



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: 200-2007-20014/2008-C-011
 (Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 06/10/2008

Title of Project: Cancer Prevention and Control Strategic Campaign and Communication Initiatives

Dates for project period:

Beginning: 09/01/2008

Ending: 03/08/2014

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)

Continuation, with revision(s)

Lead staff member:

Name: CYNTHIA GELB

User ID: CMG7

Scientific Ethics number: 4187

Contact information:

Division: DCPC

Telephone: 770-488-4708

Mailstop: K64

Please indicate your role(s) in this project:

Project officer **Technical monitor**

Principal investigator **Investigator**

Consultant **Other (please explain)**

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

YES **NO**

If YES, list those activities which are research:

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

Research

Public health practice

Check one:

Human subjects involved

Human subjects not involved

Check all that apply:

Emergency Response

Program evaluation

Surveillance

Other (please explain)

The purpose of this project is to identify gynecologic and other cancer related public health information/messages for a national awareness campaign and communication initiatives.

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 participation 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.

Cancer Prevention and Control Strategic Campaign and Communication Initiatives

The proposed formative activities are non-research because their intent is to help identify optimal cancer-related public health information and messages for a national awareness campaign and other strategic communication initiatives.

We feel that the project activities are non-research as per the: Guidelines for Defining Public health Research and Public Health Non-Research, <http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm>, which states that the "major difference between research and non-research lies in the primary intent of the activity." "The primary intent of non-research in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Knowledge may be gained in any public health endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered."

The purpose of the proposed formative activities is to develop and test materials and messages for consumers and health care providers with a representative sampling of the intended audiences. This will help ascertain that messages are clear and compelling to the target audience(s), and appropriate for the proposed media. We anticipate that concept testing of materials may be combined with focus groups to assess knowledge, behavior and attitudes related to gynecologic and other cancers. Focus group testing with consumers will take place in 3-4 cities in the U.S., with at least 3 English groups and 1-2 Spanish groups in each city, and health care provider groups will take place in 3-4 cities or via the internet or telephone.

Up to 9 participants will be included in each focus group and will be drawn from the target audiences using standard market research techniques, and will represent geographic and demographic diversity to assure appropriate audience representation. As a result of these activities, DCPC will raise awareness about gynecologic and other cancers to reduce mortality.

A contractor, under CDC Technical Monitor supervision, will develop a recruitment plan, moderator guide and other testing tools, and will conduct focus groups. All testing shall be under the direction and approval of the Technical Monitor.

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
<p>CYNTHIA GELB - HEALTH COMMUNICATION SPECIALIST</p> <p>staff member completing this form</p>	<p>06/10/2008</p>	<p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u> Please review this as soon as possible.</p>
<p>NAHEED LAKHANI - ORISE FELLOW</p> <p>Team Lead</p>	<p>06/10/2008</p>	<p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p>
<p>NAHEED LAKHANI - ORISE FELLOW</p> <p>Division ADS</p>	<p>06/10/2008</p>	<p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p>
<p>JOAN REDMOND-LEONARD - PUBLIC HEALTH ANALYST</p> <p>ADS, Deputy ADS, or Human Subjects Contact</p>	<p>06/20/2008</p>	<p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p>

List of Grantees

Grantee # Grantee Name

