challenge is to understand the mechanisms or pathways through which contexts may exert their effects, positive or negative, on the etiology of specific diseases so as to intervene effectively on a community level to reduce disease burdens.

It is unlikely that a single research initiative will identify a unique intervention that could reduce the burden of every disease in every community setting (3). Faced with this reality, this FOA focuses attention on type 2 diabetes, an increasingly common disease of adults that is closely linked to obesity, ectopic fat accumulation and processes of atherosclerosis, e.g., coronary heart disease, stroke. Based on observable disparities in diabetes prevalence and incidence across the 3000+ counties in the United States, this FOA will focus on the study of community contexts scaled to counties. Public health interventions applied at the county level might be relatively amenable to implementation and evaluation.

By narrowing its objectives in these ways, the **purpose of this funding opportunity** is to understand better the mechanisms or pathways through which environmental or socioeconomic circumstances (contexts) have their greatest influence on a community's exposure specifically to type 2 diabetes.

Component A of this research initiative will support parallel studies based on different hypotheses in distinct community settings. Each of the parallel studies will have achievable objectives that may incrementally advance public health knowledge related to diabetes and related cardiometabolic conditions.

Component B will provide coordinating services to all the awardees under Component A to maximize the statistical power and generalizability of their aggregated results.

As outlined in following sections of this FOA, applicants for Component A should develop an epidemiologic research design that will seek to understand substantial geographic disparities between counties selected for study because they are at high- or low-risk of diabetes. Hypotheses should be proposed to describe the contextual factors, harmful or protective, that contributed to these disparities. Tests of these hypotheses should proceed through focused data collection and appropriate use of analytic methods that acknowledge multiple sources or levels of data. As part of this research initiative, the Component A awardees will also be asked to form a collaborative protocol that contains a selected subset of variables common to other awarded sites, as well as site-specific protocol with exposures and outcomes particularly relevant to the awardee's target population.

Component B of this FOA will support a Coordinating Center to manage the collaborative work among Component A awardees. The awardee for Component B will not also receive an award for Component A.

Healthy People 2020 and other National Strategic Priorities

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

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

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

- Nutrition, Physical Activity, and Obesity

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

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

Public Health Impact

Starting with the identification of geographic disparities in cardiometabolic health this research initiative will use related contextual information to identify modifiable pathways by which county-level characteristics contribute to disparities in disease burden. Data collected from counties at high- and low-cardiometabolic risk will test hypothesized relationships between area characteristics and disease outcomes. To the extent that the contexts are modifiable, the findings will help to design and justify public health programs that are equitable (serving the general population as well as those deemed at high-risk) and also designed to require relatively little use of personal resources or individual agency (4). Success in these research projects will point the way to future epidemiologic research in which the study of geographic disparities in disease risk could enhance the public-health approaches to other major disease groups.

Relevant Work

In 2015 the National Committee on Vital and Health Statistics convened a workshop dedicated to the development of community indicators that would increase opportunities to improve health at the local level. The Workshop Summary (5) presented a preliminary list of contextual domains that included modifiable factors through which community partnerships might measure and improve local health. Others have proposed a "Health in All Policies" framework recognizing that many determinants of health come from outside of the traditional health sector (6). Partnership with non-health sectors is needed to address a variety of structural, intermediary, and cross-cutting contextual domains associated with health inequities.

2. Approach

This FOA is comprised of two components. Component A supports applications aimed at examination of the modifiable characteristics at the community, environmental, and individual level that explain large disparities in type 2 diabetes and related chronic conditions across counties in the United States. Following the award, grantees will collaborate to establish a common protocol and data management plan for the collection of a core set of exposure and outcome varaibles to permit multi-center analyses.

Component B of this FOA solicits applications for a study Coordinating Center (CC) to provide logistics, data management and analysis support to the multi-center research study funded under component A.

Component A of this FOA focuses its research interest in three ways:

a. Concentration on type 2 diabetes and cardiometabolic conditions that frequently occur together after childhood. These include (but are not limited to) gestational diabetes, coronary heart disease, hypertension, stroke, obesity, and ectopic fat accumulation (e.g., fatty liver). Proposals should investigate community-level disparities defined by relatively high or low prevalence (or incidence) of type 2 diabetes along with at least one related cardiometabolic condition.

b. In order to define pertinent geographic disparities, the proposed research should focus on counties (or comparable jurisdictions designated as "Parish" or "City") in the United States characterized as having a high or low prevalence or incidence of type 2 diabetes and cardiometabolic conditions. Counties chosen for study might be unique examples or combinations of counties (not necessarily contiguous). The choice of these disparate counties should be driven by an intention to test one or more pre-specified hypotheses that could identify or confirm mechanisms/pathways by which environmental or socioeconomic circumstances (contexts) in those counties have influenced cardiometabolic health. The hypothesized mechanisms might act through pathways that tend to increase or decrease risk of disease. The choice of counties should also consider the availability of data and the feasibility of obtaining the required information.

c. In the selected counties, hypotheses about one or more pertinent contextual factors may be considered from a wide variety of domains (see examples below). In many instances, assessments of such factors at the county level are openly available on the internet. Proposals will need to consider carefully the relevance, timeliness, and quality of such published assessments. Existing county-level sources often cannot reflect the depth or detail needed for understanding pathways and mechanisms. Thus, an applicant should propose to complement available county-level data with the collection of new primary data through focused surveys of individuals, families, institutions, or physical sources (e.g., air, water).

The list of domains (below) is offered only by way of providing examples. Individual awardees will possibly choose to pursue only one or up to four such domains. The domains listed here are not intended to be prescriptive or exclusive.

Example domains:	**Examples of features to explore:**
• Ambient pollution	water sources, atmospheric particulate matter
• Anthropometry	body fat distribution, leg/trunk ratio
• Built environment	physical activity resources, greenspaces
• Education	school dropouts, enrollment stability
• Employment	wages, work conditions, job stability, unionization, vacations
• Food	patterns of consumption, availability, barriers to access
• Housing	occupant density, noise level, segregation practices
• Metabolomes	insulin resistance, hepatic steatosis, dietary deficiencies

- Microbiomes species richness
- Sleep experience histories by age, prospective diaries, nocturnal blood pressure
- Stress or depression interview instruments, cortisol assays, social supports
- Tobacco exposures smoking initiation, taxation & prices, public policies
- Toxic exposures occupational & residential histories, hair or nail clippings
- Transportation travel to work, to school

Within these research boundaries (a-c; above), the four awards under Component A will likely cover a range of etiologic concepts, study hypotheses and distinct panels of counties selected for study. Through the engagement of multi-disciplined researchers working in different parts of the USA, this FOA presents an opportunity to strengthen the overall research initiative through collaboration among the awardees and eventual integration of their epidemiologic databases.

Component B of this FOA, with such cooperation in mind, will establish a data management, analysis, and study Coordinating Center (CC) to collaborate with award recipients from Component A. The sole awardee for Component B shall work with the Component A awardees to identify core, shared elements of population selection and recruitment and a subset of exposure and outcome variables that lend themselves to multi-center analyses. The CC will also facilitate the formation of a Steering Committee consisting of the Principal Investigators from each study site. The awardee for Component B will not also receive an award for Component A.

Objectives/Outcomes

The four Principal Investigators from Component A and the Principal Investigator from Component B (Coordinating Center) will have shared responsibilities to develop and sustain collaborative efforts for this research program. The Cooperative Agreement Terms and Conditions of Award (Section IV., 4) outline these obligations in substantial detail.

Component A:

The specific objectives under **Component A** are to:

- Identify potentially modifiable pathways by which environmental or socioeconomic circumstances (contexts) may contribute to county-level disparities in type 2 diabetes and related cardiometabolic diseases.
- Evaluate such pathways by developing testable research hypotheses.
- Collaborate with related, parallel projects so as to enhance the power and generalizability of research findings.
- Mitigate eventually those harmful pathways and adverse consequences related to one or more contextual factors.
- Strengthen eventually those salutary pathways and favorable consequences related to one or more contextual factors.

Component B:

The specific objectives under **Component B** are to:

- Create and maintain a central data repository and create protocols and mechanisms to secure transmission of data and relevant data management reports between the CC and the study sites under Component A.
- Develop and implement the plan for selecting core variables during Year 1 that will facilitate data sharing among the Component A awardees.
- Determine the need for shared laboratory facilities that could collect, analyze and archive laboratory specimens and related biomarker or environmental materials.
- Ensure the training and certification of staff at the study sites on measurement and study procedures as outlined in the protocol and manual of operations.
- Provide statistical and other analytic support to the multi-center study.
- Establish and maintain a study website and organize the steering committee meetings, external advisory board meetings, and workshop meetings.
- At the end of the funding cycle the CC will also be responsible for the preparation and release of data sets to appropriate repositories for public use.
- Act, directly or through a subcontractor, as a central laboratory for the analyses of specimens from the study sites and ensure rapid transmission of the results.

Target Population

Component A:

By way of defining a community, Component A of this FOA focuses on counties (or comparable jurisdictions designated as “Parish” or “City”). There are 3,143 counties in the United States (7) from which may be chosen unique examples or combinations of counties (not necessarily contiguous) characterized as having high- or low-risk of type 2 diabetes and at least one related cardiometabolic condition.

The identification of eligible counties based on their high or low risk of diabetes may be guided by critical reading of recent articles in the peer-reviewed literature or review of authoritative datasets. Recent compilations of county-level mortality statistics attributed to all causes, the underlying cause, or multiple-cause listings (8) may help to confirm the validity of the county selections. An epidemiologic comparison of the selected counties may require consideration of variations between counties according to characteristics other than those defined by health outcomes. County-level sociodemographic descriptors (e.g., age structure, educational attainment, income levels, distribution of ancestral groups) are often available and may be used as covariates. Systems describing, comparing, or grouping US counties have been developed by the Department of Agriculture (7), the Centers for Disease Control and Prevention (9), the Census Bureau (10), and other organizations. In the application and research plan, the applicant should clearly describe the counties or jurisdictions and the size of the sub-populations included in the proposed research/study, with special emphasis on underserved and at-risk populations.

Component B: Not applicable

Collaboration/Partnerships

Component A:

Investigators under Component A are encouraged to form or expand collaborations/partnerships with researchers or agencies (e.g., local governments, voluntary organizations, community-based institutions) that have established interests in reducing the chronic-disease burden. Such relationships could be useful for planning and/or execution of their focused research plans. It may be appropriate alternatively to engage private agencies equipped to collect items (e.g., questionnaire responses; biological or environmental specimens) from designated locations and individuals in sites distributed across multiple US counties.

Component B:

As described throughout this FOA, Component B will establish a Coordinating Center to promote collaboration among the awardees to Component A. This collaboration will form a common protocol for a selected subset of exposure and outcome variables to permit multi-center analyses. Applicants are expected to identify key partners and form or expand collaborations/partnerships that will facilitate accomplishment of study objectives.

Component A and B:

After awards are made under this FOA, scientific or program staff at CDC’s National Center for Chronic Disease Prevention and Health Promotion will be available as requested to assist in any aspects of the project.

Evaluation/Performance Measurement

Component A:

Internal evaluation during the first project year should be measured by the refinements made to its study design, commitments made to professional staffing and potential collaborators, and updated reviews of existing data that describe contextual factors in each of the selected counties.

In subsequent funded years, success should be measured by execution of the study protocol, procurement and/or collection of necessary data, appropriate validation of data elements, timeliness of epidemiologic analyses, and participation in the collaborative, multi-center analyses.

Component B:

Evaluation/performance should address measurements of quality of promoting and facilitating a multi-center and collaborative environment among the award recipients, providing statistical and analytical support to the multi-center study, the coordination of study 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; to maintain study-wide timeline management; and to facilitate the exchange of abstracts, manuscripts, presentations, fact sheets, and other scientific materials among the collaborating centers and the funding agency.

Translation Plan

Component A and B:

Awardees will be expected to present findings at professional meetings and at formal briefings for health and policy makers. They should submit results to peer-reviewed journals, and also disseminate aspects of their work through diverse media such as a study website and policy briefs.

OMB/PRA may not apply.

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References:

1. Commission on the Social Determinants of Health. Closing the gap in a generation: Health equity through action on the social determinants of health Geneva: World Health Organization; 2008 [Available from: http://www.who.int/social_determinants/thecommission/finalreport/en/.]
2. Frieden TR. A framework for public health action: the health impact pyramid. Am J Public Health. 2010;100(4):590-5.
3. Braveman P, Egerter S, Williams DR. The social determinants of health: coming of age. Annu Rev Public Health. 2011;32:381-98.
4. Adams J, Mytton O, White M, Monsivais P. Why are some population interventions for diet and obesity more equitable and effective than others? The role of individual agency. PLoS Med [Internet]. 2016; accessed 04 October 2016; 13(4):[e1001990]. Available from: http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001990.
5. National Committee on Vital and Health Statistics (NCVHS), Walter G. Suarez, Raj Chanderraj, Bruce B. Cohen, Llewellyn J. Cornelius, Nicholas L. Coussoule, et al. Advancing Community-Level Core Measurement: A Progress Report and Workshop Summary Hyattsville, MD: National Center for Health Statistics, CDC; 2016 [(33 pp)]. Available from: http://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/CoreMeasuresWorkshop.pdf.
6. Hall M, Graffunder C, Metzler M. Policy Approaches to Advancing Health Equity. J Public Health Manag Pract. 2016;22 Suppl 1:S50-S9.
7. USDA Economic Research Service. County Typology Codes Washington: USDA; 2015 [updated December 07, 2015. Available from: http://www.ers.usda.gov/data-products/county-typology-codes.aspx.
8. Centers for Disease Control & Prevention. WONDER Online Databses Atlanta: US Department of Health and Human Services; 2016 [updated July 12, 2016. Available from: http://wonder.cdc.gov/.
9. Centers for Disease Control and Prevention. How to Use CHSI 2015 Atlanta: US Department of Health and Human Services; 2015 [Available from: http://wwwn.cdc.gov/CommunityHealth/info/HowtoUseReport.
10. U.S. Census Bureau. American Community Survey - Data Tables & Tools Washington: U.S. Department of Commerce; 2016 [updated 19 September 2016. Available from: http://www.census.gov/acs/www/data/data-tables-and-tools/index.php.

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: $20,000,000

Funds Available and Anticipated Number of Awards. The estimated total level of funding (direct and indirect for entire project period in dollars) that is available for the FOA for the entire project period,9/30/2017 - 09/29/2022, is $20,000,000.

It is estimated that 5 awards will be made under this FOA, four under component A (total funding $16,000,000) and one under component B (total funding $4,000,000). Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.

Budget and Project Period. The estimated total funding (direct and indirect costs) for the first budget period is $4,000,000 ($3,200,000 for Component A; $800,000 for Component B), The estimated total funding (direct and indirect) for the entire project period,9/30/2017 - 09/29/2022, is $20,000,000. Under both component A (first budget period funding $3,200,000) and B (first budget period $800,000), the estimated average award for year 1 will be $800,000.

Anticipated Number of Awards: 5

Award Ceiling: For both Components A and B no award for the first 12-month project period will exceed $800,000.

Award Floor: For both Components A and B no award for the first 12-month project period will be made for less than $400,000.

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

Award Ceiling: $800,000 Per Budget Period

Award Floor: $400,000 Per Budget 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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

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

Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

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 include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

Component A:

(1) The applicant must clearly identify that the geographic regions chosen for analysis are US counties (or comparable US jurisdictions).

(2) For each county chosen, an applicant should provide a current estimate of the resident population, including distributions by sex, age groups and major ancestral groups.

(3) The applicant must describe the burden of type 2 diabetes in each county chosen as being either high or low risk as documented within the most recent five years.

(4) The applicant must describe the burden of a cardiometabolic condition related to type 2 diabetes in each county chosen as being either high or low risk as documented within the most recent ten years.

(5) If collaborating partners are proposed, applicants must provide letters of support from these proposed partners specifying the commitment of the parties involved including the terms of access to data and populations and any specified limits to collaboration.

(6) An application that exceeds the ceiling value of the specified award range will be considered non-responsive and will not receive further review.

Component B:

(1) An applicant must include a research team with one or more statisticians or epidemiologists with established interests in multilevel analysis, that is, the creation and interpretation of statistical models including parameters that vary at more than one level. Prior published experience with such statistical methods (e.g., nested or hierarchical modeling) should be described in regard to the study of variations by geographical place.

(2) An applicant must include a research team that includes staff with training and/or expertise relevant to developing an active website for the coordination of research protocols and parallel data collection by scientific staff located in varied research environments.

(3) An application that exceeds the ceiling value of the specified award range will be considered non-responsive and will not receive further review.

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

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Evidence of **3. Special Eligibility Criteria** listed above must be presented in Appendix A. If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.

Component A:

(1) Is each of the counties (or comparable US jurisdictions) proposed for study identified consistently by its name and state?

(2) For each county chosen, are current population estimates provided in tabular or graphic form, including distributions at least by sex, age, and major ancestral groups?

(3) For each county chosen is evidence provided (in a table or list) establishing a high or low burden within the past five years of type 2 diabetes, as might be illustrated by diabetes prevalence, incidence, cause-specific mortality, or claims for medical care?

(4) For each county chosen, is evidence provided (in a table or list) establishing a high or low burden within the past ten years of a related cardiometabolic condition, as might be illustrated by prevalence, incidence, or other data collected through systematic sampling of the community?

(5) Does the applicant identify external or institutional partners associated with the research proposal? If yes, is there a recent letter of support from that proposed partner which details the terms of access to data and populations and any specified limits to collaboration?

(6) Is the amount requested by the applicant for year one or for the total award period not greater than the ceiling amount specified for that period?

Component B:

(1) Consistent with information in the Research & Related Senior/Key Person Section of the SF424 (R&R), does the application support one or more statisticians or epidemiologists with established interests in multilevel analysis? For at least one of these researchers is there a referenced publication that addresses statistical methods (e.g., nested or hierarchical modeling), including the study of variations by geographical place?

(2) Consistent with information in the Research & Related Senior/Key Person Section of the SF424 (R&R), does the application support at least one staff member with training and/or expertise relevant to developing an active website for the coordination of research protocols and parallel data collection by scientific staff located in varied research environments?

(3) Is the amount requested by the applicant for year one or for the total award period not greater than the ceiling amount specified for that period?

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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

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

Only one application per institution (normally identified by having a unique DUNS number) per component is allowed. If an applicant organization intends to apply to more than one component in this FOA, applicant must submit separate applications for each component applying to.

Applications should clearly indicate the Component for which the applicant is applying and should include at the beginning of the title, the respective component under which the application should be considered (i.e., **Component A** or **Component B.)**

As defined in the HHS Grants Policy Statement,

(http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html), 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 Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf, except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

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

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

3. Letter of Intent

Due Date for Letter of Intent: **01/13/2017**

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 1/13/17 prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the Applicant

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this funding opportunity

The letter of intent should be sent to:

Michael A. Brown

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5118

Email: mab5@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).
Follow the page limits stated in the SF 424 (R&R) unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

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

Human Subjects Section

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

Other Research Plan Sections

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

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies).
Follow the page limits in the SF 424 (R&R) Application Guide unless otherwise specified in the FOA. All instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf must be followed along with any additional instructions provided in the FOA.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Research Plan

The applicants research plan should address activities that will be conducted over the entire project period. The Research Plan narrative is comprised of components 2 and 3 above. NOTE: that the research Strategy is divided into three parts: 1)Significance, 2) Innovation, and 3) Approach.

Consistent with the Background, Purpose, and Approach outlined earlier in Section I of Part 2, the applicants' research plan must address activities that will be conducted during the 5- year project period and must include the following items:

Component A:

Study design:

- Identification and justification of the choice of the proposed selected counties to be included in the study.
- Rationale for the selection of the contextual factors to be evaluated.
- Research hypotheses aimed at identifying or confirm mechanisms/pathways by which environmental or socioeconomic circumstances (contexts) in the selected counties have influenced cardiometabolic health
- The availability of data and the feasibility of obtaining the required information for comparing counties at low or high risk for diabetes.
- Analysis plan, including methods, sample sizes and power calculations.
- Potential generalizability of findings.
- The process of developing common protocols and core data elements in collaboration with other Component A awardees: Include examples of prior experience with multi-center studies.
- Human subjects protection considerations that may exist.
- Potential value from the proposed research/study for policy, systems changes, community changes, and individual/population behavioral changes related to diabetes risk and complications, with a focus on high-risk, underserved populations.

Sources of data, and the applicant's access to these:

- Description of existing datasets and data systems that permit comparison of low and high diabetes risk counties
- Evidence of continuous data access and, if needed, use in the form of letters of commitment or memorandum of understanding.
- Summaries of existing data collected in recent years on county populations by race/ethnicity, sex, and age, the incidence and prevalence of diabetes and of related cardiometabolic diseases; risk factors associated with diabetes and its complications;

Staffing and Milestones for Development and Implementation Process

- The Research Team: The applicant should provide evidence of the experience of the principal investigator and co-investigators in undertaking complex public health-related or community-based studies that (a) make use of data from diverse data sources; (b) are multi-disciplinary (could include, but not limited to socioeconomic, food/agricultural and built environment research, epidemiology, public policy, economics, individual and organizational behavioral science, statistics); (c) involve multi-center collaboration throughout the study process; (d) result in peer-reviewed journal publications; and (e) provide decision-support for public and private policy makers.
- The Principal Investigator: The applicant should describe and provide evidence of the principal investigator's (a) expertise; (b) established leadership in designing and conducting complex studies that make use of multiple sources of data, (c) strong track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences, and policy forums; (d) his/her commitment to collaborate and contribute to a multi-center study, including participating in up to two face-to-face meetings as well as periodic televideo conferences each year; and (e) the percentage of time allocated by the PI to this research program.
- Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (a) describe the person's expertise; (b) provide evidence of their contributions to relevant complex studies, including their publications in peer-reviewed journals and presentations made at professional and scientific conferences; and (c) specify the percentage of time that will be committed to this research program.
- Identify tasks and provide a timeline for key milestones and protocol development activities to occur in the first 12-months of the project. Include milestones that will be used to demonstrate progress toward having, if required, an Institutional Review Board (IRB) - approved protocol and an OMB approved protocol.
- Describe the staffing plan for the 5-year project period. Include project organizational charts with key personnel.
- How and by whom will the quality oversight and supervision be provided for the research team.
- If a position is yet to be filled, provide a position description in the appendix.
- Include the percentage of time each will devote to the project.

Detailed Budget and Line-item Justification.

A detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods. Travel costs for up to three people, including the PI, for three annual meetings with CDC and the Steering Committee and subcommittees should be included in the budget of the first Budget Period and costs for two in-person meetings in annual continuation plans and budgets.

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

Component B (Coordinating Center), the applicant should include:

- Description of past experience in directing and operating a coordinating center for collaborative, population-based, large-scale epidemiological research projects that included coordination of multi-site studies, development of training/certification programs, monitoring site performance and progress of studies, and providing governance support.
- Description of experience in providing data management, analysis, and statistical support to multi-site research studies that included development and management of a multi-site database, the design, analysis, and interpretation of data, and the development/production of data summaries and statistical reports.
- The Research Team: The applicant should provide evidence of the experience of the principal investigator and co-investigators in undertaking complex public health-related or community-based studies that (a) make use of data from diverse data sources; (b) are multi-disciplinary (including, but not limited to socioeconomic, food/agricultural and built environment research, epidemiology, public policy, economics, individual and organizational behavioral science, statistics); (c) involve multi-center collaboration throughout the study process; (d) result in peer-reviewed journal publications; and (e) provide decision-support for public and private policy makers.
- The Principal Investigator: The applicant should describe and provide evidence of the principal investigator's (a) expertise; (b) established leadership in designing and conducting complex studies that make use of multiple sources of data, (c) strong track record of publishing study findings in peer-reviewed journals and making presentations at professional and scientific conferences, and policy forums; (d) his/her commitment to collaborate and contribute to a multi-center study, including participating in up to two face-to-face meetings as well as periodic televideo conferences each year; and (e) the percentage of time allocated by the PI to this research program.
- Other Researchers: For each proposed co-investigator and other members of the research team, the applicant should (a) describe the person's expertise; (b) provide evidence of their contributions to relevant complex studies, including their publications in peer-reviewed journals and presentations made at professional and scientific conferences; and (c) specify the percentage of time that will be committed to this research program.
- Description of experience with working with centralized laboratories and tracking of specimens.
- Identify tasks and provide a timeline for key milestones and protocol development activities to occur in the first 12-months of the project. Include milestones

that will be used to demonstrate progress toward having, if required, an Institutional Review Board (IRB) - approved protocol and an OMB approved protocol.
- Description of the staffing plan for the 5-year project period. Include project organizational charts with key personnel.
- Desciption of how and by whom will the quality oversight and supervision be provided for the research team.
- If a position is yet to be filled, provide a position description in the appendix.
- Include the percentage of time each will devote to the project.

Detailed Budget and Line-item Justification.

A detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods. Travel costs for up to three people, including the PI, for three annual meetings with CDC and the Steering Committee and subcommittees should be included in the budget of the first Budget Period and costs for two in-person meetings in annual continuation plans and budgets.

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

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

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.
Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.
If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.
Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.
Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_redirect .htm? id=11123).
Information on the submission process is provided in the SF424 (R&R) Application Guide.
Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.
Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.

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

Due Date for Applications: **02/14/2017**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions,and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
For more information on expanded authority and pre-award costs, go to:
http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf .
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants,cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.
Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Awardees who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see:http://www.cdc.gov/grants/additionalrequirements/index.html for revised AR-25.

Funds will be restricted until:

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

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

12. Other Submission Requirements and Information

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**
Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.
For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders: All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

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

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.
See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ 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 Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

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

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

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

Significance

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

Component A:

- Are the contextual domains under study related to populations that bear a substantial cardiometabolic burden in the United States?
- ·Are hypothesized linkages between county-level contextual factors and cardiometabolic health consistent with established or previously reported biomedical or sociological mechanisms of action?
- Will the clarification of a proposed mechanisms/pathway likely encourage other investigators to investigate similar domains in additional populations?

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?

For Component A and B:

- Among the PI(s) and other collaborators are there at least three professionals whose prior work includes publications in peer-reviewed journals or academic text books related to epidemiology, sociology, statistics, epidemiology or environmental sciences?
- Among these three experienced professionals have all had at least two such publications during the most recent 5-year period?
- Among the PI(s) and other collaborators is there at least one staff member with a professional, post-graduate degree in statistics (or a closely related field)?
- Is there at least one other staff member with a professional, post-graduate degree related to medical practice or to biological science?
- Has the PI or at least one senior professional worked as part of a multi-center research project, including experience in the collaborative development of protocols, study design, and conduct of multi-center analyses.

Component B:

- Is the PI an experienced biostatistician, epidemiologist, physician, or other professional with experience in directing a coordinating center for a collaborative, population-based, large-scale epidemiological research project?
- Does the applicant's project team include senior statistical staff that will devote substantial time to developing data analysis methods for use in the study?
- Does the applicant demonstrate experience in developing materials and methods for the recruitment of participants in population-based studies?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Component A:

- Within the given cost constraints, are the application's hypothesized mechanisms/pathways amenable to study on a community level?
- Has the applicant planned for resources (staffing, equipment) or collaborative subcontracts sufficient to collect data required for characterization of the studied counties?

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:

- Have counties been selected that properly represent high- and low-risk levels of adult cardiometabolic health?
- Does the application consider sampling frames and population scale to estimate the statistical power available for hypothesis testing?
- Does the applicant consider how the associations between exposures (contextual factors) and outcomes (cardiometabolic status) in these selected counties may be challenged by the quality or applicability of available county-level data?
- Does the application address difficulties with inferring causal pathways (mechanisms) where exposures and outcomes may have been measured in approximately the same time period?
- ·Where measured contextual factors may confound one another, does the applicant propose ways to disentangle the relative impact of these confounding factors?
- ·Has the applicant offered one or more approaches for developing a multi-center collaborative protocol?

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 mulit-center study?
- ·Does the applicant describe experience in development and management of websites?
- ·Does the applicant describe experience in developing a common protocol for a core set of common variables and hypotheses?

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:

- Have counties been selected that properly represent high- and low-risk levels of adult cardiometabolic health?
- Does the application consider sampling frames and population scale to estimate the statistical power available for hypothesis testing?
- Does the applicant consider how the associations between exposures (contextual factors) and outcomes (cardiometabolic status) in these selected counties may be challenged by the quality or applicability of available county-level data?
- Does the application address difficulties with inferring causal pathways (mechanisms) where exposures and outcomes may have been measured in approximately the same time period?
- ·Where measured contextual factors may confound one another, does the applicant propose ways to disentangle the relative impact of these confounding factors?
- ·Has the applicant offered one or more approaches for developing a multi-center collaborative protocol?

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 mulit-center study?
- ·Does the applicant describe experience in development and management of websites?
- ·Does the applicant describe experience in developing a common protocol for a core set of common variables and hypotheses?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 , the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/grants/additionalrequirements/index.html).

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

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http:// www.cdc.gov /maso Policy /Policy_women.pdf and http:// www.gpo.gov /fdsys /pkg /FR-1995-09-15 /pdf/95-22950.pdf #page=1) and the policy on the Inclusion of Persons Under 21 in Research (http:// www.cdc.gov /maso /Policy /policy496.pdf).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern

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

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

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plan(s)

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

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

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

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

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

• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.
Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

4. Review and Selection Process

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

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.
In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.
CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this funding opportunity announcement.
In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:
(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.
CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

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

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

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

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2010

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Distinguishing Public Health Research and Public Health Nonresearch

AR-32: FY 2015 Enacted General Provisions

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

AR-25: Data Management and Access

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

Data Management Plan

Consistent with the terms of and activities expected under the funding opportunity announcement (FOA), awardees must develop and submit a DMP generally during the project planning phase, but in any event, prior to the initiation of generating or collecting public health data. Accordingly, the DMP may be evaluated during the application, study proposal, or project review process or during other times in the project period. For FOAs that involve already defined projects which include data collection or generation at the time of application, applications submitted without the required DMP may be deemed non-responsive for award. For FOAs where CDC specifies that submission of the DMP is deferred to a later period, funding restrictions may be imposed pending submission and evaluation of the DMP. For awards where data collection or generation activities may become necessary during the project period, DMPs will be required to be submitted and evaluated during the project period of the award. These DMPs also will be required to comply with this AR. In all instances described above, the reviewing officials have to approve an acceptable DMP. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements.

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

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

Access to and Archiving of the Data

Awardees whose terms of award do not include submitting data to CDC are expected to plan and prepare for access to and archiving/long-term preservation of collected and/or generated data within the funding period, as set forth below. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data which should be made accessible within a year of the end of a collection cycle. In addition, awardees should ensure the quality of data they make accessible and seek to provide the data in a nonproprietary format. Awardees who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award.

For public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be provided on request under a data-use agreement.

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

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

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

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

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

Either refer to the current Releasing and Sharing Data Policy AR-25 here (http://www.cdc.gov/grants/additionalrequirements/index.html#ar25) and/or replace it on the PGO website with the Data Access and Management policy and add the link above as an AR.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

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

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

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

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

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

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

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

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

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

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

Data Management Plan(s)

CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

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

4. Cooperative Agreement Terms and Conditions

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 Part 75, and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers 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 PD(s)/PI(s) of **Component A** awardees will have the primary responsibility for:

1. Designing and conducting research to address the described research objectives of this cooperative agreement.
2. Establishing goals and objectives that are realistic, measurable, and time-oriented for the project.
3. Obtaining the appropriate Institutional Review Board approvals for research involving human subjects.
4. Participating in steering committee and subcommittee, CDC-sponsored meetings as scheduled by the steering committee and CDC.
5. Collaborating with other study investigators and following common protocol(s) and manuals of operations developed by the Steering Committee.
6. Conducting studies, including multi-center studies agreed upon in Year 1 for implementation beginning in Year 2, and disseminating findings in peer-reviewed journals, technical reports, research and policy briefs, presentations at professional and scientific conferences and policy forums, as appropriate, and contributing scientific findings to appropriate Web sites or other channels for sharing findings.
7. Assuring and maintaining the confidentiality of all study data.
8. Make use of local analytic support, center-specific and shared datasets.
9. The Principal Investigator will attend in-person and televideo conference call study meetings, as scheduled by the steering committee in consultation with CDC.
10. Other members of the research team will participate in appropriate subcommittee and CDC-sponsored meetings.
11. Ensure adequate staffing, oversight, and mentoring in support of the research team and its activities.

The Recipient Organization under **Component A** will retain custody of and have primary rights to the information, data and software developed of this award, subject to U.S. Government rights of access and consistent with current DHHS, PHS, and CDC policies.

The PD(s)/PI(s) of the**Component B** awardee (Coordinating Center [CC]) will have the primary responsibility for:

1. Promoting and facilitating a multi-center and collaborative environment among the award recipients.
2. Facilitating the formation of a Steering Committee (SC) consisting of the Principal Investigators from each study site. The SC will have a minimum of three meetings in year 1 and two meetings in each of the following years and regular teleconferences throughout the year. The SC may create sub-committees as appropriate to accomplish its goals.
3. Coordinating the statistical analyses and data management aspects of the study. The CC will have both scientific and administrative functions.
4. Reviewing the study protocol and assisting in the development of the statistical design for the multi-center study, analyzing study results, and reviewing all manuscripts for statistical considerations. Based on input from the Steering Committee, the CC will prepare and update the protocols and manuals of operation, if required provide materials to aid in participant recruitment and retention, and ensure the training and certification of staff at the study sites as outlined in the study protocol.
5. Establishing a database to accommodate data generated by each study site, developing a data transmission system, and assessing data quality and completeness throughout the study.
6. Establishing, directly or through subcontracts, a central laboratory, as determined by the Steering Committee.
7. Providing statistical reports on the progress of the study at Steering Committee meetings and facilitating communication among investigators, including scheduling meetings and conference calls, developing agendas and documenting minutes, and maintaining membership rosters and committee lists.

The CC will not retain custody of or have primary rights to the data and software developed under this award. Primary rights to collected data will remain with the awardees under Component A.

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

- An HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.
- At the request of the awardee, CDC will provide consultation to the project and will serve as consultants on the study steering committee and subcommittees.
- Additionally, an HHS/CDC agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award. The Scientific Program Official (SPO) will:
    - Be named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
    - Monitor performance against approved project objectives; and
    - Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include:

- 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 and a NCCDPHP Project scientist as a consultant, to answer questions and provide scientific guidance. A chairperson will be selected from the non-Federal Steering Committee members. A Chairperson must have proven evidence of leadership ability and be able to make an adequate time commitment to the cooperative agreement.

- The Steering Committee will meet initially to develop the protocol and throughout the year to discuss the progress of the study. It will have primary responsibility for developing common research designs, protocols and manuals of operations, facilitating the conduct and monitoring of studies, and reporting study results. The Steering Committee must approve the protocol, changes to protocols, and manuals of operation. The Principal Investigator of each study site will be responsible for the execution of the protocol and will provide progress reports to the Steering Committee. The Steering Committee will also develop policies relating to access to 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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports
The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (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 shoul 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.
- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.
- Additional Reporting Requirements:

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

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:https://era.nih.gov/registration_accounts.cfm
FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission. Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp 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 athttp:// era.nih.gov/ commons /index.cfm.
3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)

Michael A. Brown

Scientific Program Official (SPO)

Extramural Research Program Operations and Services (ERPOS)

Centers for Disease Control and Prevention

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Scientific Review Official

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Email: kva@cdc.gov

Financial/Grants Management Contact(s)

LaKasa C. Wyatt

Grants Management Specialist

(CDC/OCOO/OFR/OGS)

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Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

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

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

FY17 DP17-001

Amendment 1 2/7/2017

Questions from Potential Applicants and CDC Responses are noted in red.

A text modification has been made in Executive summary to change form C to form D. https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf

Question 1: "We just wanted to confirm whether a proposal using secondary data sources would be acceptable? (For example, a study that merged individual level

outcomes with a second dataset on community characteristics)?

Answer: As outlined in the FOA, "Component A supports applications aimed at examination of the modifiable characteristics at the community, environmental, and individual level that explain large disparities in type 2 diabetes and related chronic conditions across counties in the United States. Following the award, grantees will collaborate to establish a common protocol and data management plan for the collection of a core set of exposure and outcome variables to permit multi-center analyses." The FOA does not preclude submission of a proposal using secondary data sources. However, the FOA does indicate in **Section I. Funding Opportunity Description; 2. Approach; Component A of this FOA focuses its research interest in three ways; item C:** "In the selected counties, hypotheses about one or more pertinent contextual factors may be considered from a wide variety of domains (see examples below). In many instances, assessments of such factors at the county level are openly available on the internet. Proposals will need to consider carefully the relevance, timeliness, and quality of such published assessments. Existing county-level sources often cannot reflect the depth or detail needed for understanding pathways and mechanisms. Thus, an applicant should propose to complement available county-level data with the collection of new primary data through focused surveys of individuals, families, institutions, or physical sources (e.g., air, water)."

Question 2: Title of this RFA is - Community Characteristics Associated with Geographic Disparities in Diabetes and Cardiometabolic Health. In a traditional sense I do not see the "Geographic Disparities" component in this RFA. What's CDC's expectation regarding "Geographic Disparities" in this study?

Answer: Geographic disparities are described at several points in Section I. Funding Opportunity Description and are central to the FOA purpose which is the "examination of county-level disparities in type 2 diabetes and cardiometabolic conditions to enhance understanding of disease determinants. Applicants will test hypotheses aimed at clarifying the contribution of environmental or socioeconomic circumstances to diabetes geographic disparities". These disparities refer to disease experience defined at the level of counties (as geographic units). Some examples include

(1) In the FOA **Background and Purpose** it indicates " applicants for Component A should develop an epidemiologic research design that will seek to understand substantial geographic disparities between counties selected for study because they are at high- or low-risk of diabetes."

(2) In the FOA **Public Health Impact** it indicates "Starting with the identification of geographic disparities in cardiometabolic health this research initiative will use related contextual information to identify modifiable pathways by which county-level characteristics contribute to disparities in disease burden. Data collected from counties at high- and low- cardiometabolic risk will test hypothesized relationships between area characteristics and disease outcomes."

(3) In the FOA **Approach** it indicates "b. In order to define pertinent geographic disparities, the proposed research should focus on counties (or comparable jurisdictions designated as "Parish" or "City") in the United States characterized as having a high or low prevalence or incidence of type 2 diabetes and cardiometabolic conditions. Counties chosen for study might be unique examples or combinations of counties (not necessarily contiguous). The choice of these disparate counties should be driven by an intention to test one or more pre-specified hypotheses that could identify or confirm mechanisms/pathways by which environmental or socioeconomic circumstances (contexts) in those counties have influenced cardiometabolic health."

(4) In the FOA **Objectives/Outcomes; Component A** it indicates "The specific objectives under Component A are to "Identify potentially modifiable pathways by which environmental or socioeconomic circumstances (contexts) may contribute to county-level disparities in type 2 diabetes and related cardiometabolic diseases."

Question 3: About how to incorporate the Central Laboratory into the application. I'm not sure if this is a question you can answer or not, but is it only necessary to include information about the lab, or should the budget include money for the lab? The reason I ask is that it is difficult to estimate the funding necessary for a lab without knowing the biomarkers or other exposures that may be estimated in the lab, as well as how many.

Answer: FOA does not specify, therefore applicants should include an estimate as they see appropriate. After funding, then more specific plans for lab activities and costs will be determined and funding adjusted as needed, or budget revised.

Questions related to the application package should be addressed by the "Application Submission Contacts" in Section VII Agency Contacts."In the FOA under **Approach** it indicates "Component B of this FOA solicits applications for a study Coordinating Center (CC) to provide logistics, data management and analysis support to the multi-center research study funded under component A."

In the FOA under **Collaborative Partnerships** it indicates "Component B will establish a Coordinating Center to promote collaboration among the awardees to Component A. This

collaboration will form a common protocol for a selected subset of exposure and outcome variables to permit multi-center analyses."

In the FOA under **Research Plan; Detailed budget and Line-item Justification** it indicates "A detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods."

Question 4: In addition to selecting low- and high-diabetes counties, it is acceptable to include average-diabetes counties?

Answer: Within the FOA, under Section **III. Eligibility Information; 5. Responsiveness**, elements 3 and 4 require evidence that counties chosen for study be characterized by "a high or low burden" of type 2 diabetes (and of a related cardiometabolic condition). Thus, there is no expectation in the FOA to include counties of "average-diabetes".

Question 5: We would like to use survey and/or administrative health data that are proprietary and so cannot be released. Are there particular criteria we should include in our justification (e.g. a data use agreement)? Should we describe all elements or only those relating to health data?

Answer: The FOA requires that applicants who plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed.

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

- Descriptions of the data to be produced in the proposed project
- How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
- Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
- Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified

The FOA also describes that each Component A awardee will have responsibility to provide data to the Coordinating Center and the other awardees.

Out of concern for scientific replicability and validity, the burden falls generally on the applicant to explain in great detail why the application's data source would not be open to review by the project's Coordinating Center, by the other Component A awardees, and by the larger scientific community.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues). The justification can include information such as a data use agreement.

Question 6: The question has come up regarding data sharing as this is a requirement listed in the RFA. ? data however can not be made publicly available - does that preclude the group from applying or can they justify in their data management plan which components of the data could become public and which components need to remain private?

Answer: The FOA requires that applicants who plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed.

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

- Descriptions of the data to be produced in the proposed project
- How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
- Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
- Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified

The FOA also describes that each Component A awardee will have responsibility to provide data to the Coordinating Center and the other awardees.

The burden falls on the applicant to explain in great detail why the application's data source would not be open to review by the scientific community.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues). The justification can include information such as a data use agreement.

Question 7: In meetings with co-investigators and state partners, there is considerable interest in also investigating contextual factors related to access to health care. This domain was noticeably absent from the examples provided in the RFA. We also intend to investigate social and built environmental domains; however, we would appreciate guidance on whether including health system context would be considered to be responsive to, and within the scope of, the current announcement.

Answer: Health care access was not listed in the FOA among the examples of contextual domains that might be addressed in applications for Component A. This absence does not rule out inclusion of health care access as one of the domains to be considered; the FOA list of examples was not intended to preclude other examples.

Question 8: How should we provide the estimates for Years 2-5 in the application? Please confirm we only budget narrative/justification for Year 1.

Answer: The FOA states in the **Research Plan Detailed Budget and Line-item Justification.** A detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants should also provide budget estimates for each of the other Budget Periods; and in **3. Additional Review Considerations Budget and Period of Support** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

Question 9: 1. Please confirm that the award ceiling for Component A (alone) is $800,000 total costs in Year 1. Are there any award ceilings for Years 2-5?

Answer: In **Section II. Award Information**, the FOA indicates "Award Ceiling: For both Components A and B no award for the first 12-month project period will exceed $800,000."

Question 10: Please confirm that the supporting materials are part of the appendix.

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

Answer: In the **Research Plan** for both Components A and B the FOA indicates "Supporting materials may be attached and shall show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal."

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."

Question 11: I downloaded the Adobe package from grants.gov and wanted to make sure there were no additional components to be added to this. The information below implies that

a. 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.

Answer: Questions related to the application package should be addressed by the **"Application Submission Contacts" in Section VII Agency Contacts."**

Question 12: Can we include a listing of "selected counties" (~300 in all!) and their population characteristics in the Appendix? The RFA indicates that we must name selected counties and their demographics. We are not sure if that is supposed to be placed into the actual grant or if we can put in the appendix

Answer: The county list can be in application or an appendix.