

Centers for Disease Control and Prevention

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

Assessing the Burden of Diabetes By Type in Children, Adolescents and Young Adults (DiCAYA)

RFA-DP-20-001

Application Due Date: 01/14/2020

Assessing the Burden of Diabetes By Type in Children, Adolescents and Young Adults (DiCAYA)

RFA-DP-20-001

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Assessing the Burden of Diabetes By Type in Children, Adolescents and Young Adults (DiCAYA)

Activity Code

U18

Amendment 2. made December 20, 2019

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

Amendment 1. made December 4, 2019

1. **Part 2., Section IV, 5. PHS 398 Research Plan Component, Other Research Plan Section, The Link Has been updated.**

1. **Part 2., Section IV, 5. PHS 398 Research Plan Component, Other Research Plan Section, The Heading "Research Plan" has been added.**

Participating Organizations:

Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Division of Diabetes Translation (DDT)

National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-20-001

Assistance Listings (CFDA) Number(s)

93.945

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this NOFO is to assess the incidence and prevalence of diabetes among children, adolescents and young adults in the United States and provide estimates by diabetes type, age,

sex, race/ethnicity and geographic area. Component A focuses on surveillance of incidence and prevalence of diabetes among children and adolescents (<18 years). Component B focuses on surveillance of incidence and prevalence of diabetes among young adults (18 to <45 years). Component C serves as a Coordinating Center to provide an infrastructure for standardized approaches, analytical methods, and surveillance measures. It also serves as a repository for the Component A and B data and provides consolidated estimates by diabetes type, age, race/ethnicity and geographic area.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-20-001, 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: 12/09/2019	**12/09/2019**
Application Due Date: 01/09/2020	**01/14/2020**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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

Scientific Merit Review:	**03/10/2020**
Secondary Review:	**04/16/2020**
Estimated Start Date:	**09/30/2020**
Expiration Date:	**01/15/2020**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply**

to this program.

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

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

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

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

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

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

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

Executive Summary

Purpose.

The purpose of this Notice of Funding Opportunity Announcement (NOFO) is to conduct surveillance to assess the incidence and prevalence of diabetes among children, adolescents and young adults in the United States and provide estimates by diabetes type, age, sex, race/ethnicity and geographic area.

This NOFO has three (3) components to achieve the purpose of the program:

- Component A focuses on surveillance of incidence and prevalence of diabetes among children and adolescents (<18 years).
- Component B focuses on surveillance of incidence and prevalence of diabetes among young adults (18 to <45 years).
- Component C serves as a Coordinating Center to provide an infrastructure for standardized approaches, analytical methods, and surveillance measures. It also serves as a repository for the Component A and Component B data and provides consolidated estimates by diabetes type, age, sex, race/ethnicity and geographic area.

Mechanism of Support. Cooperative Agreement funding mechanism (CDC U-18).

Funds Available and Anticipated Number of Awards. The participating organizations, NCCDPHP and NIDDK, intend to commit approximately $3,000,000 in FY 2020 (direct and indirect) to fund up to five awards under Component A, up to five awards under Component B and one award under Component C.

- Component A**:** It is anticipated that up to five awards will be made for up to $250,000 (direct and indirect) each in FY2020.
- Component B: It is anticipated that up to five awards will be made for up to $250,000 (direct and indirect) each in FY2020.
- Component C: It is anticipated that one award will be made for up to $500,000 (direct and indirect) in FY2020.
- Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications

Budget and Project Period. The estimated total funding (direct and indirect) for all components for the first budget period, 09/30/2020 to 09/29/2021, is $3,000,000, including up to $594,000 from NIH and up to $2,406,000 from CDC. The estimated total funding (direct and indirect) for the entire project period, 09/30/2020 to 09/29/2025, is up to $15,000,000.

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. Only one application per institution (normally defined as having a unique DUNS number) per component is allowed for this NOFO. Applicants must submit separate applications if applying to more than one component. Applicants can apply for Component A, or for Component B, or for Component A and B. Applicants applying for Component C cannot apply for Component A or Component B.

Application Type. New (type 1).

Special Date(s). None.

Application Materials. See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf%20

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

NOFO is posted on https://www.grants.gov/

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

Diabetes mellitus is one of the most common chronic diseases in the United States, with over 30 million people having the disease in 2017. While the prevalence and incidence of diabetes is highest among older adults, diabetes is one of the most common chronic diseases in childhood and young adulthood. Among youth under 20 years of age, the prevalence in 2009 was 2.2 per 1,000 or 1 out of 455 youth. Among young adults 18-44 years, 3.0 million have diabetes. Diabetes requires lifelong treatment, management and care to reduce the occurrence of complications and improve quality of life. Understanding the burden of diabetes in the younger population will assist with future health care planning and public health prevention efforts.

Diabetes is a spectrum of metabolic diseases caused by defects in insulin secretion, insulin action, or both. The majority of diabetes cases cluster into two categories: type 1 diabetes, caused by an absolute deficiency of insulin, usually due to the autoimmune destruction of the beta cells of the pancreas, and type 2 diabetes, resulting from a combination of insulin resistance and beta cell failure. The hallmarks of the underlying pathophysiologic process of type 1 diabetes are the loss of endogenous insulin secretion and presence of diabetes autoantibodies (DAA). While type 1 diabetes is typically thought of as occurring in childhood and type 2 diabetes is typically thought of as occurring in adulthood, both may occur at all ages. Type 1 diabetes accounts for nearly 98% of diabetes in children < 10 years, 87% of cases in youth 10-19 years and 5% of cases among adults. Type 2 diabetes was previously thought to only occur during adulthood, but now accounts for approximately 15% of diabetes cases diagnosed in childhood and adolescence. For both type 1 and type 2 diabetes, the majority of new cases are diagnosed during adulthood.

The SEARCH for Diabetes in Youth Study (Population Based Registry of Diabetes in Youth), demonstrated that the incidence of both type 1 and type 2 diabetes in the U.S. is increasing. In children and adolescents aged <20 years, the SEARCH for Diabetes in Youth Study reported a 1.4% annual increase in the incidence of type 1 diabetes (from 19.5 cases/100,000 youth per year in 2002-2003 to 21.7 cases/100,000 youth per year in 2011-2012) and a 7.1% annual increase in type 2 diabetes (from 9.0 cases/100,000 youth per year in 2002-2003 to 12.5 cases/100,000 youth per year in 2011-2012). It is unknown whether this increase is due to a shift to a younger age of onset of both type 1 and type 2 diabetes.

Estimates from the National Health Interview Survey show the annual percent change of the incidence and prevalence of diabetes among young adults is + 3.2% and +4.3%, respectively. However, whether this is type 1 or type 2 diabetes is unknown since there are fewer estimates of the incidence of diabetes by type among young adults (18 to 45 years). Recent estimates of the prevalence of diabetes by type among young adults are based on data collected in national

health surveys using self-report of age of diabetes onset, insulin use and of diabetes type. However, these criteria can lead to misclassification as type 1 diabetes can occur at any age, there is increasing prevalence of type 2 diabetes in adolescents, and often people with type 2 diabetes also need insulin treatment to control hyperglycemia. In addition, the sample size of national surveys will limit the capacity to assess incidence by age, sex, race/ethnicity, or geographic region.

Electronic health records are increasingly used for public health surveillance efforts and this includes their use in surveillance of type 1 diabetes. A number of published algorithms validate diabetes type and the identification of diabetes cases within electronic health records in a variety of settings. The accuracy of correctly identifying diabetes by type varies for type 1 and type 2 diabetes with higher sensitivities and positive predictive values for type 1 diabetes. Electronic health records, or administrative data, do have a number of limitations including potential misclassification or missing cases and population representativeness.

Continued surveillance allows us to track trends and is needed to assess future trends. CDC, in collaboration with NIDDK, previously funded two initiatives to address surveillance of diabetes among children, adolescents and young adults: 1) SEARCH for Diabetes in Youth (Population Based Registry of Youth with Diabetes), NOFO PA 00097, DP-05-069, DP10-001, contract #2010-Q-12412 and DP15-002; 2) Study to Assess the Incidence of Type 1 Diabetes in Young Adults (Diabetes in Young Adults (DiYA) Study) DP16-005. The SEARCH Population-Based Registry ascertained incident cases of diabetes in individuals < 20 years of age annually from 2002 through 2019. The DiYA study assessed incidence of diabetes by type in young adults aged 20-45 years in 2017.

The SEARCH for Diabetes in Youth (Population Based Registry of Youth with Diabetes) has provided invaluable information on surveillance of both type 1 and type 2 diabetes among youth in the U.S. By the end of the current funding cycle, SEARCH will be able to assess trends in the incidence of type 1 and type 2 diabetes from 2002 to 2019 by age, sex, and race/ethnicity. The SEARCH study has conducted active diabetes surveillance in five geographic areas of the U.S. (Cincinnati, Ohio; Colorado; Seattle, Washington; South Carolina; and Southern California). Although the combined population of youth under surveillance at these centers presents similar demographic and socio-economic characteristics of the US youth population, a number of US Census regions including the Northeast (Middle Atlantic and New England areas), the West South Central, the East South Central, Pacific and West North Central are not represented. There may be regional differences in the incidence of type 1 diabetes. It is also unknown whether the geographic distribution of type 2 diabetes among children and adolescents mirrors that observed among adults (https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html). To address this limitation, this NOFO anticipates funding sites that are geographically representative of the US and US Census regions.

There are even fewer estimates of the incidence of type 1 and type 2 diabetes among young adults. The DiYA study was funded to determine the incidence of type 1 diabetes in the young adult population. This study was funded for two years and will provide estimates of the incidence of diabetes, overall and by type. It is limited to the Kaiser Permanente population in southern and northern California only for 2017. Therefore, there is a need for data for diabetes in young adults that will allow continuous monitoring of diabetes prevalence and incidence by type across all major US race/ethnicity groups and geographic regions.

Surveillance methods used for children, adolescents and young adults for this NOFO should build upon methods developed in these and other studies, including the use of electronic health information for surveillance, databases and data sources, as well as direct case reports from health care providers, a network of provider clinics, laboratory and pharmacy data or a network of health insurance providers. The goal of this study is to assess the incidence and prevalence of diabetes by type among children, adolescents and young adults. Applications submitted to this NOFO should build on past diabetes surveillance studies, particularly those that have developed algorithms to identify diabetes cases and distinguish diabetes type using electronic health records (EHRs). This new initiative includes surveillance of prevalence and incidence of diabetes in the population aged 0-45 years by diabetes type. Estimates include reports by diabetes type, age, sex, race/ethnicity and geographic area. This new NOFO will focus on important attributes of surveillance such as simplicity of surveillance methods, flexibility to incorporate emerging research, sustainability over time, data quality, representativeness, and timeliness of the methods to assess the burden of diabetes among children, adolescents and young adults.

Healthy People 2020 and other National Strategic Priorities

This NOFO supports the following diabetes Healthy People 2020 objective: To "reduce the disease and economic burden of diabetes mellitus (DM); and improve the quality of life for all people who have, or are at risk for, diabetes" by providing data on the burden of diabetes among U.S. children, adolescents and young adults (0 to 45 years of age) by age, sex, race/ethnicity and diabetes type.

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

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

Measurable outcomes of this NOFO will be in alignment with the Division of Diabetes Translation mission statement, “to reduce the preventable burden of diabetes through public health leadership, partnership, research, programs and policies that translate science into practice.”

Public Health Impact

This announcement directly supports the CDC Strategic Framework and Division of Diabetes Translation mission by assessing the burden of diabetes among children, adolescents and young adults to inform decision-making and prioritize national public health objectives. Results from this study will provide valuable estimates on the incidence and prevalence of type 1 and type 2 diabetes among children and adolescents and young adults. This announcement will assist in the achievement of health equity by identifying health disparities, and will assist in reducing the preventable burden of diabetes by applying surveillance and research to identify and prioritize sub-populations for diabetes prevention and prevention of co-morbidities.

Relevant Work

CDC previously funded two initiatives to address surveillance of diabetes among children, adolescents and young adults: 1) SEARCH for Diabetes in Youth (Population Based Registry of Youth with Diabetes), Notice of Funding Opportunity Announcements (NOFO) PA 00097, DP-05-069, DP10-001, contract #2010-Q-12412 and DP15-002; 2) Study to Assess the Incidence of Type 1 Diabetes in Young Adults (Diabetes in Young Adults (DiYA) Study) DP16-005. The SEARCH Population-Based Registry ascertained incident cases of diabetes in individuals < 20 years of age annually from 2002 through 2019. The DiYA study assessed incidence of diabetes by type in young adults aged 20-45 years in 2017.

This NOFO builds upon the methods and lessons learned in the SEARCH and DiYA studies in the use of electric health records as a method of surveillance. Specifically, this NOFO aims to utilize the tested methods established in SEARCH and DiYA, but expand the geographic representation for children, adolescents and young adults with type 1 and type 2 diabetes. In addition, this NOFO aims to focus on important attributes of a public health surveillance methods including simplicity, flexibility, and data quality; acceptability by system stakeholders; sensitivity, positive predictive value (PPV), representativeness, timeliness and stability over time.

Surveillance applicants are encouraged to review methods reported from DP15-002 and DP16-005 in developing their proposals.

2. Approach

The overall objective of this announcement is to assess the burden of diabetes by conducting surveillance for the incidence and prevalence of diabetes among children and adolescents (< 18 years) and young adults (18 to < 45 years) in the United States and provide estimates by diabetes type, age, sex, race/ethnicity and geographic area. It is expected that the population under surveillance should be well characterized by demographic factors, health insurance status and geographic region. There are three components in this NOFO:

1. Component A (Surveillance of Children and Adolescents): To conduct a standardized population-based approach to ascertainment, validation, and classification of diabetes aimed at gaining knowledge on incidence, prevalence, and secular trends of diabetes in children and adolescents (< 18 years) by age, sex, race/ethnicity, diabetes type, and geographic area;
2. Component B (Surveillance of Young Adults): To conduct a standardized population-based approach to ascertainment, validation, and classification of diabetes aimed at gaining knowledge on incidence, prevalence, and secular trends of diabetes in young adults (age 18 to <45 years) by age, sex, race/ethnicity, diabetes type, and geographic area;
3. Component C (Coordinating Center): To provide an infrastructure for standardized approaches, analytical methods, and measures to be used for surveillance. To provide statistical expertise and serve as a data repository. To conduct administrative functions to support the coordination of the multiple registries, including maintaining an internal and external website for data entry and for the dissemination of information among study investigators and to the public and provide consolidated estimates.

Applicants can apply for Component A, or for Component B, or for Component A and B. Applicants applying for Component C cannot apply for Component A or B. Applicants must submit a separate application for each component they are applying to.

Objectives/Outcomes

Component A and B:

The objective of Components A and B is to provide annual estimates of the incidence and prevalence of type 1 and type 2 diabetes among children and adolescents (Component A) and young adults (Component B) in the United States overall and by age group, sex, race/ethnicity and geographic area.

Possible approaches include the use of electronic health information and diabetes registries. The selected approach should use validated methods to identify and classify diabetes type. It is expected that each applicant for Component A and/or Component B will include detailed information on the denominator of the population under surveillance and its representativeness to the overall geographic population.

Information collected from medical records or electronic health records will be used for estimating the incidence and prevalence of diabetes by type. No direct contact with individuals diagnosed with diabetes as a means of data collection through surveys or biospecimens is anticipated under this announcement for standard surveillance methods.

Component C

Through Component C, a Coordinating Center will support the population based registries of Components A and B. The main objectives of the coordination center related to support include

1. Maintain a central data repository and create data protocols and mechanisms to secure transmission of data and relevant data management reports between the awardees for Components A, B and C.
2. Maintain an internal and external website for data entry and dissemination of information among study investigators and to the public.
3. Ensure the training and certification of staff in Component A and B sites on (a) procedures stated in the protocol and manual of operation relating to standard definition for diabetes and (b) transfer of data to a central repository.
4. Provide expertise and leadership in population-based surveillance development, methodology, implementation, and evaluation.
5. Provide statistical and other analytic support including development of analytic methods for validation of diabetes by type.
6. Provide biostatistical expertise and support timely dissemination of study results and estimates of diabetes incidence and prevalence among children, adolescents and young adults.

Target Population

Component A and B:

The target population is children and adolescents (< 18 years;Component A) and young adults (18 years to < 45 years; Component B) in the U.S. The population under surveillance at each

applicant's site should be demographically and geographically representative of the population of children, adolescents, and young adults included in the applicant's site. The overall population under surveillance, that includes all awardees for Components A and B, should be demographically and geographically representative of the population of children, adolescents, and young adults in the United States.

Collaboration/Partnerships

Component A:

- Applicants are expected to have access to a research infrastructure and established access to diabetes cases among children and adolescents. This could include an established long-term population based childhood diabetes registry or access to longitudinal electronic health records.
- Applicants should provide evidence of established and well-defined working relationships with organizations and/or outside entities expected to participate in the proposed research.
- Applicants should demonstrate partnerships with health care networks or systems to access information on cases of diabetes among children and adolescents. Applicants should demonstrate experience in working collaboratively with research partners.

Component B:

- Applicants are expected to have access to a research infrastructure and established access to diabetes cases among young adults. This could include an established long-term population based diabetes registry or access to longitudinal electronic health records.
- Applicants should provide evidence of established and well-defined working relationships with organizations and/or outside entities expected to participate in the proposed research.
- Applicants should demonstrate partnerships with health care networks or systems to access information on cases of diabetes among young adults. Applicants should demonstrate experience in working collaboratively with research partners.

Component C:

- Applicants are expected to collaborate with members in Components A and B and other partners to accomplish the goals and objectives of the study.
- Applicants should demonstrate experience in coordination of multi-center studies, data management and analysis. Applicants should demonstrate experience in working collaboratively with research partners.

Evaluation/Performance Measurement

Component A and B:

- The applicants are expected to incorporate evaluation/performance measures that include

approaches for identifying cases of diabetes and validation of diabetes by type. Emphasis should be on rigorous scientific approaches and methodologies.

- These evaluation/performance measures are expected to include methods to assess sensitivity, specificity and positive predictive value of diabetes case identification overall and by diabetes type. Selected evaluation methods should provide for assessment of whether the accuracy of the methods differ by race/ethnicity, socioeconomic status, insurance coverage or geographic area.
- Further, selected evaluation/performance measures should provide an assessment of consistency of methods over time, and measurement of completeness of case ascertainment. Selected evaluation measures are expected to include a description of the population under surveillance and how it will be ascertained for estimation of incidence and prevalence.

Component C:

- Evaluation/performance measures are expected to include quality assurance and quality control measures. Description of activities for on-going study progress, oversight, data management, and quality control and assurance measures should include metrics that will be used and methods to ensure high data quality and accuracy of incidence and prevalence results. Performance measurements should include statistical approaches to adjust for data limitations and/or combine data sources to produce estimates.

Translation Plan

Applicants for Components A, B, and C are expected to work collaboratively with each other and in consultation with CDC to develop methods for aggregating data and presenting joint analyses that will produce results comparable across sites. Applicants are expected to communicate the findings to the larger scientific and public health communities. The results are expected to be communicated through peer-reviewed journals, presentations at scientific meetings, and other means. Applicants will provide relevant estimates to CDC to support the National Diabetes Statistical Report. Applicants are expected to engage with public health entities to translate the findings for the state or local communities.

OMB/PRA is not expected to apply.

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Section II. Award Information

Funding Instrument Type: Cooperative Agreement

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

Application Types Allowed:

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

Estimated Total Funding: $15,000,000

The estimated total funding (direct and indirect costs) for the first budget period is $3,000,000 (including up to $594,000 from NIH and $2,406,000 from CDC), and the estimated total funding (direct and indirect) for the entire project period is $15,000,000.

It is anticipated that 11 award(s) will be made under this NOFO RFA-DP 20-001.

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

Component A: (up to five awards) $250,000

Component B: (up to five awards) $250,000

Component C: (up to one award) $500,000

Awards issued under this NOFO are contingent on the availability of funds and submission of 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.

Anticipated Number of Awards: 11

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (for Components A and B $250,000 and for Component C $500,000), HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements

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

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

Award Ceiling: $500,000 Per Project Period

Award Floor: $180,000 Per Project Period

Total Period of Performance Length: 5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/ sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments County governments City or township governments Special district governments Independent school districts Public and State controlled institutions of higher education Native American tribal governments (Federally recognized) Public housing authorities/Indian housing authorities Native American tribal organizations (other than Federally recognized tribal governments) Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education Private institutions of higher education For profit organizations other than small businesses Small businesses 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:

Faith-based or Community-based Organizations
Regional Organizations
Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.
Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of

the status is required. Attach with "Other Attachment Forms."
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Additional Information on Eligibility

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:

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
• Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.

• 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.

• Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency.

For an applicant to be even considered they must be responsive to the following.

Component A:

- Applicants must provide evidence of access to population under surveillance (denominator) representative of the age group specified for population < 18 years of age.

Component B:

- Applicants must provide evidence of access to population under surveillance (denominator) representative of the age group specified for population 18 to < 45 years of age.

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

Component C:

- Not Applicable

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.

Component A/B/C:

- Applicants may not request funding above the ceiling amount for the first 12 month budget period (includes direct and indirect costs).

Component A:

- Applicants must provide evidence of access to population under surveillance (denominator) representative of the age group specified for population < 18 years of age. Evidence can be in the form of a letter(s) of agreement with home institution, data use agreements (if data obtained from other sources). Evidence should be placed in Appendix A.

Component B:

- Applicants must provide evidence of access to population under surveillance (denominator) representative of the age group specified for population 18 to < 45 years of age. Evidence can be in the form of a letter(s) of agreement with home institution, data use agreements (if data obtained from other sources). Evidence should be placed in Appendix A.

If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/ Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- Grants.gov
- eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to

complete. However, it is best to start the registration process at least two weeks prior to application submission.

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

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

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

10. Number of Applications

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

Only one application per institution (normally defined as having a unique DUNS number) per component is allowed for this NOFO. Applicants must submit separate applications if applying to more than one component. Applicants can apply for Component A, or for Component B, or for Component A and B. Applicants applying for Component C cannot apply for Components A or B.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.
If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the

Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

The forms package associated with this NOFO 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 NOFO. 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 grant 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. 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: **12/09/2019**

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

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

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

The letter of intent should be sent to:

Marcella Law, MPH

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)-488-5416

Email: mah7@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

Other Research Plan Sections

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

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• A description of the data to be collected or generated in the proposed project;
• Standards to be used for the collected or generated data;
• Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of
provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights -
this section should address access to identifiable and de-identified data);
• Statement of the use of data standards that ensure all released data have appropriate documentation that
describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation
and access are not justified (this section should address archiving and preservation of identifiable and deidentified
data).
Examples of DMPs may be found here: USGS, http://www.usgs.gov/products/data-and-tools/data-management/data-management-plans

Research Plan

Applicants' research plan must address activities that will be conducted during the 5-year project period and should include the following items:

All Components (A, B and C):

- Provide staffing plan that defines roles, responsibilities and qualifications of the team and expected contribution of key/collaborative partners.
- Provide detailed time line including realistic and measurable milestones for the proposed activities. Include detailed budget plan that is linked to the activities and milestones.
- Describe plans for data dissemination and production of reports. Describe plans for preparing annual estimates. Data on incidence and prevalence should be provided within 6 months of completion of data collection and cleaning. Reports include interim progress and final reports, technical reports, professional presentations and publications

that will be produced collaboratively with CDC.

Component A:

- Describe incidence of type 1 and type 2 diabetes among children and adolescents in the population for the applicant study site.
- Describe the method of surveillance for incidence and prevalence of diabetes by type among children and adolescents. Include description of the population source, by overall size, age, race/ethnicity, health insurance status, socio-economic distribution and geographic representation.
- Describe the population source/denominator. Include details on representativeness to the source population and the general, geographic population. Include information on racial/ethnic minority and socio-economically disadvantaged populations. Describe how the population size will be ascertained for the estimation of incidence, prevalence and secular trends for the five years of the study.
- Describe the study design and methodological approach including methods to identify and validate diabetes cases by type.
- Describe research infrastructure and summary of site specific data sources to identify incident and prevalent diabetes cases in the population. This could include, but is not limited to, a diabetes registry or electronic health record system.
- Describe partnership/network(s) which will provide information to diabetes cases within the population source. Describe plan for partners and collaboration to accomplish goals of surveillance effort including identification of roles, effort and commitment.

- Describe experience in collaborating with other partners in a multi-center study.
- Describe readiness/preparation to coordinate with other sites/awardees (Components A and B), including the Coordinating Center (Component C), on data base development, data management, data sharing, development of data reports, data analysis, and protocol development. Include letters of support, publications, abstracts and reports demonstrating previous collaborations.
- Describe methods for study-wide coordination. Describe readiness/preparation to coordinate with other sites/awardees (Components A and B and C), including data sharing with Component C.
- Describe the applicant institutional research infrastructure to carry out large, complex, population based projects. Include information on applicants' physical facilities, data management and computer resources and facilities for data retrieval and storage. Include description of staffing and management plans.
- Describe training or developing doctoral, post-doctoral and junior investigators. This may include investigators with a demonstrated interest and history in working with populations with health disparities. Provide detailed plan for training and developing post-doctoral and junior investigators.
- Provide letter (s)of support from the applicant's institution that commits the institution to (a) on-going research with this project; (b) a specified percentage of the researchers' time to spend on this research project; (c) continued access to data source(s)/ data set(s); (d) approval for travel for required staff and PIs to attend project meetings to CDC Atlanta, in local commute area or Steering Committee-related meetings; and (e)

maintain IRB oversight of human subjects research activities.

Component B:

- Describe incidence of type 1 and type 2 diabetes among young adults in the population for the applicant study site.
- Describe the method of surveillance for incidence and prevalence of diabetes by type among young adults. Include description of the population source, by overall size, age, race/ethnicity, health insurance status, socio-economic distribution and geographic representation.
- Describe the population source/denominator. Include details on representativeness to the source population and the general, geographic population. Include information on racial/ethnic minority and socio-economically disadvantaged populations. Describe how the population size will be ascertained for the estimation of incidence, prevalence and secular trends for the five years of the study.
- Describe the study design and methodological approach including methods to identify and validate diabetes cases by type.
- Describe research infrastructure and summary of site-specific data sources to identify incidence and prevalence of diabetes cases in the population. This could include, but is not limited to, a diabetes registry or electronic health record system.
- Describe partnership/network(s) which will provide information to diabetes cases within the population source. Describe plan for partners and collaboration to accomplish goals of surveillance effort including identification of roles, effort and commitment.
- Describe experience in collaborating with other partners in a multi-center study.
- Describe readiness/preparation to coordinate with other sites/awardees (Components A and B), including the Coordinating Center (Component C), on data base development, data management, data sharing, development of data reports, data analysis, and protocol development. Include letters of support, publications, abstracts and reports demonstrating previous collaborations.
- Describe methods for study-wide coordination. Describe readiness/preparation to coordinate with other sites/awardees (Components A and B and C), including data sharing with Component C.

- Describe the applicant institutional research infrastructure to carry out large, complex, population based projects. Include information on applicant's physical facilities, data management and computer resources and facilities for data retrieval and storage. Include description of staffing and management plans.
- Describe training or developing doctoral, post-doctoral and junior investigators. This may include investigators with a demonstrated interest and history in working with populations with health disparities. Provide detailed plan for training and developing post-doctoral and junior investigators.
- Provide letter (s) of support from the applicant's institution that commits the institution to (a) on-going research with this project; (b) a specified percentage of the researchers' time to spend on this research project; (c) continued access to data source(s)/ data set(s);(d) approval for travel for required staff and PIs to attend project meetings to CDC Atlanta, in local commute area or Steering Committee-related meetings; and (e)

maintain IRB oversight of human subjects research activities.

Component C:

- Describe experience in directing and operating a coordinating center for collaborative, population based large scale epidemiologic research and/or surveillance projects that include coordination of multiple sites, common protocols, monitoring of site performance, monitoring study progress and providing logistical governance support.
- Describe experience in providing data management, analysis and statistical support to multi-site research projects. Include development and management of multi-site database, design, analyses and interpretation of data and development of data summaries and statistical reports.
- Describe understanding of surveillance methods and activities including creation of appropriate denominator for incidence and prevalence estimates, potential problems and solutions to address representativeness of estimates and completeness of case identification.
- Describe the applicant institutional research infrastructure to carry out large, complex, population based projects. Include information on applicant's physical facilities, data management and computer resources and facilities for data retrieval and storage. Include description of staffing and management plans.
- Describe methods for study-wide coordination. Include plans for development and maintenance of central data system or data base, data management and coordination with sites from Components A and B. Describe readiness/preparation to coordinate with other sites/awardees (Components A and B), on data base development, data management, data sharing, development of data reports, data analysis, protocol development.
- Describe training or developing doctoral, post-doctoral and junior investigators. This may include investigators with a demonstrated interest and history in working with populations with health disparities. Provide detailed plan for training and developing post-doctoral and junior investigators.
- Provide letter (s) of support from the applicant's institution that commits the institution to (a) on-going research with this project; (b) a specified percentage of the researchers' time to spend on this research project; (c) continued access to data source(s)/ data set(s); (d) approval for travel for required staff and PIs to attend project meetings to CDC Atlanta, in local commute area or Steering Committee-related meetings; and (e) maintain IRB oversight of human subjects research activities.

Data Management Plan

CDC requires awardees for projects that involve the collection or generation of public health data with federal funds to submit a Data Management Plan (DMP) prior to the initiation of generating or collecting public health data unless CDC will aggregate and disseminate the data. Public health data means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. In initial funding applications, the DMP should be addressed within the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application, either as a stand-alone DMP within this section or with a statement explaining why a DMP is not included. The DMP must be updated and submitted to CDC at least annually, or whenever plans for data collection or

generation activities change. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements. The contents of the DMP are described in AR-25. The DMP may be presented in a table, a narrative format, or as a checklist.

Public health data are expected to be made freely available to the public (in a de-identified format) and archived long-term unless there are compelling reasons not to do so. When it is not feasible to make data freely available to the public, it may be possible to make data available to users on a restricted basis. The DMP should describe the expected level of public access, if any, and must justify the planned access level and describe how privacy and confidentiality will be protected. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data from ongoing surveillance systems which should be made accessible within 12 months of the end of a collection cycle. Awardees who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award. For data underlying scientific publications such as peer review journal articles, awardee should make the data available coincident with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set accompanying a scientific paper should consist of a machine-readable version of the data tables shown in the paper.

To view brief descriptions of relevant CDC requirements visit: https://www.cdc.gov/grants/additional-requirements/ar-25.html

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 30 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms

and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.
CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.
Applicants are able to access, view, and track the status of their applications in the eRA Commons.
Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.
Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

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

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

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

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

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

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

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

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **01/14/2020**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants,

cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.
Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please
see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

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).

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.

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

Reimbursement of pre-award costs is / is not allowed. All HHS/CDC awards are subject to the

terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf or speak with your Grants Management Specialist (GMS).

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

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

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

Duplication of Efforts

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

are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

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

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

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

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.
The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.
If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

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

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm

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

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

Section V. Application Review Information

1. Criteria

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

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

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

Significance

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

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Component A:

- Does the applicant provide sufficient evidence to demonstrate assembly of a team with experience in the surveillance methods proposed, multi-site studies and a body of work that has contributed to improvement in public health practice and population health?
- Does the applicant provide evidence to demonstrate success in conducting research among children and adolescents (the population under surveillance)?
- Does the applicant include adequate plan for training and development of post-doctoral and junior investigators?
- Is there sufficient knowledge and expertise with surveillance for diabetes?

Component B:

- Does the applicant provide sufficient evidence to demonstrate assembly of a team with experience in the surveillance methods proposed, multi-site studies and a body of work that has contributed to improvement in public health practice and population health?
- Does the applicant provide evidence to demonstrate success in conducting research among young adults (the population under surveillance)?
- Does the applicant include adequate plan for training and development of post-doctoral and junior investigators?
- Is there sufficient knowledge and expertise with surveillance for diabetes?

Component C:

- Does the applicant provide sufficient evidence to demonstrate assembly of a team with experience in the surveillance methods proposed, multi-site studies and a body of work that has contributed to improvement in public health practice and population health?
- Does the applicant provide evidence to demonstrate statistical expertise in surveillance methods and data analysis?
- Does the applicant include adequate plan for training and development of post-doctoral and junior investigators?
- Is there sufficient knowledge and expertise with surveillance for diabetes?

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/B/C:

- Does the application demonstrate the potential to increase efficiency in diabetes surveillance and advance diabetes surveillance methodology?
- Does the application propose innovative methods for sustainable surveillance addressing unique challenges in surveillance of type 1 and type 2 diabetes?

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 and B:

- Does the applicant provide a robust approach to identify and validate incident and prevalent cases of type 1 and type 2 diabetes in the population under surveillance? Does the applicant adequately describe (a) the population source (including size, sex, age, race/ethnicity, medical insurance status, socio-economic status and geographic distribution); (b) partnership/network(s) which will provide access to information on diabetes cases; (d) data sources that will be used; (e) population (denominator); (f) methods for estimating incidence and prevalence and trends over the five years of the study.

- Does the applicant provide detailed description of the denominator for the population under surveillance? Is the applicant able to define a denominator based on geographic area, specified age range, race/ethnicity that is representative of the population under surveillance?
- Does the applicant have access to health information, both hospital and non-hospital sources, to determine incident cases of diabetes? This could include electronic health information, electronic health records from a single health insurance company, and a network of providers, laboratory and pharmacy data or a network of health insurance providers. Does the applicant have access to data from prior years to confirm each incident case is a new cases and not previously diagnosed with diabetes?
- Does the applicant describe a sound approach to optimize the data collection, validation and quality control?
    - Does the applicant include an assessment of completeness of the data, possibility of multiple entries for an individual patient, flexibility and timeliness of the system?
    - Does the applicant include a robust evaluation plan to assess the surveillance of type 1 and type 2 diabetes among children and adolescents (Component A) or young adults (Component B).
- Does the Principal Investigator or co-Principal Investigator have a history of conducting competitively funded peer reviewed research on epidemiology of diabetes or population based surveillance studies? Is there evidence of prior experience in working collaboratively in a multi-site study or with a standard protocol?
- Does the applicant provide letter (s) of support from the applicant's institution that commits the institution to (a) ongoing research with this project; (b) a specified percentage of the researchers' time spent on this research project; (c) continued access

to and use of the dataset(s); (d) approval of travel for required staff to attend Observational Study Monitoring Board related meetings and (e) maintaining IRB oversight of human subjects research?

Component C:

- Does the applicant describe a sound approach to optimize data collection, validation and quality control?
- Does the applicant provide evidence of biostatistical and epidemiological experience in surveillance?
- Does the applicant describe an approach to evaluate sensitivity, specificity, positive predictive value of the data?
- Does the applicant include a robust evaluation plan to assess the surveillance of incident and prevalent type 1 and type 2 diabetes among children, adolescents and young adults?
- Does the Principal Investigator or co-Principal Investigator have a history of conducting competitively funded peer reviewed research on epidemiology of diabetes or population based surveillance studies?
- Does the applicant provide evidence of prior experience in working collaboratively to carry out a population based multi-center study or standard protocol?
- Does the applicant describe an approach to disseminate results within 6 months of completion of data collection?
- Does the applicant provide a letter of support from the applicant's institution that commits the institution to (a) ongoing research with this project; (b) a specified percentage of the researchers' time spent on this research project; (c) continued access to and use of the dataset(s); (d) approval of travel for required staff to attend Observational Study Monitoring Board related meetings and (e) maintaining IRB oversight of human subjects research?

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/B/C:

- Does the applicant describe an institutional research infrastructure to carry out large, complex, population-based projects?
- Does the applicant provide description of the applicants' physical facilities, data management and computer resources, and facilities for data retrieval and storage?

Component A/B:

- Is there a network of providers or health care systems, including electronic health records from a single health insurance company, network of provider clinics, laboratory

and pharmacy data or network of health insurance providers that can be accessed to identify incident diabetes cases among children and adolescents (Component A) or young adults (Component B).

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

Inclusion of Women, Minorities, and Children

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

Vertebrate Animals

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

(https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

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

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

3. Additional Review Considerations

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

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

Investigators responding to this funding opportunity announcement should include a detailed stand-alone DMP in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. The AR-25 (AR 25 Data Management and Access) 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 be a standalone section of the application.

For each collection and/or generation of public health data funded by this award, the DMP 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).

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.

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

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

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

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

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term

preservation and access are not justified (this section should address archiving and preservation
of identifiable and de-identified data).
Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

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

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

- Will receive a written critique.

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

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

- Geographic diversity of study sites that includes geographic representative of the US or US Census regions.

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

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

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to

future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-25: Data Management and Access

CDC requires recipients 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.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

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

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

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into

the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

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

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

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

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC

must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

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

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

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

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

- Information collection consistent with OMB approval, as deemed necessary.
- Development of IRB packages, as deemed necessary.

Component A and B:

- Participating in the Steering Committee, the primary governing body of the study comprised of the PIs from each site.
- Establishing and maintaining a network/partnership(s) with health care providers and/or health care systems with access to information on incident and prevalent cases of diabetes among children and adolescents (Component A) or young adults (Component B).
- Participating in methodology and protocol development of the study, on-going data collection and follow-up, quality control, data analysis and interpretation and dissemination of study results (including in peer reviewed journals).
- Execution of the protocol and provision of progress reports to the CDC and Observational Study Monitoring Board as described below.
- Collaborating with other study investigators and following common protocol(s) and manuals of operation developed by the Steering Committee.
- Maintaining an effective and adequate management and staffing plan.
- Assuring and maintaining confidentiality of all study data.
- Performing joint analyses with aggregate data and communicating the results to the scientific and public health community (though publications, abstracts and publications) and to the general community.
- Coordinate PIs and key staff for project meetings with CDC Scientific Consultants. Convene a project meeting at CDC or in a commuting area to the grantee location.
-

Component C:

- Formation of the Steering Committee consisting of a PI from each study site. The Steering Committee will have one in person meeting each year and regular teleconferences throughout the year. The Steering Committee may create sub-committees as appropriate to accomplish its goals.
- Coordination of statistical analysis and data management aspects of the study. Reviewing study protocol and providing leadership in the development of epidemiologic and statistical approach for surveillance and the design, implementation and quality control for multi-site surveillance activities.
- Analyzing study results and reviewing all manuscripts and study results for statistical considerations. Prepare and update protocols and manuals of operation, and ensure training and certification of staff at study sites.
- Establish a database to accommodate data generated by each study site, developing an electronic data transmission system if needed, assessing the data quality and completeness throughout the study.
- Execution of the protocol and provision of progress reports to the CDC and External Scientific Evaluation Committee as described below.
- Provide progress reports of the study to the Steering Committee meetings, facilitate communication among investigators including scheduling meetings, conference calls, developing agendas, documenting minutes and maintaining membership rosters and committee lists.

- Maintaining an effective and adequate management and staffing plan.
- Assuring and maintaining confidentiality of all study data.
- Establish an Observational Study Monitoring Board (OSMB) that will be appointed by the Steering Committee. The OSMB will consist of a chair, scientists with expertise in epidemiology, biostatistics, diabetes, surveillance and a member of the community. The OSMB will evaluate the study protocol proposed by the Steering Committee based on the importance of the question to be addressed, the scientific merit of the design, feasibility and consistency with NCCDPHP missions and policies. The OSMB will provide a written critique and final recommendation to the applicants. During the implementation phase, the OSMB will monitor each research center for adherence to recommended protocol or procedural changes or early termination of any award for poor performance. Grantees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

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

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access http://intranet.cdc.gov/od/oads/spa/dma/index.html

- NCCDPHP is a consultant with scientific and programmatic involvement during the conduct of the project, providing management oversight and scientific consultation as requested by the Awardees.
- Support the grantees' activities by consulting and providing scientific and public health consultation and assistance in the development of activities related to the cooperative agreement.
- Assist in facilitating communication among grantees' for the development of common multi-center protocol(s), quality control, interim data monitoring, data analyses, interpretation, reporting and coordination.
- Ensure adherence of human subject requirements and approval of study protocol by appropriate local IRB(s), for all cooperating institutions participating in the study.
- Serve as in an advisory capacity as a non-voting member on the Steering Committee
- Facilitate the process of obtaining Certificates of Confidentiality in the form of 301(d), as appropriate.
- Collaborate to produce technical reports and manuscripts for peer-reviewed publications as appropriate. Provide assistance for joint analysis with aggregate data.

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

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

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

Areas of Joint Responsibility include:

- The Steering Committee, the main governing board of the study, will be comprised of the Principal Investigator from each study site from Component A and B, the Principal Investigator from Component C (the Coordinating Center) and a NCCDPHP Project scientist(s) as non-voting consultant. A chairperson will be selected from the non-Federal Steering Committee members. A Chairperson must have proven evidence of leadership ability and be able to make an adequate time commitment to the cooperative agreement.
- The Steering Committee will meet initially to develop the protocol and throughout the year to discuss study progress. It will have primary responsibility for developing common research designs, protocols, manual of operations, facilitating the conduct and monitoring of studies, and reporting study results. The Steering Committee must approve the protocol, changes to the protocol and manuals of operation. The Principal Investigator of each study site will be responsible for the execution of the protocol and provide progress reports to the Steering Committee. The Steering Committee will also develop policies relating to access to patient data and specimens and ancillary studies. It will establish guidelines for presentations at scientific meetings and for writing and publishing manuscripts on the findings of the study.
- Each member of the Steering Committee will have one vote, with the NCCDPHP Project scientist(s) as a non-voting member. Grantee members of the Steering Committee will be required to accept and implement policies approved by the Steering Committee. To promote the development of a collaborative program among awardees, Principal Investigators are expected to attend Steering Committee meetings and participate in conference calls on a regular basis.

5. Reporting

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

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

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of

satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

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

2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends**.

3. **A final progress report**, invention statement, equipment/inventory report, and the

final FFR are required **90 days after the end of the period of performance**.

B. Content of Reports

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

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

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

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

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

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques,

inform policy, or use of technology in public health. Questions to consider in preparing this section include:

- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

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

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

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

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

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

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

- Additional Reporting Requirements:

N/A

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

calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

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

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

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

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

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

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the period of performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

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

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking

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

Scientific/Research Contact(s)

Marcella Law, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
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Atlanta, GA 30342
Telephone: (770)-488-5416
Email: mah7@cdc.gov

Peer Review Contact(s)

Jaya Raman, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: (770)-488-6511
Email: kva@cdc.gov

Financial/Grants Management Contact(s)

Staff Contact Name - Sharon Cassell

Grants Management Specialist
Centers for Disease Control and Prevention (CDC)
Office of Financial Resources (OFR)
Office of Grants Services (OGS)
Global Health Security Branch (GHSecB)
Telephone: (770) 488-2703
Email: scassell@cdc.gov

Section VIII. Other Information

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

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

Amendment II. Questions and Answers from Potential Applicants and CDC Responses

QUESTION 1: Is a separate DUNS number needed if one site collaborates with another in the application process?

ANSWER 1: No, a separate DUNS number is not necessary. Only one application per institution (normally identified by having a DUNS number is allowed for each component.

QUESTION 2: This RFA says for components A and B, proposing a budget more than $250,000 in the first year will not be allowed. How about the remaining 4 years? Can I propose a 5-year grant? Does each year's budget have to be <=$250,000?

ANSWER 2: Yes, the applicant is expected to propose a 5year grant. Each year budget cannot exceed $250,000 (direct and indirect costs) for Component A or Component B as stated on Page 3, Funds Available and Anticipated Number of Awards and on Page 13-14, Section II Award Information

QUESTION 3: Our first question is related to how the CDC defines Institution in the age of consolidation between medical centers. For example, the NYU Langone Health System has two medical schools (one in NYC and one in Mineola on Long Island. Each medical school has its own DUNS number and they each have to build and maintain their own research programs. Can one medical school (say NYU-Winthrop and NY Long Island School of Medicine) apply for the CoC while the other (NYU-Langone and the NYU School of Medicine) applies for one or both clinical centers? Each school has its own administration and functions fairly

independently of the other.

ANSWER 3: Please see Page 4 of the NOFO, Number of Applicants, "Only one application per institution (normally defined as having a unique DUNS number) per component is allowed for this NOFO. Applicants must submit separate applications if applying to more than one component. Applicants can apply for Component A, or for Component B, or for Component A and B. Applicants applying for Component C cannot apply for Component A or Component B."

QUESTION 4. Can an investigator can be on multiple proposals, especially can an investigator work on Component C with one Institution and have a subcontract as an MPI or a co-PI with another institution?

ANSWER 4: Page 4 (Executive Summary: Eligible Project Directors/Principal Investigators (PDs/PIs), says "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." The NOFO further says (Page 4, number of PDs/PIs, that "Applicants 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-PI.

QUESTION 5. I would like to submit an application for funding, but I've never done this before. Can you give me some advice on how to determine if my organization would be eligible to apply?

ANSWER 5: Pages 15-21 (Section III. Eligibility Information). The NOFO provides a detailed list of eligibility criteria for potential applicants. For more details on the application process, we also recommend reviewing the guidance and information on the www.grants.gov website.