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: 01/05/2009

Title of Project: Improving the Quality and Delivery of CDC's Heart Disease and Stroke Prevention Programs

Dates for project period:
Beginning: 06/01/2009
Ending: 06/01/2012

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.

[X] **New** [ ] **Revision**
[ ] **Continuation, without revision(s)** [ ] **Continuation, with revision(s)**

Lead staff member:
Name: LAUREN GASE
User ID: HRV9
Scientific Ethics number: 150518

Contact information:
Division: DHDSP
Telephone: 770-488-8007
Mailstop: K47

Please indicate your role(s) in this project:
[ ] **Project officer** [X] **Technical monitor**
[ ] **Principal investigator** [ ] **Investigator**
[ ] **Consultant** [X] **Other (please explain)**
Lead Evaluator

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** [X] **Public health practice**

Check one:
[ ] **Human subjects involved**
[ ] **Human subjects <u>not</u> involved**

Check all that apply:
[ ] **Emergency Response**
[X] **Program evaluation**
[ ] **Surveillance**
[ ] **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

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 to 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)**

[ ] **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.

A. The Division for Heart Disease and Stroke Prevention (DHDSP) recognizes the importance of ensuring that its activities are useful, well implemented, and effective in achieving its intended public health goals. The purpose of this project is to assess the relevance, quality and impact of DHDSP training, technical assistance and guidance to its public health partners. A series of assessments is planned based in the DHDSP Evaluation Plan. The assessments will be conducted in a phased approach over the next three years to reflect the types of training, technical assistance and guidance provided at various times by DHDSP. The evaluation information will help DHDSP staff understand the extent to which their activities and services are reaching the intended partners, whether they are deemed to be useful by those partners, and whether DHDSP efforts improve public health practices.

The DHDSP is seeking clearance from the Office of Management and Budget to conduct a series of surveys, interviews, and focus groups. Respondents will be the DHDSP's partners in state and local government as well as organizations in the private sector. A majority of questions will be drawn from a question bank pre-approved by OMB. To minimize burden, whenever possible, information will be collected through online surveys. In-person and telephone interviews will be used when web surveys are impractical, more burdensome, or in-depth responses are required. If interactions among respondents are desirable, focus groups will be conducted.

This data collection will conform to ethical practices for survey administration and implement procedures to protect the confidentiality of respondents. All respondents will be informed that their responses will be kept confidential unless otherwise specified by the law. They will be notified that their participation is voluntary and assured that they will not be penalized in any way if they choose not to participate. Consent will be obtained from all participants before they begin the survey.

The information collections will be supervised by a CDC staff member. Most instruments will be designed, distributed, and analyzed by a collaborative team consisting of a contractor and a DHDSP staff member or solely by internal DHDSP staff.

B. The proposed project is classified as Public Health Practice/Program Evaluation. The purpose of the project is program improvement. Results of the evaluation will be used to strengthen relationships between the DHDSP and its partners, enhance the impact and effectiveness of the DHDSP's activities and products, and strengthen the organizational effectiveness of the DHDSP. By asking partners to identify their current needs, to describe how DHDSP activities address these needs, and to identify new DHDSP activities that they would find helpful, the DHDSP will be better able to improve existing activities as well as prioritize areas for additional or expanded services.

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
DIANE DUNET - TEAM LEAD, HEALTH SCIENTIST	01/05/2009	[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:

Tracking NO. _____

MICHAEL SCHOOLEY - BRANCH CHIEF Team Lead	01/06/2009	[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:
ROBERT MERRITT - BRANCH CHIEF, ESB Division ADS	01/07/2009	[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:
ADS, Deputy ADS, or Human Subjects Contact		[ ] 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:

List of Grantees

Grantee #	Grantee Name