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: 12/14/2009

Title of Project: Prevention Research Centers Program National Evaluation Reporting System

Dates for project period:
Beginning: 07/01/2010
Ending: 06/30/2013

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: JOANNE GRUNBAUM
User ID: JPG9
Scientific Ethics number: 16905

Contact information:
Division: DACH
Telephone: 770-488-5542
Mailstop: K45

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

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 <u>not</u> involved**

[X] **Public health practice**
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.

PURPOSE
The purpose of the data collection is to collect data from funded grantees to accomplish the following:
1. Monitor compliance with cooperative agreement requirements
2. Identify needs for training and technical assistance
3. Evaluate progress made in achieving PRC-specific goals and activities
4. Obtain information needed to respond to Congressional and other inquiries regarding program activities and effectiveness
5. Summary program activities across all 35 funded PRCs
6. Identify PRCs with similar activities and link them with each other

SPECIFIC DETAILS
Data will be collected annually from each grantee via web-based surveys and telephone interviews. The Web-based survey will collect data related to projects funded by sources other than CDC, training programs, number of people trained, and number and types of PRC interactions with health departments and other government agencies; and the telephone interviews will collect data that do not lend themselves to survey-based methodology and require some qualitative discussion including number of staff hired, environmental and policy changes and the dissemination and adoption of effective interventions.

CDC STAFF
CDC staff will develop the surveys, analyze the data, and develop reports

PROJECT SELECTION STATUS
The project is public health practice -- collecting data to assure that grantees are performing as required under their cooperative agreement. No personal identifiers will be collected through the web-based survey or telephone interview. In addition, no personally identifiable information is collected by CDC on individuals participating as subjects in PRC research or training activities.

CONSULTANTS
Not applicable

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
JOANNE GRUNBAUM - HEALTH SCIENTIST	12/14/2009	[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: This form is required so that the OMB package can move forward

Tracking NO. _____

KURT GREENLUND - EPIDEMIOLOGIST Team Lead	12/14/2009	[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:
KURT GREENLUND - EPIDEMIOLOGIST Division ADS	12/14/2009	[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:
JOAN REDMOND-LEONARD - PUBLIC HEALTH ANALYST ADS, Deputy ADS, or Human Subjects Contact	12/28/2009	[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:

List of Grantees

Grantee #	Grantee Name