Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Real-world effectiveness of structured lifestyle interventions in preventing type 2 diabetes

RFA-DP-22-001

02/01/2022

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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

Real-world effectiveness of structured lifestyle interventions in preventing type 2 diabetes

Activity Code

U18

Amendment II. Made January 27, 2022

- Section I. Changed application due date to 2/1/2022 and expiration date to 2/2/2022.
- Section IV. Changed application due date to 2/1/2022.

Amendment I. Made December 17, 2021

- Section I. Funding Opportunity Description, 2. Approach, Objectives and Section IV. Application and Submission Information, Research Plan, Core components: specific language has been added.
- Section II. Award Information, Award ceiling per budget period corrected.
- Section III. Eligibility Information, 5. Responsiveness: Component A and B ceilings added, editing added.
- Section IV. Application and Submission Information, 3. Letter of Intent information added. The LOI date changed to 12/27/2021.
- Section VI. Award Administration Information, 2. CDC Administrative requirements: language added.
- Section VIII. Questions from Potential Applicants and CDC Responses to date: added

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-22-001

Assistance Listings Number(s)

93.068

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity Announcement (NOFO) is to create a research network consisting of multiple study sites for assessing (1) system and individual level barriers and facilitators to participation in and completion of structured lifestyle intervention (SLI) programs as implemented by the CDC National Diabetes Prevention Program (NDPP), including the Medicare Diabetes Prevention Program (MDPP) and (2) the long-term effectiveness and cost-effectiveness of NDPP/MDPP.
This NOFO has two (2) components:
Component A-Longitudinal cohort: The purpose of Component A is to establish a study cohort to:

1. identify system and individual level barriers and facilitators to the enrollment and completion of the NDPP/MDPP, and
2. evaluate the long term (≥5 years) effectiveness and cost-effectiveness of the NDPP/MDPP, which includes the effect of the SLI programs on:

(a) reducing type 2 diabetes onset;
(b) improving cardiovascular disease (CVD) risk factors including body mass index (BMI), blood pressure and lipid levels, and smoking status;
(c) improving health-related quality of life;
(d) reducing health care services utilization and costs.

Component B-Coordinating Center: The purpose of component B is to provide the infrastructure for data storage (if needed), harmonizing data collection and data analysis based on a core study protocol; ensure statistical, logistics, and communications support to enhance the efficiency and productivity for component A activities.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-22-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:
12/27/2021
12/27/2021

Application Due Date:
02/01/2022

02/01/2022

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time.

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:
03/23/2022

Secondary Review:
05/13/2022

Estimated Start Date:
09/01/2022

Expiration Date:
02/02/2022

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.

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

The purpose of this Notice of Funding Opportunity Announcement (NOFO) is to create a research network consisting of multiple study sites for assessing (1) system and individual level barriers and facilitators to participation in and completion of structured lifestyle intervention (SLI) programs as implemented by the CDC National Diabetes Prevention Program (NDPP), including the Medicare Diabetes Prevention Program (MDPP), and (2) the long-term effectiveness and cost-effectiveness of NDPP/MDPP.

This NOFO has two (2) components:

Component A: Applicants for component A will establish a study cohort to (1) identify system and individual level barriers and facilitators to the enrollment and completion of the NDPP/MDPP and (2) evaluate the long term (≥5 years) effectiveness and cost-effectiveness of the NDPP/MDPP, which includes the effect of the SLI programs on (a) reducing type 2 diabetes onset; (b) improving cardiovascular disease (CVD) risk factors including body mass index (BMI), blood pressure and lipid levels, and smoking status, (c) improving health-related quality of life; and (d) reducing health care services utilization and costs.

Component B: The Coordinating Center provides the infrastructure for data storage (if needed), harmonizing data collection and data analysis based on a core study protocol; ensure statistical, logistics, and communications support to enhance the efficiency and productivity for component A activities.

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

Funds Available and Anticipated Number of Awards. The estimated total funding (direct and indirect) for the entire period of performance is $16,000,000 to support up to 6 awards in two components:

1. Component A**:** It is anticipated that up to 5 awards will be made for up to $570,000 (direct and indirect) each in FY2022.
2. Component B: It is anticipated that one award will be made for up to $350,000 (direct and indirect) in FY2022.

Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of eligible applications.

Budget and Project Period. The estimated total funding (direct and indirect) for all components for the first budget period, 09/01/2022 to 08/31/2023, is $3,200,000. The estimated total funding (direct and indirect) for the 5-year period of performance, September 1, 2022 to August 31, 2027, is $16,000,000.

Application Research Strategy Length: Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.

Eligible Institutions/Organizations. Institutions/organizations listed in Section III, 1.A. are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs). Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

NOTE: CDC does NOT make awards to individuals directly.

- **Number of PDs/PIs.** Applications may include more than one PD/PI; however, the first PD/PI listed on the application will be the "contact PD/PI" for all correspondence. Any additional PDs/PIs are permitted but would be referred to as Co-PIs.
- **Number of Applications.** If an applicant organization intends to apply to more than one component in this NOFO, the applicant must submit separate applications for each component. To be funded for Component B, applicants are not required to apply for and be funded for Component A. The PI for Component A may be different from the PI for Component B.
- **Application Type.** New (type 1).
- **Special Date(s).** None.
- **Application Materials**. *See **Section IV.1** for application materials*
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

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

In 2018 an estimated 88 million Americans aged 18 years or older had prediabetes, representing about one third of the US adult population. In 2002, the landmark US Diabetes Prevention Program (DPP) study showed that a structured lifestyle intervention (SLI) was effective in delaying/preventing type 2 diabetes in adults with impaired glucose tolerance (IGT). The SLI was an intensive lifestyle modification program consisting of structured behavioral training sessions aiming at changing diet and physical activity behaviors of individuals who had overweight/obesity and at high risk of type 2 diabetes. The effectiveness of the DPP SLI was similar in all racial/ethnic groups (1-6).

Follow-up data from the US DPP trial and similar trials in China, Finland, and India and computer simulation studies have demonstrated that SLI programs are both effective and cost-effective beyond the active intervention period (7-10). However, the long-term effectiveness and cost-effectiveness of the DPP-like SLI programs as implemented in a real-world setting remain largely unknown because of changes in enrollment criteria and translation strategies of the SLI programs. For example, the study populations in nearly all earlier major type 2 diabetes prevention trials included persons with IGT. In comparison, the SLI programs as implemented in the real-world setting, enrolled persons with prediabetes defined by HbA1c, fasting glucose, or 2-hour glucose levels, or based on type 2 diabetes risk scores with or without blood test values. Also, the SLI program in the US DPP trial included 16 core sessions in the first six months and additional monthly follow-up sessions after that. The intervention program in the trial was delivered in person (group or one-on-one). In contrast, the SLI programs in the real-world settings vary in delivery methods (e.g., in-person versus virtually or individual versus group coaching) and intervention intensity (e.g., frequency of contacts or intervention duration).

Two recent type 2 diabetes prevention trials tested the effectiveness of the SLI in persons with prediabetes identified by HbA1c or impaired fasting glucose (IFG) criteria, but findings from these trials were mixed (11, 12). The Diabetes Community Lifestyle Improvement Program (D-

CLIP) study found a stepwise intervention including lifestyle intervention plus metformin as needed was effective in reducing type 2 diabetes incidence among persons with IGT or IFG plus IGT, but not in persons with isolated IFG (11). The Norfolk Diabetes Prevention lifestyle intervention found that the SLI was effective in reducing type 2 diabetes incidence in persons with IFG and A1c levels of ≥6.0% to <6.5% (12). The study did not include persons with prediabetes with HbA1c values of 5.7% to 5.9%, which account for a significant proportion of the prediabetes population. A systematic review of US studies published between 2003 and 2011, and that translated the DPP trial lifestyle curriculum to real-world settings, found that among the 28 studies included, there was considerable variation in design (four randomized controlled trials, two cluster randomized controlled trials, twenty single group pre-post studies, and two nonrandomized controlled studies), setting (twelve were based in community environments, such as community centers, recreation centers, and faith-based organizations, eleven were conducted in health care facilities, and four studies used online tools), and analytic approach (13). Generally, studies offering more core sessions achieved greater attendance and greater weight loss. In addition, lay educators were as effective in motivating participants to lose weight as qualified professionals, contributing to lower cost of the programs (13). However, these translational trials normally lasted less than 2 years and nearly all studies used body weight reductions as their primary study outcomes. Thus, the long-term effectiveness of the interventions implemented in these trials on type 2 diabetes prevention remains unclear.

In 2010, Congress authorized CDC to establish and manage the NDPP to scale the DPP-like SLI programs nationwide. Eligibility criteria for the NDPP enrollment are broader than those used in the DPP clinical trial, including people with prediabetes, or at high risk for developing type 2 diabetes defined by a score of 5 or higher on the CDC/American Diabetes Association (ADA) Prediabetes Risk Test. A participant entering the DPP must have a high diabetes risk based on either family history, clinical risk factors, history of gestational diabetes mellitus (GDM), or glucose level (HbA1c, fasting or 2-hour after an OGTT glucose levels). The program consists of 16 hourly sessions held at approximately weekly intervals during the first 6 months, followed by a minimum of six sessions held at approximately monthly intervals during months 7–12. The specifics of program delivery can be customized by stakeholders as long as key criteria are met, including the use of a CDC-approved curriculum that focuses on lifestyle change with a moderate physical activity of 150 minutes or more each week, healthy eating, and weight loss of 5–7% over a 1-year period of time. As of July 2021, there were 554,721 people in 1,961 recognized organizations enrolled in the NDPP program.

In March 2016, the HHS Secretary announced that the Diabetes Prevention Program model met the statutory eligibility criteria for expansion into Medicare, based on the results of a model test and the ensuing statement by the CMS Office of the Actuary certifying that expansion of the model would reduce net Medicare spending.
The Medicare Diabetes Prevention Program (MDPP) is a SLI program designed to prevent type 2 diabetes in individuals 65 years and older with prediabetes, as defined by the threshold values of any of the three blood glucose tests (A1c, fasting or 2-hour glucose levels). The MDPP consists of a minimum of 16 intensive “core” sessions of a CDC approved curriculum delivered over six months in a group-based, classroom-style setting and monthly follow-up meetings after the first six months. A payment up to $761 per participant meeting retention goals is reimbursed over a two-year period to MDPP suppliers that achieve the primary goal of at least 5 percent

weight loss by participants in 2021.

Using different enrollment criteria and program specification in the implementation of the DPP-like SLI in the NDPP/MDPP is likely to result in different effectiveness and cost-effectiveness than shown in the original clinical trials, translational trials, and computer simulation studies. In addition, participation in and completion of the NDPP curriculum as well as reaching the 5 percent weight loss goal have been lower among eligible individuals, in particular among racial and ethnic minority groups in the NDPP/MDPP (14), who are at higher risk of developing type 2 diabetes than non-Hispanic white people. The low participation and completion rates of the NDPP could change the effectiveness and cost-effectiveness of the SLI program in real-world settings. Identifying the determinants of the lower uptake of the NDPP in all eligible populations especially in minority groups is critical to improving the effectiveness and cost-effectiveness of the NDPP and MDPP and reducing diabetes-related health disparities.

The purpose of this Notice of Funding Opportunity Announcement (NOFO) is to assess system and individual barriers to and facilitators of participation in the SLI programs of the NDPP/MDPP, and to evaluate the long-term effectiveness and cost-effectiveness of the SLI as implemented in the NDPP/MDPP using real-world data. The study population are individuals who are eligible for the NDPP/MDPP, i.e., persons with prediabetes (defined by HBA1c, fasting glucose, or 2-hours glucose levels, or any combinations of the three measures), or high-risk scores of developing type 2 diabetes identified by risk score tools or risk equations. The SLI programs to be evaluated include interventions that are delivered in person, virtually, or a combination of the two in the NDPP/MDPP.

Healthy People 2030 and other National Strategic Priorities

This NOFO supports the Diabetes Healthy People 2030 objectives: Reduce the number of diabetes cases diagnosed yearly — D-02; Reduce the proportion of adults who don't know they have prediabetes — D-06; Reduce the rate of death from any cause in adults with diabetes — D-09

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

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

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

Public Health Impact

This NOFO is designed to assess system and individual barriers to and facilitators of participation in the NDPP/MDPP, and to evaluate the long-term effectiveness and cost-effectiveness of the SLI program as implemented in the NDPP/MDPP using real-world data. Preventing type 2 diabetes through implementing the SLI program nationwide is the main goal of

the NDPP/MDPP to reduce the harmful health and economic impact of diabetes for the nation. In 2018, 34.2 million Americans had diabetes.

Findings from this NOFO will provide critical information needed to further improve the NDPP/MDPP. Identifying the system and individual barriers to and facilitators of participation in and completion of the NDPP/MDPP is critical to increasing the participation rate in these programs. Selecting the most appropriate population to intervene in the NDPP/MDPP and implementing the most effective and cost-effective SLI strategies to the target population can improve the program efficacy. Specifically, results from this work could provide answers to the following questions:

1. What are the barriers to and facilitators of enrollment in and completion of the NDPP/MDPP? How do health equity-related characteristics, including socio-economic status, neighborhood environment, language and culture, housing, and transportation access such as public transit, differ between those who enrolled (intervention group) and those who were eligible but did not enroll (control group) and between those who successfully complete the program and those who drop out before program completion?
2. What are the long-term (≥5 years) effectiveness and cost-effectiveness of the SLI used in the NDPP/MDPP for type 2 diabetes prevention among adults with high risk of developing type 2 diabetes in a real-world setting in the US?
3. How do the effectiveness and cost-effectiveness of the SLI differ by eligibility criteria (e.g., blood test vs risk test, IFG, IGT)?
4. How do the effectiveness and cost-effectiveness of NDPP/MDPP differ by program delivery mode (in-person, online/virtual, group, individual)?
5. What is the most effective and cost-effective strategy to implement and expand the SLI program in the NDPP/MDPP?

Relevant Work

CDC created the National DPP to address the increasing burden of type 2 diabetes in the United States (National Diabetes Prevention Program | Diabetes | CDC). Through partnerships between public and private organizations, this national program offers evidence-based interventions that help prevent type 2 diabetes in communities across the United States (https://coveragetoolkit.org/). The NDPP lifestyle change program is offered through CDC-recognized organizations, including community-based organizations, hospitals, provider groups, pharmacies, and health plans. These organizations deliver the program in person, online, through distance learning (e.g., remote classroom or telehealth), or a combined approach. Since 2018, the MDPP is offering a SLI program designed to prevent type 2 diabetes in individuals 65 years and older with prediabetes.

About 2,000 recognized organizations and over a half million people enrolled in the NDPP as of July of 2021. From 2012 to 2016, 35.5% of the participants achieved the 5% weight loss goal, 41.8% met the physical activity goal of 150 min per week (14). About half of participants in the NDPP lifestyle change program were retained past 28 weeks. Individuals who were younger or were members of racial/ethnic minority populations and who reported less physical activity or less early weight loss were significantly less likely to be retained in the NDPP (15). Changes in diabetes incidence, CVD risk factors and health care expenditures among the NDPP participants have not been evaluated. Barriers to participate in and to complete the NDPP have not been systematically examined.

The effectiveness and cost-effectiveness of the SLI that were shown in the original clinical trials, translational trials, and computer simulation studies may not hold for the NDPP/MDPP due to using different enrollment criteria, different SLI program delivery methods, and much lower program participation and completion rates.

2. Approach

Objectives

Component A - Longitudinal Cohort:
The primary objective of Component A is to collect data needed for establishing a longitudinal electronic study cohort for answering the two primary research questions: 1) what are the system and individual level barriers to and facilitators of participation in and completion of NDPP/MDPP and (2) what are the long-term effectiveness and cost-effectiveness of SLI programs as implemented in the NDPP/MDPP, measured in reduction of incidence of type 2 diabetes, and improvements in CVD risk factors and in health related quality of life (HRQoL).

The study participants are those who meet the CDC NDPP or MDPP eligibility criteria. Applicants will be expected to identify records of eligible individuals who participate (intervention group) and who do not participate (control group) in the NDPP/MDPP. For the first study objective, applicants shall be able to collect information from both intervention and control groups on their basic socioeconomic characteristics, barriers to and facilitators of NDPP/MDPP enrollment, retention, and completion, including but not limited to availability of NDPP/MDPP providers, physician referrals, access to healthy foods and facilities for physical activities such as gyms and other exercise facilities, built environment to support walking/biking, or parks or trails, neighborhood safety including violence, unsafe air or water, and other health and safety risks, distance to NDPP/MDPP providers, availability of transportation to NDPP/MDPP providers if walking and biking are not feasible, internet access, socio-economic and employment status, urban/rural residence, knowledge of NDPP/MDPP programs, and competing obligations – e.g., nightshift worker, dual caregivers (parent + child), social support/network, community cohesion and more. For the second study objective, applicants shall demonstrate the capacity to collect/link individual level data from different entities, i.e., SLI program information from the NDPP/MDPP providers, electronic health records from health care providers, and health care utilizations and cost data from the insurance claims, and to be able to obtain/link these individual-level data for a minimum of 5 years after NDPP/MDPP enrollment or study entry (i.e., data from the NDPP/MDPP providers are not needed for the control group). The intervention cohort shall include NDPP/MDPP delivered either in person, virtually, or a combination of the two.

The longitudinal cohort includes records of all eligible individuals as defined in the NDPP/MDPP and are divided into two groups: the intervention group, which consists of those who participated in the NDPP/MDPP (either completing or not completing the program); the control group, which consists of those who met the NDPP/MDPP enrollment criteria but did not enroll in the program. Information to be collected for the intervention group includes (1) individual medical/health electronic records data, health care utilization and cost data at least two years prior to the NDPP/MDPP enrollment, and 5 years after the enrollment; (2) demographics, and social determinants of health (SDOH) information (About Social Determinants of Health

(SDOH) (cdc.gov)), attitude to the SLI program (e.g., perceived benefits and barriers); and (3) information on the specific SLI program a participant received (type of the program, number of sessions attended), cost and payment of the SLI program and, healthy behavioral changes such as changes in diet and physical activities of the participants if such data is available from the NDDP/MDPP providers or other sources. Information needed for the control group is the same as for the intervention group except the SLI program information. Data on health-related quality of life for both intervention and control groups is also expected. Potential data sources are electronic data records or data systems from SLI program providers, electronic health records from participants' routine healthcare providers, claims data from the health insurance companies, data from devices and/or big data aggregators (i.e., for neighborhood characteristics), additional surveys of the study participants and/or NDPP/MDPP providers. Applicants for Component A are expected to demonstrate ability to collect all data components and to establish partnerships with organizations that processed the data including, but not limited to, data collection companies, community organizations, SLI providers, health care providers, employers, and health care insurance companies. Capacity to include and follow-up individuals' records from socio-demographic disadvantaged groups is required and is expected to be described in detail.

Establishing a control group is required for Component A. The control group is expected to have a similar health profile as the NDPP/MDPP participants (i.e., eligible but not referred, or referred and not enrolled in NDPP/MDPP). Applicants are expected to describe in detail the data and methods used in establishing the control group and for the follow-up of these individuals' records.

Each applicant for component A is expected to describe in detail their strategy for identifying and follow-up of the study cohort, data collection method, and analytic approach used for the data analysis. A minimum sample size of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant. The 5,000 individuals' electronic records include those who already completed the SLI program before this study or those who enroll in and complete the SLI in the first year of the NOFO period to meet the five-year follow-up requirement of the SLI participants. Additional information on study sample size will be described in the next section.

Component B - Coordinating Center:
Through Component B, a Coordinating Center will support the research activities of Component A. The main objectives of the coordination center related to support include:

1. Maintain the central data (or aggregate data) repository for the longitudinal cohort; create a common data protocol and mechanisms to secure harmonization of data within the cohort sites and between sites; transmit data and relevant data management reports between the recipients for Component A.
2. Provide expertise and leadership in population-based longitudinal data collection, surveillance, methodology, implementation, and evaluation.
3. Provide expert statistical and other analytic support including development of analytic methods and files for validation of pre-diabetes and diabetes diagnosis.
4. Provide innovative biostatistical expertise and support timely dissemination of study results and estimates of real-life type 2 diabetes incidence among adults participating in SLIs.

Objectives/Outcomes

Outcomes:

Component A - Longitudinal Cohort:

The primary outcomes of Component A are: (1) significant barriers to and facilitators of enrollment in and completion of the NDPP/MDPP; and (2) the long term (≥5 years) effectiveness and cost-effectiveness of the NDPP/MDPP. The effectiveness of the NDPP/MDPP is measured in primary and secondary outcomes. The primary outcome is incidence rate of type 2 diabetes. The secondary health outcomes include CVD risk factors and HRQoL. The cost outcome includes changes in health care services utilization and cost before and after the enrollment of the NDPP/MDPP and cost of the programs. Cost-effectiveness measures include cost per case of diabetes prevented and cost per quality-adjusted life year gained. All outcomes are for overall study population and by age group, sex, race/ethnicity, social-economic category, and eligibility criteria for the NDDP/MDPP (HbA1c, fasting glucose, or OGTT, or diabetes risk score).

A minimum of 5,000 NDPP/MDPP participants and an equal or greater number of matched controls is required for each applicant. The total number of participants includes any SLI delivery mode (in-person, virtual or combination of the two). Including participants from all three delivery modes are preferred. The study population should also be socio-demographically diverse and include those who are socioeconomically disadvantaged. The proportion of socioeconomically disadvantaged and ethnic minority groups included in the study should be equal to or greater than their corresponding proportion of the national population with pre-diabetes.

The funding recipients are expected to:

1. Establish an electronic study cohort of persons who are eligible for NDPP/MDPP to identify barriers and facilitators to participating in or completing the NDPP/MDPP, including but not limited to social determinant factors, availability of NDPP/MDPP providers, physician referrals, access to healthy foods and facilities for physical activities, neighborhood safety, distance to NDPP/MDPP providers, availability of transportation to NDPP/MDPP providers, internet access, socio-economic and employment status, urban/rural residence, knowledge of NDPP/MDPP, and competing obligations – e.g., nightshift worker, dual caregivers (parent + child), social support/network, community cohesion and more.
2. Conduct detailed descriptive and modeling analyses of the electronic cohort population (NDPP/MDPP completers, non-completers, and controls) to identify significant barriers to and facilitators for participating in and completing the NDPP/MDPP.
3. Estimate incidence rate of type 2 diabetes for NDPP/MDPP enrollees (completers and non-completers) and risk of type 2 diabetes relative to controls (eligible but not enrolled).
4. Estimate incidence rate of type 2 diabetes in subgroups by age group, sex, race/ethnicity, social-economic category, and eligibility criteria for the NDDP/MDPP (Hb A1c test, fasting or OGTT test, or diabetes risk score).
5. Estimate trends in diabetes risk factors, including, but not limited to bodyweight, BMI, blood glucose levels, dietary and physical activity behaviors.
6. Estimate trends in CVD risk factors, including, but not limited to, BMI, blood pressure, lipid levels, and smoking status.
7. Estimate the intervention cost of the NDPP/MDPP.

8. Estimate trends in health services utilization and cost at least two years before the follow-up and at least 5 years during the follow-up.
9. Estimate the HRQoL at the baseline and during the follow-up.
10. Assess longitudinal epidemiological associations between NDPP/MDPP enrollment criteria, program delivery mode, compliance with the SLI program, provider characteristics and the above outcomes (type 2 diabetes, CVD risk factors, HRQoL, and heath care utilizations and expenditures) with adequate controls and follow-up time.
11. Estimate the cost-effectiveness of the NDPP/MDPP as measured by cost per case of diabetes prevented and cost per quality-adjusted life year.
12. Estimate the effectiveness and cost-effectiveness of the NDPP/MDPP by type 2 diabetes risk level defined by value of the A1c test, fasting or OGTT test or risk score.
13. Estimate the effectiveness and cost-effectiveness of the NDPP/MDPP by delivery mode.
14. Estimate the effectiveness and cost-effectiveness of the NDPP/MDPP by age group and race/ethnic group.

Target Population

Component A - Longitudinal Cohort:
The target population is adults (≥18 years old) in the U.S. at a high risk of developing type 2 diabetes. Applicants' sites are expected to have access to socio-demographically disadvantaged and diverse populations.

Collaboration/Partnerships

Component A - Longitudinal Cohort:
Applicants are expected to demonstrate ability to collect all electronic data components needed to build the longitudinal electronic study cohort as described above. Applicants are expected to link NDPP/MDPP participant information to their electronic medical records and health insurance /Medicare claims data at least two years before the intervention and five years or more after the intervention so that NDPP/MDPP participants (completers and non-completers) can be followed longitudinally. Applicants are also expected to link electronic medical records, health insurance /Medicare claims data for the control group similar to the intervention group for comparing the two groups. Surveying study participants and/or NDPP/MDPP providers to collect information on barriers to and facilitators of participation and completion of the programs, HRQoL, and programs cost, and sources of payments is anticipated. Accessing individual electronic data for the SLI program each NDPP/MDPP enrollee participated in is also required. Applicants are anticipated to show their abilities to link data from all entities that have different data components. These entities include NDPP/MDPP providers, clinical records from the participants' health providers, health insurance/Medicare claim data, and individual-level demographic, socio-economic, health, and health behavioral information of the study participants. Data collection methods can be prospective or a combination of retro- and prospective methods. Applicants using either approach are expected to describe their methods in detail.

Applicants are expected to 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 demonstrate partnerships with health care networks or systems to access information on study participants. Applicants are expected to demonstrate experience in

working collaboratively with research partners.

Component B - Coordinating Center:
Applicants are expected to collaborate with recipients of component A and other partners to accomplish goals and objectives of the study.
The applicant should demonstrate experience in coordination of multi-center studies, data management and innovative analysis. Applicants should demonstrate experience in working collaboratively with research partners.

Evaluation/Performance Measurement
Component A - Longitudinal Cohort:
The applicants are expected to be evaluated based on

1. Ability to collect all longitudinal core data (described below under Research Plan) for the study cohort, including proposed approaches for the data collection, commitment from entities/organizations to contribute the data, experience with working with different partners. Ability and experience to analyze the data collected.

2. Technical approaches to achieve the two study objectives. Justifications for all measures and analytical methods used to assess the barriers to and facilitators of NDPP/MDPP participation and completion, and effectiveness and cost-effectiveness of the SLI program, approaches to identify and validate persons with pre-diabetes and type 2 diabetes and controls for the study, and statistical and economics methods for the data analysis. Strategies and methods used to ensure validity and accuracy of data on race/ethnicity, socioeconomic status of the study population, measures for health services utilization and cost, SLI program cost and health-related quality of life. Methods to collect valid and accurate information on participant's eligibility at the NDPP/MDPP enrollment, SLI program structure and delivery mode, and participant compliances with the SLI programs.

3. Approaches to reach, enroll, and follow-up socio-demographically disadvantaged and diverse populations.

Emphasis should be on rigorous scientific approaches and methodologies and feasibility of the data collection.

Component B - Coordinating Center:
Applicants for Component B are expected to provide:
1) Evidence of organizational experience and capabilities, including, but not limited to: site support, governance support, and staff training plans; plans to ensure the quality and integrity of collected data; plans to maintain accurate and timely information on the progress of study and site performance;

2) Evidence of staff experience and capabilities, including, but not limited to: demonstration of innovative analytic approaches to evaluating research data; and the qualifications and research experience of the management and analytic team.

3) Evidence of specialized capabilities and experience in large scale network coordination, including, but not limited to, previous experience with design, administration, management, and coordination of multi-site studies.

Translation Plan

Applicants for Components A and B are expected to work collaboratively to establish a longitudinal electronic cohort and develop innovative methods for aggregating data and presenting joint analyses that will produce results comparable across sites. Applicants are expected to communicate the findings to the larger scientific and public health communities. The results are expected to be timely communicated through peer reviewed journals, presentations at scientific meetings, and other means. Applicants are expected to engage with public health entities to translate the findings for the state or local communities. **OMB/PRA** may apply.

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13. Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? Health Affairs 31, NO. 1, 2012: 67–75.
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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:

$16,000,000

The estimated total funding (direct and indirect) for the 5-year period of performance, September 1, 2022 to August 31, 2027, is $16,000,000. It is anticipated that 6 awards will be made under this NOFO RFA-DP-22-001.
Funding for the first 12-month (including both direct and indirect costs):
Component A: (up to 5 awards) $570,000 per award
Component B: (1 award) $350,000

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

Anticipated Number of Awards:
6
Award Ceiling:
For Component A:
Award ceiling: $570,000
Award floor: $200,000
For Component B:
Award ceiling: $350,000
Award floor $200,000

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

Award Ceiling:
$570,000
Per Budget Period

Award Floor:
$200,000
Per Budget Period

Total Period of Performance Length:
5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (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:
99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

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)

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

Additional Eligibility Category:

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

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations

Regional Organizations

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

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

Component A - Longitudinal Cohort:

- Applicants must provide evidence of being able to access electronic records for building a cohort of individuals meeting eligibility criteria for the NDPP/MDPP (both participated in the NDPP/MDPP and not participated but eligible for the NDPP/MDPP program), individual program participation information of the NDPP/MDPP participants, medical records and health services utilization and cost data of all study participants.
- A minimum number of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant.
- If the application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

Component B - Coordinating Center:
Not Applicable

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Component A - Longitudinal Cohort:

- Applicants may not request funding above the ceiling amount ($570,000.00) for the first 12-month budget period (includes direct and indirect costs).
- Applicants must provide evidence of being able to access a cohort of individuals meeting eligibility criteria for the NDPP/MDPP (both participated in the NDPP/MDPP and not participated but eligible for the NDPP/MDPP program), individual program participation information of the NDPP/MDPP participants, medical records and health care utilization and expenditure data for all study participants.
- A minimum sample size of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant.
- Evidence can be in the form of a letter(s) of agreement with home institution, data use agreements (if data obtained from other sources). Evidence should be placed in Appendix A.

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

Component B - Coordinating Center:
Applicants may not request funding above the ceiling amount for the first 12-month budget period (includes direct and indirect costs).
If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.
If your application is incomplete or non-responsive to these requirements, it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

Component B - Coordinating Center:
Applicants may not request funding above the ceiling amount ($350,000.00) for the first 12-month budget period (includes direct and indirect costs).
If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.

If your application is incomplete or non-responsive to these requirements, it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

6. Required Registrations

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. 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.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US Instructions for NSPA NCAGE.pdf
- 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 DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. 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.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at 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 DUNS number to the recipient organization.

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

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

9. Cost Sharing

This 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.

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

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

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

Application guides for FORMS-F and FORMS-G 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 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

Please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.

3. Letter of Intent

Due Date for Letter Of Intent 12/27/2021

12/27/2021
12/27/2021
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 for the review. Prospective applicants are asked to submit a letter of intent that includes the following information:
Name of the Institution:
Descriptive title of proposed research, including Component
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions (if applicable)
Number and title of this funding opportunity

The letter should be emailed to: Researchnofo@cdc.gov. Include the NOFO number in the email subject line.

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 time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

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

All instructions in the SF424 (R&R) Application Guide 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 Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

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

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

- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

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

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

Application guides for FORMS-F and FORMS-G 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 5-year project period and should include the following items:
Component A - Longitudinal Cohort:

I. Study components

- 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 for data dissemination and production of reports. Reports include interim progress and final reports, technical reports, professional presentations and publications that will be produced collaboratively with CDC.

II. Core components

Each site is required to provide all of the following core data:

1. Age-specific control groups (i.e., younger than 65 years and 65 years and older, respectively, for the NDPP and MDPP).
2. The number of controls for the overall and stratified analyses will be provided based on power calculations for primary and secondary outcomes if the minimum 5,000 of required number was not adequate. The 5,000 individuals enrolled include those who already completed the SLI program before this study or those who enroll in and complete the SLI in the first year of the NOFO period to meet the five-year follow-up requirement of the SLI participants.
3. Controls are defined as persons who are eligible for the NDPP/MDPP such as with pre-diabetes (based on either HbA1c, fasting or 2-hour plasma glucose, or history of GDM) and elevated BMI; or high-risk scores of developing type 2 diabetes identified by risk score tools or risk equations but they
    a. have not been referred to NDPP or MDPP, or
    b. have been referred but did not enroll in NDPP or MDPP, and

    c. have electronic medical records and health insurance claim data for at least 2 years before and 5 years after the study baseline entry.

4. A follow up time of ≥5 years from the participants' enrollment in NDPP/MDPP (for enrollees) or from baseline cohort entry (for controls).
5. A minimum sample size of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant. The composition of the program enrollees by delivery mode (in person, virtual, or combination) can be varied depending on type of data available to the applicants. The proportion of the racial/ethnic minority populations and socio-economically disadvantaged groups in the study population should be equal to or greater than their corresponding proportions of the national population with pre-diabetes.
6. Applicants with a high proportion of or only in-person NDPP/MDPP enrollees is highly encouraged.
7. Applicants with a high proportion of or only racial/ethnic minority or socio-economically disadvantaged enrollees and controls are highly encouraged.
8. Zip codes or county of residence for cohort participants.
9. Information on SDOH at baseline and during follow-up.
10. Laboratory results, referral notes, and/or risk scores for NDPP or MDPP eligibility at baseline.
11. Quantitative data on the following variables at baseline, at least once during follow-up, and at the end of follow-up as follows:
    a. Metabolic markers, including but not limited to bodyweight, BMI, blood glucose levels (A1c, fasting, or 2-hour glucose test), dietary and physical activity behaviors
    b. CVD risk factors, including, but not limited to, blood pressure, BMI, blood lipid levels, and smoking status
    c. Measures for potential barriers to and facilitators of participation in and completion of SLI programs, including but not limited to factors related to social determinants of health, neighborhood environments, transportation, distance to SLI program site, internet access, urban/rural residence, competing obligations – e.g., nightshift worker, dual caregivers (parent + child), social support/network, community cohesion
12. HRQoL measures, 36-Item Short Form Survey (SF-36) or justification if an alternative measure is proposed.
13. Access to health care records at least two years before enrollment in the SLI program and 5 years or more follow-up after enrollment. Access to health care records for controls. Access to health care records is expected to be maintained through the entire follow-up period.
14. Access to health insurance claims data for NDPP/MDPP participants and for controls, for longitudinal tracking of the health care services utilization and medical cost data. Access to health insurance claims is expected to be maintained throughout the entire follow-up period.
15. Information on prescription/usage of metformin and other drugs (for glycemic control and CVD treatment) throughout the follow-up time.

16. The study design and electronic data collection can be prospective or a combination of retro- and prospective data collection.

III. Analytic approach

- Describe the overall study design to achieve the two main study objectives.
- Estimate unadjusted and adjusted incidence rate (cases/person-years) of type 2 diabetes among adults at high risk of type 2 diabetes, as defined above, participating in the NDPP/MDPP and among controls.
- Describe the method of computing and comparing incidence rate of type 2 diabetes overall and across strata of age, sex, race/ethnicity, socio-economic status, program completion, program delivery mode, and various ways to define prediabetes based on different blood tests and thresholds of the test values, or other type 2 diabetes risk factors.
- Describe the method of computing and comparing measures of barriers and facilitators to participating in and completion of the NDPP/MDPP overall and across strata of age, sex, race/ethnicity, socio-economic status, program delivery mode, and program completion.
- Provide a justification of the sample size needed for the study, overall, for controls, and for stratifications of interest. Include a justification for the choice of statistical tests, approaches to accounting for correlated variables, missingness.
- Describe in detail the population source, overall size, details on demographic, socio-economic, and clinical characteristics.
- Describe type of referral and utilization of NDPP/MDPP (type of delivery methods, number of sessions, time in the program).
- Describe the methodological approach, including methods to identify and validate pre-diabetes and type 2 diabetes cases, CVD risk factors, heath-related quality of life measures, cost and payment structure of the NDPP/MDPP, health services utilization and costs.
- Describe research infrastructure and summary of site-specific data sources to identify incident type 2 diabetes cases in the study population. This could include, but is not limited to, a diabetes registry or electronic health record system.
- Describe partnership/network(s) which will provide access to health records data and to NDPP/MDPP providers' data and commitment from each partner. Describe plan for partners and collaboration to accomplish research goals including identification of roles, effort and commitment.
- Describe experience in collaborating with other partners in a multi-center study.
- Describe readiness/preparation to coordinate with other sites/recipients, including the Coordinating Center (Component B), on data base development, data management, data sharing, data analysis, development of data reports, and protocol development. Include letters of support, publications, abstracts and reports demonstrating previous collaborations.
- Describe methods for study-wide coordination.
- Describe the applicant institutional research infrastructure to carry out large, complex, population-based projects. Include information on applicants' physical facilities, data management and computer resources and facilities for data retrieval, storage, and data security. Include description of staffing and management plans.

- Describe training or developing doctoral, post-doctoral and junior investigators. This may include investigators with a demonstrated interest and history in working with populations with health disparities. Provide detailed plan for training and developing post-doctoral and junior investigators, including encouragement of diversity and inclusion of racial and ethnic minority post-docs and junior investigators.
- Provide letter(s) of support from the applicant's institution that commits the institution to (a) on-going research with this project; (b) a specified percentage of the researchers' time to spend on this research project; (c) continued access to data source(s)/data set(s); (d) approval for travel for required staff and PIs to attend project meetings at CDC Atlanta, in local commute area or Steering Committee-related meetings; and (e) maintain IRB oversight of human subjects activities.

Component B - Coordinating Center:

- Describe experience in directing and operating a coordinating center for collaborative, population based large scale epidemiologic research and/or surveillance projects that include coordination of multiple sites, common protocols, monitoring of site performance, monitoring study progress and providing logistical governance support.
- Describe experience in providing data management, innovative analyses and statistical support to multi-site research projects. Include development and management plans of multi-site database, design, analyses and interpretation of data and development of data summaries and statistical reports.
- Describe understanding of methods and activities for type 2 diabetes incidence rate estimates, potential problems and optimal solutions to address data linkage between NDPP/MDPP providers, health care providers and claims data.
- Describe understanding of potential problems and optimal solutions to address completeness of case identification.
- Describe the applicant institutional research infrastructure to carry out large, complex, projects that require building an infrastructure for data collection. Include information on applicant's physical facilities, data management and computer resources and facilities for data retrieval, storage, and security. Include description of staffing and management plans.
- Describe methods for study-wide coordination. Include plans for development and maintenance of central data system or data base, data management and coordination with sites from Component A. Describe readiness/preparation to coordinate on data base development, data management, data sharing, development of data reports, data analysis, and core protocol development.
- Describe training or developing doctoral, post-doctoral and junior investigators. This may include investigators with a demonstrated interest and history in working with populations with health disparities. Provide detailed plan for training and developing post-doctoral and junior investigators.
- Provide letter(s) of support from the applicant's institution that commits the institution to (a) on-going research with this project; (b) a specified percentage of the researchers' time to spend on this research project; (c) continued access to data source(s)/data set(s); (d) approval for travel for required staff and PIs to attend project meetings at CDC Atlanta,

in local commute area or Steering Committee-related meetings; and (e) maintain IRB oversight of human subjects activities.

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 10 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 20 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.

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

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

Please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.

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/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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

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

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

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

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

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

a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 02/01/2022

02/01/2022
Electronically submitted applications must be submitted no later than 5:00 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 Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/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.

See Section VI.1.

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

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

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

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e., grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Application Submission

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

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

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

Important reminders:

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. 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.

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.d/////

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

Investigator(s)

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

Component A - Longitudinal Cohort:

- Does the applicant provide sufficient evidence to demonstrate assembly of a team with experience related to the proposed research, multi-site studies and a body of work that has contributed to improvement in public health practice and population health?
- Does the applicant provide evidence to demonstrate success in conducting research requiring linkage between SLI providers, health care providers, and health insurance providers?
- Does the applicant provide sufficient evidence to demonstrate success in conducting research requiring establishment of an electronic longitudinal study cohort of persons at high risk of developing type 2 diabetes who participated in the NDPP/MDPP and their comparison group with all required core data component and study sample size?
- Does the applicant provide sufficient evidence to demonstrate success in the collection, analysis, and inference on SDOH related outcomes?
- Does the applicant include adequate plan for training and development of post-doctoral and junior investigators?
- Is there sufficient knowledge and expertise with identifying pre-diabetes and type 2 diabetes?

Component B - Coordinating Center:

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

Innovation

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

application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Component A - Longitudinal Cohort:

- Does the application demonstrate the capability of using innovative methods to identify barriers to participation in and completion of the SLI in the NDPP/MDPP?
- Does the application demonstrate the potential in advancing data linkage methodology for collecting data from various sources and entities?
- Does the application propose innovative methods for sustainably addressing unique challenges in assessing long-term effectiveness and cost-effectiveness of type 2 diabetes prevention in a real-world setting?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) justification for inclusion of minorities and members of socially and disadvantaged groups, in terms of the scientific goals and research strategy proposed
Component A - Longitudinal Cohort:

- Does the applicant provide a robust approach to identify and validate incident cases of type 2 diabetes in the population under study? Does the applicant adequately describe (a) partnership/network(s) which will provide access to information on pre-diabetes and diabetes cases; (b) data sources that will be used; (c) population (individuals eligible for the NDPP or MDPP); (d) methods for estimating incidence rate and trends over the five years of the study.
- Does the applicant provide detailed description of the population under study? Is there over-representation of minority groups, and socio-economic diversity of the sample?
- Does the applicant provide detailed description for the required number of study participants?
- Does the applicant provide detailed description for the required composition of the study participants by the racial/ethnic minority populations and economically disadvantaged groups?
- Does the applicant provide detailed description of strategies used to recruit minority groups and/or low socioeconomic groups who are eligible for the NDPP/MDPP program to the study?
- Does the applicant provide detailed description on how to collect information needed to assess barriers to participate in and complete the NDPP/MDPP SLI programs?

- Does the applicant have access to health information, to determine pre-diabetes and incident cases of diabetes? This could include electronic health information, electronic health records from a single health insurance company, and a network of providers, laboratory and pharmacy data, or a network of health insurance providers. Does the applicant have access to data from prior years to confirm each incident case is a new case and not previously diagnosed with type 2 diabetes?
- Does the applicant describe a sound approach to optimize the electronic data collection, validation and quality control?
    - Does the applicant include an assessment of completeness of the data, possibility of multiple entries for an individual patient, flexibility and timeliness of the system?
    - Does the applicant include a robust evaluation plan to assess the incidence rate (cases/person-years) of type 2 diabetes among adults participating in NDPP/MDPP and among controls?
- Does the Principal Investigator or co-Principal Investigator have a history of conducting competitively funded peer reviewed research on epidemiology of diabetes or longitudinal cohort studies? Is there evidence of prior experience in working collaboratively in a multi-site study or with a standard protocol?
- Is there evidence of prior experience in working collaboratively with SLI providers, health care and health insurance providers?
- Does the applicant provide letter(s) of support from the applicant's institution that commits the institution to (a) ongoing research with this project; (b) a specified percentage of the researchers' time spent on this research project; (c) continued access to and use of the dataset(s); (d) approval of travel for required staff to attend Observational Study Monitoring Board related meetings and (e) maintaining IRB oversight of human subjects research?

Component B - Coordinating Center:

- Does the applicant describe a sound approach to optimizing electronic data collection, validation and quality control?
- Does the applicant provide evidence of biostatistical and epidemiological experience in coordinating large cohort studies?
- Does the applicant include a robust evaluation plan to assess the incidence of type 2 diabetes among adults at high risk?
- Does the Principal Investigator or co-Principal Investigator have a history of conducting competitively funded peer reviewed research on epidemiology of diabetes or health system-based studies?
- Does the applicant provide evidence of prior experience in working collaboratively to carry out health care based multi-center study or standard protocol?
- Does the applicant describe an approach to disseminate results within 6 months of completion of data collection?

Does the applicant provide a letter of support from the applicant's institution that commits the institution to (a) ongoing research with this project; (b) a specified percentage of the researchers' time spent on this research project; (c) continued access to and use of the dataset(s);

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

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Component A and B

- Does the applicant describe an institutional research infrastructure to carry out large, complex projects involving an infrastructure to collect individual-level electronic data from SLI providers, health care and health insurance providers?
- Does the applicant provide description of the applicants' physical facilities, data management and computer resources, and facilities for data retrieval and storage?
- Is there a network of providers or health care systems, including electronic health records from a single health insurance company, network of provider clinics, laboratory and pharmacy data or network of health insurance providers that can be accessed to identify pre-diabetes and incident diabetes cases among adults participating in NDPP/MDPP?

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).

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

Inclusion of Women, Minorities, and Children

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

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

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

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

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

3. Additional Review Considerations

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

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

updated and submitted to CDC at least annually, or whenever plans for data collection or generation activities change. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements. The contents of the DMP are described in AR-25. Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for OMB approved template and guidance. Public health data are expected to be made freely available to the public (in a de-identified format) and archived long-term unless there are compelling reasons not to do so. When it is not feasible to make data freely available to the public, it may be possible to make data available to users on a restricted basis. The DMP should describe the expected level of public access, if any, and must justify the planned access level and describe how privacy and confidentiality will be protected. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data from ongoing surveillance systems which should be made accessible within 12 months of the end of a collection cycle. Awardees who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award. For data underlying scientific publications such as peer review journal articles, awardee should make the data available concurrently with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set accompanying a scientific paper should consist of a machine-readable version of the data tables shown in the paper.

Applications from Foreign Organizations

N/A

Resource Sharing Plan(s)

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

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

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

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

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;

- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

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

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

The budget can include both direct costs and indirect costs as allowed.

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

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

- Will 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.

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

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in

this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under 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.

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. 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 grantee's business official.

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

Additional Requirement – 34: Accessibility Provisions and Non-Discrimination Requirements

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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: http://www.plainlanguage.gov/plLaw/index.cfm.

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

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

> The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply

with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

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

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

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

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

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

Data Management Plan(s)

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

This new requirement ensures that CDC is in compliance with the following; Office of

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

The AR-25 https://www.cdc.gov/grants/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 Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

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

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

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

Component A - Longitudinal Cohort:

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

Component B - Coordinating Center:

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

- Coordinating annual meetings of the Observational Study Monitoring Board (OSMB) that will be appointed by the CDC. The OSMB will consist of a chair, scientists with expertise in epidemiology, biostatistics, diabetes, surveillance and a member of the community. The OSMB will evaluate the study protocol proposed by the Steering Committee based on the importance of the question to be addressed, the scientific merit of the design, feasibility and consistency with NCCDPHP missions and policies. The OSMB will provide a written critique and final recommendation to the CDC. During the implementation phase, the OSMB will monitor each research center for adherence to recommended protocol or procedural changes or early termination of any award for poor performance.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

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

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

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above. Additionally, an HHS/CDC agency Scientific Program Official (SPO) will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be:

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

Areas of Joint Responsibility include:

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

5. Reporting

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

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

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

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

A. Submission of Reports

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

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:
    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current

budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

b) Leadership/Partnership: list project collaborations and describe the role of external partners.

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

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

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

- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations 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 calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to

submit a letter explaining the reason and date by which the Grants Officer will receive the information.

The due date for final FFRs is 90 days after the Period of Performance end date.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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

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

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

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable,

describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

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
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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

Natalie Darling
Scientific Program Official Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE Mailstop F-80
Atlanta, GA 30341
Telephone: 770.488.5740

Email inquiries to: researchnofo@cdc.gov
Note: Include NOFO number in the email subject line when submitting questions

Financial/Grant Management Contact

Angie N. Willard
Grants Management Specialist CDC Office of Grants Services
Telephone: 770-488-2863
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.

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).

APPENDIX A

Questions from Potential Applicants and CDC Responses

Q1. Component A: Is there an exclusion for this participant number requirement for small states?

Response to Q1:
Per Section III. Eligibility Information/3. Additional Information on Eligibility and 5. Responsiveness, all applicants must provide evidence of being able to **access** electronic records for building a cohort of individuals meeting eligibility criteria for the NDPP/MDPP (both participated in the NDPP/MDPP and not participated but eligible for the NDPP/MDPP program), individual program participation information of the NDPP/MDPP participants, medical records and health services utilization and cost data of all study participants. Thus, there is no exclusion. A minimum number of 5,000 NDPP/MDPP program enrollees and equal or greater number of matched controls is required per applicant.

Q2. Component A: "A minimum number of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant." Is this a number of NDPP/MDPP participants that should be achieved over the course of the project? OR is this the number of eligible individuals that should be demonstrated to exist already in the electronic records?

Response to Q2:
Yes. A minimum sample of 5,000 participant electronic records for the intervention group (participants in the NDPP/MDPP). The equal or a greater number of matched controls electronic records (5,000 or more) should be followed for at least 5 years for new-onset type 2 diabetes. See Section I. Funding Opportunity Description, 2. Approach; Section IV. Application and Submission Information, 5. Research Plan, Core components.

Q3. Component A: Applicants are required to submit a budget for a 5-year period of performance with a ceiling of $900,000 for all five years and the first-year award ceiling is $570,000. Those ceilings include both indirect and direct costs. Is my interpretation of the budget requirements correct?

Response to Q3: For Component A, an applicant's first-year ceiling is $570,000 (direct and indirect).

Q4. Component A and B: For funding opportunity, RFA-DP-22-001, could you please confirm if the indirect rate is limited to 8%?

Response to Q4: Under "Budget and Period of Support" on page 40 of the NOFO, it states the 8% only applies to foreign institutions.
"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."

Q5. Component A: I read your NOFO and was perplexed at the sample size of 10,000 per

site (I-5000 vs C-5000). I have been involved in a Cooperative U mechanism, and I am familiar with Power Analysis of such trials. The 10,000 per site (x 5 sites) sounds exorbitant. In the announcement it read, "*information on study sample size will be described in the next section*." But I could not find that section. Can you provide information of how CDC came up with such sample size?

Response to Q5:
This NOFO is intended to evaluate the long-term effectiveness and cost-effectiveness of the SLI as delivered in the NDPP/MDPP, compared with no intervention. It is an observational study, not a random clinical trial. Applicants are required to set up an *electronic* longitudinal follow-up cohort, as described in Section I. Funding Opportunity Description, 2. Approach, Objectives, Outcomes and Target population.

Q6. Component A: Do applications for Component A have to demonstrate 5,000 participants already enrolled in a structured lifestyle program, or must the demonstrate the capacity to reach 5,000 enrollees?

Response to Q6: Applications for Component A need to demonstrate the capacity to collect and link electronic data for 5,000 or more individuals enrolled in NDPP/MDPP and 5,000 or more who are eligible but not enrolled in NDPP/MDPP, which serve as a control group. The 5,000 individuals enrolled include those who already completed the SLI program before this study or those who enroll in and complete the SLI in the first year of the NOFO period to meet the five-year follow-up requirement of the SLI participants. See Section I. Funding Opportunity Description, 2. Approach, Collaboration/Partnerships; and Section IV. Application and Submission Information, Research plan, II Core components.

Q7. Component A: When does the cohort need to be assembled? I see that the grant is for 5 years and that the follow up duration for the cohort is a minimum of 5 years. This would suggest that the cohort needs to already be assembled at the time of the grant start. Or is it possible for the 5 years of follow up to extend beyond the original grant period?

Response to Q7: The follow up duration for the cohort is a minimum of 5 years which could include the electronic data from NDPP/MDPP participants who enrolled in and completed the SLI program in the first year of the grant. The data needed by the study can be collected prospectively or retrospectively (see Section IV. Application and Submission Information, Research plan, II Core components).

Q8. The guidelines for RFA-DP-22-001 note that an LOI is due 12/27/2021. However, there are no instructions on how the LOI should be submitted. Can you please provide the instructions for LOI submission? What are the requirements? Should it be submitted via email and if so, what is the email address?

Response to Q8: The NOFO will be amended in **"Section IV. Application and Submission Information, 3. Letter of Intent**" to include the following LOI instructions that were in advertently omitted:

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 for the review.
Prospective applicants are asked to submit a letter of intent that includes the following information:
Name of the Institution:
Descriptive title of proposed research, including Component
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions (if applicable)
Number and title of this funding opportunity
The letter should be emailed to: Researchnofo@cdc.gov. Include the NOFO number in the email subject line.

Q9. Component B: Can CDC clarify whether the DCC (Component B) will be doing cross-awardee analyses, for example, whether the NDPP/MDPP SLI programs reduced health care utilization and costs across awardees or whether the DCC is expected to provide more guidance to the awardees who will be doing the analyses themselves?

Response to Q9: The DCC is expected to provide cross-awardee data analysis based on a core study protocol and for those studies that use data collected from more than one awardee. Individual awardees are expected to analyze the data from their own sites. See Section I. Funding Opportunity Description, 2. Approach/Objectives, Section IV Application and Submission Information/ Research Plan/Analytic approach.

Q10. Component B: Will Component A awardees also be collecting qualitative data on the system and individual level barriers and facilitators of participating in and completing of the program? If so, would the DCC be expected to harmonize or analyze qualitative interviews or focus groups across awardees?

Response to Q10: Yes, that is correct. See also Section IV Application and Submission Information, Research Plan section III Analytic approach.

Q11. Component B: Will CDC be providing DPRP data to the DCC or would all data be provided/collected via the Component A awardees?

Response to Q11: No, CDC will not provide DPRP data. The applicants are required to collect and link all the data for the electronic longitudinal cohort. See Section I. Funding Opportunity Description/2. Approach/Objectives and Section V. Application Review Information/ Scored Review Criteria.

Q12. Component B: Is there a chance of less than 5 awardees are made for Component A? If so, will that change the funding for Component B?

Response to Q12: Section II Award Information states: "Component A: (up to 5 awards) $570,000 per award. Component B: (1 award) $350,000"

Q13. The NOFO mentions "establishing an electronic study cohort of persons who are eligible for NDPP/MDPP to identify barrier and facilitators," so is there is an expectation for sites to conduct prospective patient-level surveys and/or interviews, and would this be for the entire cohort or a subsample?

Response to Q13: Per Section I. Funding Opportunity Description/2. Approach/Objectives; Section IV. Application and Submission Information/Research Plan/Core components, additional surveys of the study participants and/or NDPP/MDPP providers is anticipated. Per Section IV. Application and Submission Information/Research Plan/Core components, overall and stratified analyses will be provided based on power calculations for primary and secondary outcomes if the minimum 5,000 of required number was not adequate.

Q14. Would it be acceptable for some constructs to rely on validated composite measures of social determinants of health (e.g., area deprivation index)?
Response to Q14: Yes.
Q15. The NOFO lists over 20 potential facilitators and barriers, so we are wondering if they all need to be assessed? Will applications still be competitive with only a subset of these included?
Response to Q15: Yes
Q16. Is the collection of HRQoL at baseline at follow-up a requirement for all 5000+ DPP participants and 5000+ non-participants?
Response to Q16: Per Section IV. Application and Submission Information/Research Plan/Core components, overall and stratified analyses will be provided based on power calculations for primary and secondary outcomes if the minimum 5,000 of required number was not adequate.