REQUEST FOR DETERMINATION OF RESEARCH STATUS

To be completed by the staff member with lead responsibility for the project and approved by branch chief (if applicable) and Division ADS. A separate PGO funding memo is required if project is research and involves human subjects regardless of the CDC staff role.

Instructions: **(1) Use this form to declare: (a) the research status of any project, (b) role or roles of CDC staff**

(2) A short summary should be attached offering specific details about the project and the role of staff.

(3) Be sure to complete all applicable items, obtain appropriate signatures and submit this form for approval.

Tracking Number: To Be Determined

(Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 06/20/2018

Title of Project: CDC-RFA-DP18-1815; Improving the Health of Americans Through Prevention and Management of Diabetes & Heart Disease & Stroke

Dates for project period:

Beginning: 09/30/2018

Ending: 06/29/2023

Dates for funding (if applicable):

Beginning: **09/30/2018**

Ending: **06/29/2023**

Project is (choose one):

NOTE: Revision, as used below, refers to any substantive change made to the project including scope of project, funding restrictions, personnel, role of CDC staff member, determination of research status, etc.

[X] **New**

[ ] **Revision**

[ ] **Continuation, without revision(s)**

[ ] Continuation, with revision(s)

Lead staff member:

Name: Jeannette May

User ID: JXM5

Scientific Ethics number: 10297

Contact information:

Division: DDT

Telephone: 770-488-5016

Mailstop: F75

Please indicate your role(s) in this project:

[ ] **Project officer**

[ ] **Technical monitor**

[ ] **Principal investigator**

[ ] **Investigator**

[ ] **Consultant**

[X] **Other (please explain)**

Assisting with funding package

1. Are any or all of the activities within this project DESIGNED to contribute to generalizable knowledge (i.e., research)?

[ ] **YES** [X] **NO**

If YES, list those activities which are research:

2. Is this CDC project research or public health practice (check all that apply)?

[ ] **Research**

Check one:

[ ] **Human subjects involved**

[ ] **Human subjects not involved**

[X] **Public health practice**

Check all that apply:

[ ] **Emergency Response**

[ ] **Surveillance**

[X] **Program evaluation**

[ ] **Other (please explain)**

3. If RESEARCH involving human subjects, has the project or research activities been reviewed by the CDC IRB for human subjects protection?

a. [ ] **NO, New project, not yet reviewed**

b. [ ] **NO, Existing project, not ready to submit**

c. [ ] **NO, Submitted for approval**

d. [ ] **YES, Reviewed and approved by CDC**

If YES, please list protocol number and expiration date

e. [ ] **NO, RESEARCH, no CDC investigators (CDC IRB not required)**

f. [ ] **N/A (Not Applicable)**

If RESEARCH, list any other CDC staff involved in this project, please include the name, role, and scientific ethics number

Name	Role (project officer, investigator, consultant, etc.)	Scientific ethics number Prin
Jeannette May		10297

IF YOU THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 45CFR46.101), PLEASE ANSWER questions 4-6, OTHERWISE SKIP TO question 7.

4. Does the proposed research involve prisoners?

[ ] **YES** **If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).**

[ ] **NO**

5. Does the proposed research involve fetuses, pregnant women, or human in vitro fertilization as targets (such that Subpart B would apply)?

[ ] **YES** **If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).**

[ ] **NO**

Educational Research

6.1 Is this research conducted in established or commonly accepted educational settings, AND does the research involve normal educational practices (e.g., research on regular and special education strategies or research on the effectiveness of, or comparison among instrucational techniques, curricula or classroom management methods)?

[ ] **YES** [ ] **NO**

Research Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational Tests

6.2 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?

[ ] **YES** [ ] **NO** **If NO skip 6.3**

Will children (<18 years of age) be research subjects?

[ ] **YES** **If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7)**

[ ] **NO**

6.2.1 Is the information obtained recorded in such a manner that human subjects can be identified directly or indirectly through identifiers (such as a code) linked to the subjects;

[ ] **YES** [ ] **NO**

6.2.2 Will any disclosure of the human subjects' responses outside of the research setting have the potential to place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation? (Examples here may include: the collection of sensitive data regarding the subjects' (or relatives' or associates') possible substance abuse, sexuality, criminal history or intent, medical or psychological condition, financial status, or similarly compromising information).

[ ] **YES** [ ] **NO**

6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior but the research is not exempt under paragraph 6.2 of this section:

[ ] **YES** [ ] **NO** **If NO skip to 6.4**

6.3.1 Will this research involve human subjects that are elected or appointed public officials or candidates for public office?

[ ] **YES** [ ] **NO**

6.3.2 Does federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? (Note: CDC can use this exemption criterion only in the case where a 308(d) Assurance of Confidentiality has been obtained to cover the research).

[ ] **YES** [ ] **NO**

Existing Data Which Is Publicly Available or Unidentifiable

6.4 Does this research involve only the collection or study of existing* data, documents, records, pathological or diagnostic specimens? (* 'existing' means existing before the study begins)?

[ ] **YES** [ ] **NO** **If NO skip to 7**

6.4.1 Is this material or information publicly available?

[ ] **YES** [ ] **NO**

6.4.2 Is this material or information recorded in such a manner by the investigator that the subjects cannot be identified directly or indirectly through identifiers linked to the subjects?

(Note: If a link is created by an investigator even temporarily, for research purposes, this criterion is not met. If a temporary link is created by clinical staff who already have access to the data, this criterion is met).

[ ] **YES** **(there are no identifying information and no unique identifiers or codes)YES**

[ ] **NO** **(there are identifiers (including codes))**

7. Please prepare and attach a short summary paragraph (<1 page); if this is new:

a. Be sure to include the purpose of the project, specific details about the project and the role of the CDC staff member (s) in the project. In explaining one's role as a consultant be particularly careful to identify involvement in things like: study design decisions, oversight of protocol development, participation in review of data collection procedures, and particpation in data analysis and/or manuscript preparation, as well as whether there will be access to identifiable or personal data.

b. Explain your project status selection (research--non-exempt, exempt, no CDC investigator or not involving human subjects; public health practice). If you selected research not involving human subjects be sure to indicate if the data includes any personal information (e.g., name, SSN), linkable study identification numbers or codes, or geographical information.

This is a new cooperative agreement program jointly funded by the Division of Diabetes Translation (DDT) and the Division for Heart Disease & Stroke Prevention (DHDSP), through a non-research Notice of Funding Opportunity. This NOFO is non-competitive (funds will be awarded to the 50 states & DC), and will support state investments in implementing/evaluating evidence-based strategies to prevent and manage cardiovascular disease (CVD) and diabetes in high-burden populations/ communities within each state and the District of Columbia, contributing to improved health outcomes. High burden populations are those affected disproportionately by high blood pressure, high blood cholesterol, diabetes, or prediabetes due to socioeconomic or other characteristics, including inadequate access to care, poor quality of care, or low income. Category A strategies focus on diabetes management and type 2 diabetes prevention. Category B strategies focus on CVD prevention and management. In both categories, applicants will select from a menu of strategies, and should focus in areas where they have capacity, subject matter expertise, and potential to achieve greatest reach and impact. Where appropriate, applicants will apply their selected Category A and B strategies in the same targeted communities/settings, so that work on these strategies may be mutually reinforcing.
CDC will provide guidance and technical assistance (TA) to ensure the success of the cooperative agreement by:
• Supporting recipients in implementing cooperative agreement requirements and meeting program outcomes; Providing TA to revise annual work plans; Assisting recipients in advancing program activities to achieve project outcomes; Providing scientific subject matter expertise and resources to support selected strategies; Collaborating with recipients to develop/implement evaluation plans that align with CDC evaluation activities; Providing TA on recipients' evaluation/performance measurement plans; Providing TA to define and operationalize performance measures; Using webinars and other social media for recipients and CDC to communicate and share tools/resources; Establishing learning communities to facilitate information-sharing among recipients; Providing professional development/training opportunities, to share the latest science, best practices, success stories, and program models; Participating in relevant meetings, committees, etc., related to the program requirements to achieve outcomes; Coordinating communication with other CDC programs and Federal agencies; Providing surveillance TA and state-specific data collected by CDC; Providing TA expertise to other CDC programs and Federal agencies on how to interface with recipients; Translating/disseminating lessons learned through publications, meetings, and other means on promising and best practices to expand the evidence base; and Hosting a meeting/training during the first year of the project period and later in the project period.

8. Please list the primary project site and all collaborating site(s).

Explanation of project components:

9. If project involves research that is funded extramurally, list amount of award that should be restricted pending IRB approval and describe which project components will be affected, if known:

Approvals (signature and position title)	Date	Research Determination / Remarks
Jeannette May - Public Health Advisor	06/22/2018	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB

staff member completing this form		Comments: Hi Pat, Here's the human subjects form for the 1815 funding package for your review. Thanks. Jeannette
Patricia Schumacher - SENIOR TEAM LEAD Team Lead	06/22/2018	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments: Approved
Elizabeth Luman - EPIDEMIOLOGIST Division ADS	06/26/2018	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments: Approve
Joan Redmond Leonard - PUBLIC HEALTH ANALYST CUC ADS, Deputy ADS, or Human Subjects Contact	06/28/2018	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments: