

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Comprehensive Analysis, Surveillance, and Statistics Initiative for Diabetes in the Young (CASSIDY)

RFA-DP-25-043

01/10/2025

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:
National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Comprehensive Analysis, Surveillance, and Statistics Initiative for Diabetes in the Young (CASSIDY)

Activity Code

U18

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-25-043

Assistance Listings Number(s)

93.945

Category of Funding Activity

HL - Health

NOFO Purpose

The objective of this NOFO is to conduct surveillance of diabetes in youth (< 18 years) and young adults (18–44 years) across health system and/or health plan membership-based centers to provide estimates of diabetes incidence and prevalence in the United States. These estimates are sought by diabetes type, demographic traits, health insurance status, and geographic area to

identify disparities in diabetes burden. The prevalence of diabetes complication risk factors, acute and chronic diabetes complications, and use of diabetes medications among youth and young adults with diabetes will also be ascertained.

This project has two (2) components to achieve the purpose of the program. Component A focuses on surveillance of diabetes among youth (< 18 years) and young adults (18–44 years). Component B serves as a Coordinating Center to provide an infrastructure for standardized approaches, analytical methods, and measures to be used for surveillance across sites. It will also develop validation protocols, serve as a data repository, and provide statistical expertise.

Key Dates

Publication Date:
To receive notification of any changes to RFA-DP-25-043, 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:
12/10/2024

Application Due Date:
01/10/2025

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 11:59 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on 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 http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552
- Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

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:
03/12/2025
This date is an estimate.

Secondary Review:
04/29/2025
This date is an estimate.

Estimated Start Date:
09/30/2025

Expiration Date:
02/09/2025

Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - 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 12 pages.

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

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

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

Executive Summary

- **Purpose**: This NOFO aims to conduct diabetes surveillance across health system and/or health plan membership-based centers to:

1. Estimate incidence and prevalence of diabetes in youth (< 18 years) and young adults (18–44 years) in the United States. These estimates are sought by diabetes type, demographic traits, health insurance status, and geographic area to identify disparities in diabetes burden.
2. Ascertain the prevalence of risk factors for diabetes complications, occurrence of acute and chronic diabetes complications, and use of diabetes medications among youth and young adults with diabetes.

This NOFO has two (2) components to achieve the purpose of the program.

1. Component A focuses on surveillance of diabetes among youth (< 18 years) and young adults (18–44 years).
2. Component B serves as a Coordinating Center to provide an infrastructure for standardized approaches, analytical methods, and measures to be used for surveillance across sites. It will also develop validation protocols, serve as a data repository, and provide statistical expertise.

- **Mechanism of Support**: U18

- **Funds Available and Anticipated Number of Awards**: The estimated total funding available, including direct and indirect costs, for the entire four (4)-year period of performance is **$12,800,000.00.** There will be up to **six (6)** awards total, including up to **five (5)** awards under Component A and **one (1)** award under Component B**.** Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Period of Performance**: The estimated total funding (direct and indirect) for the first year (12-month budget period) will be **$3,200,000.00.** During FY25, the anticipated funding amounts for the individual awards will be as follows:
    - Component A: It is anticipated that up to **five (5)** awards will be made for up to **$500,000.00** (direct and indirect) each in FY25.
    - Component B: It is anticipated that **one (1)** award will be made for up to **$700,000.00** (direct and indirect) in FY25.

  The estimated total funding (direct and indirect) for the entire Period of Performance will be **$12,800,000.00**. The period of performance is anticipated to run from **09/30/2025 to 09/29/2029.**

- **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 of this announcement are eligible to apply.
- **Eligible Project Directors/Principals 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. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs**: Applications may include more than one PI; however, the first PI listed on the application will be the “contact PI” for all correspondence.
- **Number of Applications**: Only one application per institution (normally identified by having a unique UEI number) is allowed. Applicants can apply for Component A or Component B; however, applicants cannot apply for both Component A and Component B.
- **Application Type**: New
- **Application Materials**: See Section IV.1 for application materials. Please note that SF424 (R&R) Form H is to be used when completing the application package. Please see https://grants.nih.gov/grants/how-to-apply-application-guide.html

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

Public health surveillance of diabetes and its complications is crucial for tracking and characterizing the burden of the disease, formulating health care policy, identifying high-risk groups, developing strategies to reduce the burden of this disease, and monitoring progress of primary and secondary prevention programs. Diabetes mellitus is one of the most common chronic diseases in the United States, with over 38 million people having the disease in 2021 (1). While the prevalence and incidence of diabetes is higher among older adults, diabetes is one of the most common chronic diseases in childhood and young adulthood.

The SEARCH for Diabetes in Youth study (Population Based Registry of Diabetes in Youth) found that the incidence of both type 1 and type 2 diabetes in the United States is increasing (2). Between 2002 and 2018, incidence of type 1 diabetes in children and adolescents aged <20 years increased by 2% per year and incidence of type 2 diabetes increased by 5% per year (2). In 2017-2018 there were 22.2 new cases/100,000 youth with type 1 and 17.9 new cases/100,000 youth per year with type 2 diabetes. The study also found that annual increases in type 1 diabetes incidence were generally higher among American Indian (+1.8%), Asian or Pacific Islander (+4.8%), Hispanic (+4.1%), and non-Hispanic Black (+2.9%) youth than the annual increases in type 1 diabetes observed among non-Hispanic White (+0.6%) youth. Similarly, annual increases in type 2 diabetes incidence were also found to be greater among American Indian (+3.5%), Asian or Pacific Islander (+8.9%), Hispanic (+7.2%), and non-Hispanic Black (+6.0%) youth than non-Hispanic White (+1.8%) youth.

National Health Interview Survey (NHIS) analyses suggest that trends in diabetes incidence among young adults have been relatively stable (3, 4), with a nonsignificant annual decrease of -1.2% among adults aged 18–44 years in 2008–2021 NHIS data (4). However, these results from the NHIS do not distinguish diabetes type. Estimates of diabetes incidence and prevalence by type from national surveys rely on various algorithms that include age at diabetes onset, insulin use and self-report of diabetes type (5). Because type 1 diabetes can occur at any age and people with type 2 diabetes often need insulin treatment to control hyperglycemia, such algorithms are prone to misclassification bias (5). There is however no currently accepted method to separate type 2 from type 1 diabetes in data from national surveys, so there are fewer estimates of diabetes incidence by type among young adults in the United States.

The rising incidence of diabetes among youth is a significant driver of diabetes prevalence in this segment of the population. Among youth under 20 years of age, 2.15/1,000 had type 1 diabetes and 0.67/1,000 had type 2 diabetes in 2017 (6). This represented a 45% and 95% relative increase since 2001, respectively. National estimates indicated that 5.8 million young adults aged 18-44 years had diabetes in 2021 (1). Since diabetes requires lifelong treatment, management, and care, understanding the burden of diabetes in the younger population will assist with future health care planning and public health prevention efforts.

Since 2000, the Centers for Disease Control and Prevention (CDC) collaborated with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to fund three initiatives that address surveillance of diabetes among children, adolescents and young adults: 1) SEARCH for Diabetes in Youth (Population Based Registry of Youth with Diabetes), 2) the study to Assess the Incidence of Type 1 Diabetes in Young Adults (DiYA), and 3) Assessing the Burden of Diabetes by Type in Children, Adolescents and Young Adults (DiCAYA) study.

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) and ascertained incident cases of diabetes in individuals < 20 years of age annually from 2002 to 2018 (2). The SEARCH study also developed algorithms for electronic health records to minimize bias in identifying cases of diabetes and to distinguish these cases by diabetes type. While the SEARCH study provided invaluable information about diabetes among youth, it did not address gaps in knowledge around diabetes in young adults.

The DiYA study was funded to determine the incidence of type 1 diabetes in the young adult population. The study developed methods to identify young persons with diabetes and distinguish between type 1 and type 2 or other diabetes types in electronic health records and developed algorithms validated with diabetes autoantibodies (7). The DiYA study found that type 1 diabetes may account for approximately 8% of incident diabetes cases among young adults (7). However, the DiYA study was limited to young adults in the Kaiser Permanente population in southern and northern California and only provided information for 2017.

The DiCAYA study was funded in 2020 to build upon the methods established in the SEARCH and DiYA studies and continue to estimate the prevalence, incidence, and trends of diabetes among youth and young adults (0–44 years) by diabetes type, age, sex, race and ethnicity, and geographic area (8). It includes eight surveillance centers that are either geographical, health system, or membership-based and conducts diabetes surveillance across geographically diverse populations in the United States. Moreover, the study is further refining and validating electronic health record-based computable phenotype algorithms to identify type 1 and type 2 diabetes from previous studies, testing and validating bias correction methods to adjust for differences between the patient population and general target population of inference.

In addition to the methodological contributions, the DiCAYA study has also revealed challenges in conducting surveillance across diverse centers. The differences between centers (e.g., denominators) have limited the study's ability to systematically apply methods across the network. For example, health system and membership-based centers may rely on statistical approaches such as multilevel regression with poststratification to adjust for potential differences between their patient populations and the target populations of inference, whereas geographical centers may explore capture-recapture methods to estimate completeness of case ascertainment. Due to the different denominators, it is also unclear if incidence and prevalence estimates from all three types of centers can be combined to provide a composite estimate for the entire network.

Thus, the DiCAYA study has reinforced the need to obtain generalizable estimates from a more homogeneous network.

Given the challenges listed above, the current NOFO is designed to use knowledge gained from the DiCAYA study and its predecessors while addressing DiCAYA's limitations, including improved methodological alignment and data harmonization across participating centers. Thus, this new NOFO aims to conduct surveillance of diabetes strictly across demographically and geographically representative health system and/or health plan membership-based centers to estimate the incidence and prevalence of diabetes among youth and young adults overall and by age, sex, race and ethnicity, geographic area, and diabetes type. The NOFO also intends to estimate the prevalence of risk factors for diabetes complications, occurrence of acute and chronic diabetes complications, and use of diabetes medications among youth and young adults with diabetes. This NOFO will establish a systematic, comprehensive, and sustainable surveillance system capable of providing timely information on the burden of diabetes among youth and young adults in the United States.

References:

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report website [Available from: https://www.cdc.gov/diabetes/php/data-research/index.html.

2. Wagenknecht LE, Lawrence JM, Isom S, Jensen ET, Dabelea D, Liese AD, et al. Trends in incidence of youth-onset type 1 and type 2 diabetes in the USA, 2002-18: results from the population-based SEARCH for Diabetes in Youth study. Lancet Diabetes Endocrinol. 2023;11(4):242-50.

3. Benoit SR, Hora I, Albright AL, Gregg EW. New directions in incidence and prevalence of diagnosed diabetes in the USA. BMJ Open Diabetes Res Care. 2019;7(1):e000657.

4. Saelee R, Hora IA, Pavkov ME, Imperatore G, Chen Y, Benoit SR, et al. Diabetes Prevalence and Incidence Inequality Trends Among U.S. Adults, 2008-2021. Am J Prev Med. 2023;65(6):973-82.

5. Casagrande SS, Lessem SE, Orchard TJ, Bullard KM, Geiss LS, Saydah SH, et al. Comparison of several survey-based algorithms to ascertain type 1 diabetes among US adults with self-reported diabetes. BMJ Open Diabetes Res Care. 2020;8(2).

6. Lawrence JM, Divers J, Isom S, Saydah S, Imperatore G, Pihoker C, et al. Trends in Prevalence of Type 1 and Type 2 Diabetes in Children and Adolescents in the US, 2001-2017. JAMA. 2021;326(8):717-27.

7. Lawrence JM, Slezak JM, Quesenberry C, Li X, Yu L, Rewers M, et al. Incidence and predictors of type 1 diabetes among younger adults aged 20–45 years: The diabetes in young adults (DiYA) study. Diabetes research and clinical practice. 2021;171:108624.

8. Hirsch AG, Conderino S, Crume TL, Liese AD, Bellatorre A, Bendik S, et al. Using electronic health records to enhance surveillance of diabetes in children,

adolescents and young adults: a study protocol for the DiCAYA Network. BMJ open. 2024;14(1):e073791.

Healthy People 2030 and other National Strategic Priorities

This NOFO supports the following diabetes Health People 2030 objectives: 1) reduce the number of diabetes cases diagnosed yearly (D-01); and 2) reduce the proportion of adults with diabetes who have an A1c value above 9 percent (D-03). This project will support these objectives by providing data on the burden of diabetes among US youth and young adults by age, sex, race and ethnicity and diabetes type as well as the prevalence of elevated glycemia (i.e., A1c ≥ 9.0%) among youth and young adults with diabetes.

The 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, program, and policies that translate science into practice."

Public Health Impact

This NOFO directly supports the Division of Diabetes Translation's mission by assessing the burden of diabetes among youth and young adults in the United States. This study will provide valuable estimates of diabetes incidence and prevalence among youth and young adults by diabetes type, demographic traits, health insurance status, and geographic area to identify health disparities. The study will also apply surveillance methods to provide information on the prevalence of diabetes complication risk factors, acute and chronic diabetes complications, and use of diabetes medications among youth and young adults with diabetes. Results from this NOFO will assist with the achievements of measuring how diabetes and its complications affect populations in the United States, reducing the preventable burden of diabetes, and health equity. This information will be used to inform decision-making and prioritize national public health objectives.

Relevant Work

This NOFO is associated with DP-20-001, Assessing the Burden of Diabetes by Type in Children, Adolescents and Young Adults (DiCAYA). The DiCAYA study was funded to estimate the prevalence, incidence, and trends of diabetes among youth and young adults (0–44 years) by diabetes type, age, sex, race and ethnicity, and geographic area. It includes eight surveillance centers that are either geographical, health system, or membership-based and conduct diabetes surveillance across geographically diverse populations in the United States.

This NOFO builds upon the methods and lesson learned during the DiCAYA study on how to use electronic health records to conduct diabetes surveillance among youth and young adults. Specifically, this NOFO aims to utilize the tested methods established in DiCAYA across a more homogeneous surveillance system to provide network-wide estimates of diabetes incidence and prevalence among youth and young adults. In addition, this NOFO aims to focus on important attributes of public health surveillance methods including simplicity, flexibility, data quality, representativeness, timeliness, and stability over time. Applicants are encouraged to review methods reported from DP-20-001 in developing their proposals.

2. Approach

This NOFO aims to conduct diabetes surveillance across health system and/or health plan membership-based centers to:

1. Estimate incidence and prevalence of diabetes in youth (< 18 years) and young adults (18–44 years) in the United States. These estimates are sought by diabetes type, demographic traits, health insurance status, and geographic area to identify disparities in diabetes burden.
2. Ascertain the prevalence of risk factors for diabetes complications, occurrence of acute and chronic diabetes complications, and use of diabetes medications among youth and young adults with diabetes.

There are two components in this NOFO:

- **Component A (Youth and Young Adult Diabetes Surveillance Centers):** Component A applicants should be able to create health system or health plan membership-based surveillance centers capable of identifying youth (< 18 years) and young adults (18–44 years) with incident or prevalent diabetes. Component A applicants are expected to have established access to diabetes cases among youth (< 18 years) and young adults (18–44 years) and standard operating procedures in place that allow for the development of protocols/agreements that are necessary for participation in a multi-center study (e.g., data sharing agreements).

  Awarded centers will conduct standardized ascertainment, validation, and classification of diabetes cases across their respective source population to estimate the incidence and prevalence of diabetes among youth and young adults by age, sex, race and ethnicity, diabetes type, health insurance coverage, and geographic area. Awarded centers will also characterize clinical aspects of diabetes among youth and young adults in the United States, including risk factors for diabetes complications, the occurrence of acute and chronic diabetes complications, and use of diabetes medications.

  Component A applicants are expected to have access to a large population under surveillance (i.e., denominator greater than 500,000 people) for both age groups constructed using methods such as health system utilization or health plan membership enrollment. It is expected that Component A applicants include detailed information of the population under surveillance and its representativeness to the population of youth and young adults residing within the center's geographic catchment area. This includes a complete description of the population under surveillance by age, sex, race and ethnicity, health insurance coverage, and geographic area. Component A applicants are expected to describe completeness (i.e., level of missingness) of the data across these key characteristics as well.

  Possible data sources include electronic health records, administrative claims, and diabetes registries. Component A applicants are also expected to be able to implement Common Data Models (i.e., community data standards) to allow for harmonization across heterogenous data sources and improve analytic efficiency.

- **Component B (Coordinating Center):** Component B will serve as the Coordinating Center and will provide an infrastructure for standardized approaches, analytical methods, and measures to be used for surveillance across Component A centers (common protocol). This includes creating data validation protocols and mechanisms to secure transmission of data and relevant data management reports between Component A

awardees. The Coordinating Center will also create and maintain a central data repository for the study and ensure the training and certification of staff at Component A centers on 1) the procedures stated in the protocols corresponding to definitions for diabetes and diabetes related outcomes and 2) the transfer of data to a central data repository.

The Coordinating Center will also provide innovative statistical and analytic support including the development of analytic methods to identify incident and prevalent diabetes cases, validate diabetes cases by type, correct for potential sources of bias, and aggregate and harmonize data across Component A centers. It will support the timely dissemination of network-wide results describing the incidence, prevalence, and clinical characteristics of diabetes among youth and young adults in the United States.

The Coordinating Center will conduct administrative functions to support the coordination of the Component A centers, including maintaining internal and external websites, disseminating information to study investigators and to the public, and providing consolidated estimates of the study's outcomes. It will also be responsible for developing a Steering Committee, the main governing body for the study (please refer to Section VI.4 for more information).

Applicants can apply for Component A or Component B; however, applicants cannot apply for both Component A and Component B.

Objectives/Outcomes

Component A:

The objective of Component A is for health system and/or health plan membership-based centers to identify diabetes cases among persons aged 0–44 years in their respective source populations to:

- Estimate the incidence and prevalence of diabetes among youth (< 18 years) and young adults (18–44 years) in the United States.
    - Diabetes incidence and prevalence will be estimated overall and by age, sex, race and ethnicity, diabetes type, and geographic area.
- Provide a comprehensive clinical description of youth and young adults with diabetes including, but not limited to, the prevalence of:
    - Risk factors for diabetes complications such as poor glycemic control (i.e., A1c ≥ 9.0%), hypertension, dyslipidemia, medication non-compliance, and obesity.
    - Acute and chronic diabetes complications such as hyperglycemic crisis (diabetic ketoacidosis and hyperosmolar hyperglycemic state), retinopathy, nephropathy, and neuropathy.
    - Diabetes medication use such as insulin, metformin, dipeptidyl peptidase-4 inhibitors, glucagon-like peptide-1 receptor agonists, sodium-glucose transporter 2 inhibitors, sulfonylureas, and thiazolidinediones.

Component B:

The objective of Component B is to serve as a Coordinating Center to develop and support a common protocol for the Component A centers. This will include the following activities:

- Provide expertise and leadership in diabetes surveillance development, methodology, implementation, and evaluation. Lead the development and standardization of methods to:
    - Identify incident and prevalent diabetes cases.
    - Validate diabetes cases by type.
    - Correct for potential sources of bias or ascertainment issues.
    - Aggregate data across Component A centers in a statistically reliable manner.
- Create and maintain a central data repository.
- Create protocols and mechanisms to secure transmission of data and relevant data management reports between Component A awardees.
- Ensure the training and certification of staff at Component A sites on all study protocols.
- Provide statistical expertise and support timely dissemination of network-wide results describing the incidence, prevalence, and clinical characteristics of diabetes among youth and young adults in the United States.
- Maintain internal and external website(s) for dissemination of information among study investigators and to the public.
- Process requests from external researchers interested in collaborating on ancillary studies, including potential development of restricted (deidentified) datasets with documentation (e.g., codebooks).
- Create a harmonized, deidentified dataset to be shared with CDC.
- Develop a Steering Committee for the study (please refer to Section VI.4 for more information).

Component A and B awardees are expected to communicate results to the broader scientific and public health communities through peer-reviewed journals, presentations at scientific meetings, and other means. Awardees are also expected to provide relevant results to CDC to support the National Diabetes Statistics Report.

Population of Focus

The target population is youth (< 18 years) and young adults (18–44 years) in the United States. Per the objectives of the NOFO, Component A applicants will need to identify a population for surveillance (i.e., denominator) from which incident and prevalent diabetes cases can be ascertained among youth and young adults. The population under surveillance at each Component A center should be demographically and geographically representative of the youth and young adults residing within the center's geographic catchment area.

Collaboration/Partnerships

Component A:

- Applicants should demonstrate partnerships with health systems or health plan membership networks to be able to identify diabetes cases and describe the sociodemographic and clinical characteristics among youth and young adults affected by diabetes. Applicants should demonstrate experience in working collaboratively with research partners.

- 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 are expected to have standard operating procedures in place that allow for participation in a multi-center study and the development of necessary protocols such as data sharing agreements.

Component B:

- Applicants are expected to collaborate with members in Component A 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. Applicants should demonstrate experience in coordination of multi-center studies, large data management, and innovative analysis. Applicants should demonstrate experience in working collaboratively with research partners.

Evaluation/Performance Measurement

Component A:

- Selected evaluation/performance measures are expected to include a description of the population under surveillance how it will be used to identify cases of diabetes among youth and young adults. Selected evaluation measures should provide an assessment of consistency of methods over time and completeness of case ascertainment.
- Applicants are expected to incorporate evaluation/performance measures that include approaches for identifying incident and prevalent cases of diabetes, validating diabetes type, and characterizing clinical aspects of diabetes among youth and young adults. Emphasis should be on rigorous scientific approaches and methodologies.
- Evaluation /performance measures are expected include methods to assess sensitivity, specificity, and positive predictive value of diabetes case ascertainment overall and by diabetes type. Selected evaluation methods should provide an assessment of whether the accuracy of methods differ by age group, race and ethnicity, health insurance coverage, or geographic area.

Component B:

- 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 to ensure high data quality and accuracy.
- Performance measurements should include statistical approaches to account for data limitations and/or combine Component A data sources to produce reliable network-wide estimates for all study outcomes.

Components A and B: For all performance/evaluation measurements, please upload all documents in the “Other Attachments” section of the application.

Translation Plan

Awardees are expected to work collaboratively with each other and in consultation with CDC to develop methods to provide reliable network-wide results that describe the incidence, prevalence, and clinical characteristics of diabetes among youth and young adults in the United States. Awardees 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. Awardees will provide relevant results to CDC to support the National Diabetes Statistics Report. Awardees are expected to engage with public health entities to translate findings for state and local communities.

Components A and B: For all translation plans, please upload all documents in the “Other Attachments” section of the application.

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:

CA (Cooperative Agreement)

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

Application Types Allowed:

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

Estimated Total Funding:

$12,800,000

Funding for the first 12-month budget period by Component is expected to be as follows (including both direct and indirect):

- Component A: (up to five awards) at $500,000 per award.
- Component B: (up to one award) $700,000.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (for Component A $500,000 and for Component B $700,000), CDC will consider the application non-responsive and will not enter into the review process. CDC will notify the applicant that the application did not meet submission requirements.

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

Throughout the period of performance, CDC's commitment to continuation of awards will be conditional on 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.

Anticipated Number of Awards:

6
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$700,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
4 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 (https://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.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

99 (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 encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations

Regional Organizations

Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."

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

accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR.

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

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

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

3. Additional Information on Eligibility

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

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

Component A:

- Applicants must provide evidence of continued access to health information data among youth (< 18 years) and young adults (18–44 years) during the period of performance for the purposes of diabetes surveillance. Evidence of data access can be in the form of letter(s) of agreement with home institution or data use agreements (if obtained from other sources). The letter(s) must specify that data will be available for the duration of the period of performance. Evidence must be provided in an Appendix.
- Letter(s) of agreement from the institution(s) providing data for the project that permit the applicant to participate in a multi-center study that will require data sharing with other institutions. Evidence must be provided in an Appendix.
- Applicants may not request funding above $500,000 (including both direct and indirect) in the first 12-month budget period.
- Applicants must specify they are applying for Component A in the specific aims.

Component B:

- Applicants may not request funding above $700,000 (including both direct and indirect) in the first 12-month budget period.
- Applicants must specify they are applying for Component B in the specific aims.

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 Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering

System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

(Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.

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 Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal 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 an 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 Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, 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.gov 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 SAM.gov and the SAM.gov Knowledge Base.

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 UEI number to the recipient organization.

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

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. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.

9. Cost Sharing

This NOFO 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.

Number of Applications Allowed:

- **Only one application per institution (normally identified by having a unique entity identifier [UEI]) is allowed.**

Applicants can apply for Component A or Component B; however, applicants cannot apply for both Component A and Component B.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov 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: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide 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 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.

Please note: 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.

3. Letter of Intent

Due Date for Letter Of Intent 12/10/2024

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows CDC staff to 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 Institution
Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel

Participating institutions

Place the number and title of this funding opportunity in the subject line.

The letter should be emailed to:
Celeste Sanders, PhD
Scientific Program Official
Email: CSanders4@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 at How to Apply - Application Guide 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 timeline.
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. **Other Plan(s)**
12. **Authentication of Key Biological and/or Chemical Resources**
13. **Appendix**

All instructions in the SF424 (R&R) Application Guide at How to Apply - Application Guide 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 Other Plan(s) 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 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);
- A statement (required) of any limitations you may encounter with sharing data collected or generated under this award with CDC (such as legal, regulatory, policy, or technical concerns);
- 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).

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

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/nccdphp/dch/media/files/Data-Management-Plan-template.docx

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

Research Plan

Applicants' research plan must address activities that will be conducted during the 4-year period of performance and should include the following items:

Component A:

- Include detailed information on the research infrastructure, health system and/or health plan membership network, and the specific data sources that will be used to identify incident and prevalent diabetes cases among youth and young adults. This could include,

but is not limited to, electronic health records, administrative claims, and diabetes registries.

- Describe the population under surveillance (i.e., denominator) and the geographic area covered by the surveillance center (i.e., geographic catchment area).
- Include information on the population under surveillance overall and by age, race and ethnicity, health insurance coverage, and geographic representation. Provide detailed information on data completeness and representation of youth and young adults from racial and ethnic minority groups and lower socioeconomic statuses.
- Describe the representativeness of the population under surveillance with respect to population of youth and young adults residing within the geographic catchment area.
- Provide a description of the study design and methodological approaches that will be used to identify incident and prevalent cases of diabetes, validate diabetes type, and characterize clinical aspects (prevalence of diabetes complication risk factors, acute and chronic diabetes complications, and use of diabetes medications) of diabetes among youth and young adults.
- Describe partnership/network(s) which will provide information on diabetes cases across the population under surveillance. Describe plans for collaboration to accomplish goals and surveillance efforts including identification of roles, effort, and commitment. Include letter(s) of agreement and/or data use agreements as necessary.
- Describe experience in collaborating with other partners in a multi-center study.
- Describe readiness/preparation to coordinate with other Component A awardees and the Coordinating Center (Component B awardee) on database development, data management, data sharing, development of reports, data analysis, and protocol development.
- Describe methods for network-wide coordination. Describe readiness/preparation to coordinate with other awardees, including data sharing with the Coordinating Center (Component B awardee).
- Describe the institution's research infrastructure and ability to carry out large, complex, population-based projects. Include information on the physical facilities, data management and computer resources, and facilities for data retrieval and storage. Include a description of staffing and management plans.
- 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 researchers' time to spend on this research project; (c) continued access to data source(s); (d) approval for travel for required staff and PI to attend project meetings; and (e) maintain IRB oversight of human subjects research activities.

Component B:

- 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 support.
- Describe experience in providing data management, analysis, and statistical support to multi-center research projects. Include development and management of multi-center database, design, analyses, interpretation of data, data summaries, and statistical reports.

- Describe understanding of conducting surveillance using diverse data sources (e.g., electronic health records) including approaches for estimating incidence and prevalence and addressing representativeness and ascertainment issues.
- Include a plan for evaluating surveillance activities, including ascertaining incident and prevalent diabetes cases in target population.
- Describe methods for network-wide coordination. Include plans for development and maintenance of central data system or database, data management, and coordination with Component A awardees. Describe readiness/preparation to coordinate with other awardees (Component A) on database development, data management, data sharing, development of reports, data analysis, and protocol development.
- Describe the institution's research infrastructure and ability to carry out large, complex, population-based projects. Include information on the physical facilities, data management and computer resources, and facilities for data retrieval and storage. Include a description of staffing and management plans.
- 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 researchers' time to spend on this research project; (c) approval for travel for required staff and PI to attend project meetings; and (d) maintain IRB oversight of human subjects research activities.

Components A and B:

- Provide staffing plan that defines roles, responsibilities, and qualifications of the team and expected contribution of key/collaborative partners.
- Provide detailed timeline including realistic and measurable milestones for the proposed activities. Include detailed budget plan that is linked to the activities and milestones.
- Describe plans and timeline for production of reports and dissemination of study findings. Reports should include interim progress reports, technical reports, professional presentations, and publications that will be produced collaboratively with CDC.

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 publicly 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 12 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 at .How to Apply - Application Guide.

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

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. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications 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 must be 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/support
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 01/10/2025

Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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 and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 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.

Public Health Data:

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.

Data Management Plan:

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 Other Plan(s) section of the PHS 398 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, but not limited to, any statutory limitations prohibiting data sharing, privacy and confidentiality considerations, embargo issues).

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.

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/additional-requirements/ar-25.html

Human Subjects:

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

11. Intergovernmental Review

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal Programs. No action is needed.

12. Other Submission Requirements and Information

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."

Other information: In the first 12-month budget period, include travel costs to attend one in-person meeting of funded sites.

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 Senior/Key Personnel (including any Program Directors/Principal Investigators (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.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the UEI 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 (https://www.cdc.gov/about/divisions-offices/index.html), 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 public health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Components A and B:

- To what extent will the proposed research aid in developing a scalable, sustainable, and timely surveillance system for diabetes in youth and young adults in the United States?

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 surveillance and multi-center studies?
- Does the applicant provide evidence to demonstrate success in conducting surveillance and research among youth and young adults (i.e., the population under surveillance)?
- Does that applicant have a team of investigators with sufficient knowledge and expertise in diabetes surveillance?
- Does the applicant have a body of work that has contributed to improvement in public health practice and population health?

Component B:

- Does the applicant provide sufficient evidence to demonstrate assembly of a team with experience in surveillance and multi-center studies?
- Does the applicant provide an adequate plan for coordinating a multi-center surveillance study?
- Does the applicant provide evidence to demonstrate expertise and innovation in biostatistics, data collection, and data analysis?
- Does that applicant have a team of investigators with sufficient knowledge and expertise in diabetes surveillance?
- Does the applicant have a body of work that has contributed to improvement in public health practice and population health?

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?

Components A and B:

- 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 the 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 research project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves human subjects and/or 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?

If applicable, how will populations with health disparities be considered and addressed in the design and implementation of the proposed research activities?

Component A:

- Does the applicant have access to longitudinal health information across a health system or health plan membership network that can be used to identify incident and prevalent cases of diabetes among youth and young adults? Is there an adequate description of the partnerships/networks that will provide access to information on the diabetes cases and the data sources that will be used for the project?
- Does the applicant provide a detailed description of the population under surveillance (i.e., denominator)? Is the applicant able to define a denominator within a geographic area using criteria such as utilization of a health system or enrollment in a health plan? Does the applicant have denominators greater than 500,000 people for both youth (< 18 years) and young adults (18–44 years)?
- Does the applicant adequately describe the population under surveillance, including age, sex, race and ethnicity, health insurance coverage, and geographic distribution? Is it representative of the population of youth and young adults residing within the geographic catchment area?
- Does the applicant provide a robust approach to identify and validate incident and prevalent cases of type 1 and type 2 diabetes among youth and young adults? Does the applicant have access to prior years and a thorough plan to confirm if cases of diabetes are incident or prevalent?
    - Does the applicant include a robust plan to evaluate the surveillance of type 1 and type 2 diabetes among youth and young adults?
- Does the applicant have a comprehensive plan for providing a detailed clinical description of youth and young adults affected by diabetes, the including prevalence of (a) diabetes complication risk factors, (b) acute and chronic diabetes complications, and (c) use of diabetes medications? Does the applicant describe a sound approach to optimize 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 Principal Investigator or co-Principal Investigator have a history of conducting completely funded peer-reviewed research on the epidemiology of diabetes or population-based surveillance studies? Is there evidence of prior experience in working collaboratively in a multi-center 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 to spend on this project; (c) continued access to data source(s); (d) approval of travel for required staff and PI to attend project meetings; and (e) maintaining IRB oversight of human subjects research activities?

Component B:

- Does the applicant describe a sound approach to optimize data collection, validation, and data quality?
- Does the applicant provide evidence of innovative biostatistical and epidemiological experience in surveillance?
- Does the applicant describe an approach to evaluate sensitivity, specificity, and positive predictive value of the data?
- Does the applicant include a robust plan to evaluate surveillance activities, including the ascertainment of incident and prevalent diabetes cases among the target population?
- Does the Principal Investigator or co-Principal Investigator have a history of conducting completely funded peer-reviewed research on the epidemiology of diabetes or population-based surveillance studies?
- Does the applicant provide evidence of prior experience coordinating a population-based, multi-center study with a standard protocol?
- Does the applicant describe an approach to disseminate results in a timely manner?
- 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 to spend on this project; (c) continued access to data source(s); (d) approval of travel for required staff and PI to attend project meetings; and (e) maintaining IRB oversight of human subjects research activities?

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?

To what extent will findings be disseminated to communities and populations of focus in an appropriate and accessible manner?

Component A:

- Is there evidence of health system or health plan membership network data that can be accessed to identify incident and prevalent diabetes cases among youth and young adults?

- Does the applicant provide evidence that the health information data used at their respective center can be shared with the Component B awardee (i.e., Coordinating Center) to provide network-wide estimates?

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

Component B:

- Does the applicant have a team capable of providing data management, analysis, and statistical support in a multi-center study?
- Does the applicant describe an institutional research infrastructure to carry out large, complex, population-based projects?
- Does the applicant adequately describe the physical facilities, data management and computer resources, and facilities for data retrieval and storage?

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/additional-requirements/ar-1.html).

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/women/research/index.htm) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/grants/additional-requirements/ar-28.html).

Vertebrate Animals

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

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

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

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

3. Additional Review Considerations

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

Applications from Foreign Organizations
N/A

Resource Sharing Plan(s)
Reviewers will comment on whether the Resource Sharing Plan(s) (e.g. Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

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 budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

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 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.
- Surveillance centers (Component A applicants) that provide geographic diversity to the overall network.
- Surveillance centers (Component A applicants) that provide demographic diversity to the overall network.
- Surveillance centers (Component A applicants) with denominators with at least 500,000 individuals in each age group of interest (i.e., youth [< 18 years]) and young adults [18–44 years]).
- Evidence of partnership/collaboration(s) with state and local public health entities.

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 with 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 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 review of risk may impact award eligibility.

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 45 CFR Part 75, subpart F, 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. Additionally, we may ask for additional information prior to the award based on the results of this risk review.

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 UEI, 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).

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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 recipient'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. See CDC General Terms and Conditions.

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

AR-1: Human Subjects Requirements

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

AR-7: Executive Order 12372, Intergovernmental Review of Federal Programs

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-15: Proof of Non-profit Status

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

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

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Accessibility Provisions and Non-Discrimination Requirements are incorporated into CDC General Terms and Conditions

AR-36: Certificates of Confidentiality

AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

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 applies 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: https://www.plainlanguage.gov/.

Employee Whistleblower Rights and Protections: Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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. Applicants may include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets. 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 without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. 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 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. Recipients

(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 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/additional-requirements/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/additional-requirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

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

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

- **Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additional-requirements/ar-25.html**
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The recipient will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Develop a Data Management Plan (DMP) prior to the initiation of generating or collecting public health data.

Component A:

- Participating in the Steering Committee, the primary governing body of the study comprised of the PIs from each center and NCCDPHP project scientist(s).
- Establishing and maintaining partnership(s) with health system and/or health plan membership networks with access to health information data on youth and young adults with diabetes.
- Participating in methodology and protocol development for the study, ongoing data collection, quality control, data analysis, interpretation, and dissemination of study results (including peer-reviewed journals).
- Execution of the protocol and provision of progress reports to the CDC.
- Collaborating with other study investigators and following common protocol and manuals of operation approved 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.
- Coordinate PIs and key staff for project meetings with CDC scientific consultants.

Component B:

- Formation of the Steering Committee consisting of a PI from each center and NCCDPHP project scientist(s). The Steering Committee will have 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 approaches for surveillance and the design, implementation, and quality control for multi-center 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 surveillance centers (Component A awardees).
- Establish a database to accommodate data generated by each surveillance center, developing an electronic data transmission mechanism if needed, and assessing the data quality and completeness throughout the study.
- Execution of the protocol and provision of progress reports to the CDC.
- Provide progress reports of the study to the Steering Committee and 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.
- Convene an annual in-person meeting at CDC or in a commuting area within an awardee’s location.
- Share a harmonized, deidentified dataset with CDC.

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

- **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 https://www.cdc.gov/grants/additional-requirements/ar-25.html**
- Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Collaborate with recipients in overall project planning and development, including development and selection of data collection instruments and protocols, and data abstraction forms.
- Review and approve the recipients' proposed staffing plan and proposed subcontracts.
- Assist in development of data analysis plans, analysis, and interpretation of data analysis, both quantitative and qualitative.
- Monitor and evaluate the accomplishments of the project. This will be accomplished through periodic in-person meetings, telephone calls, and review of technical reports and interim data analyses.

Additionally, a Scientific Program Officer in the NCCDPHP Extramural Research Program Office and Services (ERPOS) will be responsible for the normal scientific and programmatic stewardship of the award as described below:

- Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award.
- Serve as the primary point of contact for official pre-award activities and for all award-related activities, including an annual review of the recipient's performance as part of the request for continuation application.
- Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application.
- Carry out continuous review of all activities to ensure objectives are being met.
- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes.
- Monitor performance against approved project objectives.

Areas of Joint Responsibility include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- For applications that are successfully funded under this NOFO, the recipient agrees that upon award, the application and the summary of reviewers' comments for the application may be shared with the CDC staff who will provide technical assistance, as described above.
- The Steering Committee, the main governing board of the study, will be comprised of the PIs from each study center and NCCDPHP project scientist(s) as a non-voting consultant(s). 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 for the study. It will have the primary responsibility for developing common research designs, protocols, manuals of operation, facilitating the conduct and monitoring of studies, and reporting study results. The Steering Committee must approve the study protocol and changes to the protocol. The PI from each center 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 for any 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(s). 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, PIs 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 submit:

Annual Performance Report (APR)/RPPR is due 120 days before the end of the current budget period, or the date identified in the guidance that CDC distributes. 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.

Annual Federal Financial Report (FFR) SF-425 (Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**

Closeout Reports: a final progress report, invention statement, equipment/inventory report, and the **Final FFR (SF-425)** are required **120 days after the end of the period of performance.**

B. Content of Reports

1. Annual Performance Report (APR)/RPPR: The recipient's continuation application/progress report 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 contribute 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 the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The Final FFR (SF-425) 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.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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 (SF-425), final progress report, and Final Invention Statement and Certification within 120 days after the end of the period of performance. 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).

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 recipient'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.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

7. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be

submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

“Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

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
https://www.grants.gov/support
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
https://www.era.nih.gov/need-help
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time; closed on Federal holidays

Scientific/Research Contact(s)
Celeste Sanders, PhD
Scientific Program Official
Extramural Research Program Operations & Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30341
Email: CSanders4@cdc.gov

Peer Review Contact(s)
Catherine Barrett, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
Telephone: (404) 718-7664
Email: ohi6@cdc.gov

Grants Management Contact
Angie N. Willard
Grants Management Officer, Team Lead
Research, Branch 2
CDC/OCOO/OFR/OGS
Telephone: (770) 488-2863 | CDC iPhone: (770) 568-8762
Email: aen4@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 of Federal Regulations.