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.

[X] **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**
[ ] **Principal investigator**
[ ] **Consultant**
[X] **Technical monitor**
[ ] **Investigator**
[ ] **Other (please explain)**

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)** 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.

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,

[ ] **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.

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:

Tracking NO. 200-2007-20014/2008-C-011

Approvals (signature and position title)	Date	Research Determination / Remarks
CYNTHIA GELB - HEALTH COMMUNICATION SPECIALIST staff member completing this form	06/10/2008	[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: Please review this as soon as possible.
NAHEED LAKHANI - ORISE FELLOW Team Lead	06/10/2008	[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:
NAHEED LAKHANI - ORISE FELLOW Division ADS	06/10/2008	[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	06/20/2008	[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