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: _____

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

Date submitted: 06/28/2016

Title of Project: Million Hearts Hypertension Control Challenge

Dates for project period:

Beginning: 01/02/2017

Ending: 12/31/2019

Dates for funding (if applicable):

Beginning: _____

Ending: _____

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.

[ ] **New**

[ ] **Revision**

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

[X] **Continuation, with revision(s)**

Lead staff member:

Name: Mary George

User ID: COQ5

Scientific Ethics number: 19048

Contact information:

Division: DHDSP

Telephone: 770-488-8092

Mailstop: F77

Please indicate your role(s) in this project:

[ ] **Project officer**

[ ] **Technical monitor**

[ ] **Principal investigator**

[ ] **Investigator**

[ ] **Consultant**

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

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**

[ ] **Program evaluation**

[ ] **Surveillance**

[X] **Other (please explain)** Project to identify successful clincial practices to control hypertension.

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
Mary George		19048

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.

Million HeartsTM is a national initiative to prevent 1 million heart attacks and strokes by 2017. Achieving this goal means that 10 million more Americans must have their blood pressure under control. Million HeartsTM is working to reach this goal through clinical approaches, such as using health information technology to its fullest potential and integrating team-based approaches to care, as well as community approaches. To support improved clinical practice, CDC is announcing a Million Hearts™ Hypertension Control Challenge. Through this challenge we shall identify clinicians, practices and health systems that are able to demonstrate high levels of hypertension control within their patient population and document the systems and processes that contribute to exemplary practice. The challenge will reward and recognize a small number clinicians and health systems that are able to achieve exemplary results.

Clinical practices and health systems will self-nominate through an online portal by providing hypertension control data, a summary of their patient population and a description of sustainable clinical and support systems. Nominations will be scored using predetermined criteria and a scoring rubric and reviewed by an expert panel of judges. Finalists will participate in data verification that will involve onsite or remote record review by a third party and/or confirmation with data submitted to a known source, such as NCQA. Recognized champions will participate in the development of a success story product to be shared broadly with public health and clinical audiences.

CDC staff will develop challenge rules and criteria, data collection tools, and selection criteria. CDC staff will consult on data storage and confidentiality, any data analyses conducted, and record review protocols. The expert panel of judges will be chaired and partially comprised of CDC staff. An OMB Information Collection Request has been submitted. A contractor will be identified to develop and manage the challenge entry site with CDC oversight.

This project is considered public health practice. Then intent is to identify and share examples of clinical systems and practices that support high rates of hypertension control in a narrative or documentary format. No individual patient level data will be collected, only practice-level summary data. No generalizable knowledge will emerge from this project, only examples of successful practices that can be adopted or adapted by clinic systems and providers. A manuscript is not planned at this time. Information and success stories will be disseminated through web-based products.

Previous determination of this project ID 22486

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
Mary George - SENIOR MEDICAL OFFICER	08/01/2016	[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: This is for the reinstatement of OMB (0920-0976)
Salvatore Lucido - Health Policy and Issues Mg	08/03/2016	[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
Team Lead		Comments: Approved
Yuling Hong - 25\SENIOR SERV FEL-ASSOC DIR	08/03/2016	[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
Division ADS		Comments:
Joan Redmond Leonard - PUBLIC HEALTH ANALYST	08/08/2016	[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
CUC ADS, Deputy ADS, or Human Subjects Contact		Comments: