



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: xxxx/2016-022
 (Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 03/01/2016
Title of Project: Young Women and Breast Cancer Digital and Social Media Engagement Campaign
Dates for project period: **Beginning:** 09/09/2016 **Ending:** 09/08/2018
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:	Contact information:	Please indicate your role(s) in this project:	
Name: <u>Temeika Fairley</u>	Division: <u>DCPC</u>	<input type="checkbox"/> Project officer	<input checked="" type="checkbox"/> Technical monitor
User ID: <u>TFF9</u>	Telephone: <u>770-488-4518</u>	<input type="checkbox"/> Principal investigator	<input type="checkbox"/> Investigator
Scientific Ethics number: <u>8817</u>	Mailstop: <u>F76</u>	<input type="checkbox"/> Consultant	<input checked="" type="checkbox"/> Other (please explain)
			<u>COR</u>

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)?

<input type="checkbox"/> Research	<input checked="" type="checkbox"/> Public health practice
<i>Check one:</i>	<i>Check all that apply:</i>
<input type="checkbox"/> Human subjects involved	<input type="checkbox"/> Emergency Response <input type="checkbox"/> Surveillance
<input type="checkbox"/> Human subjects not involved	<input type="checkbox"/> Program evaluation <input checked="" type="checkbox"/> Other (please explain)
	<u>Public Education Campaign</u>

3. If RESEARCH involving human subjects, has the project or research activities been reviewed by the CDC IRB for human subjects protection?

a. <input type="checkbox"/> NO, New project, not yet reviewed	d. <input type="checkbox"/> YES, Reviewed and approved by CDC
b. <input type="checkbox"/> NO, Existing project, not ready to submit	If YES, please list protocol number and expiration date
c. <input type="checkbox"/> NO, Submitted for approval	_____
	e. <input type="checkbox"/> NO, RESEARCH, no CDC investigators (CDC IRB not required)
	f. <input type="checkbox"/> 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
Temeika Fairley		8817

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 instructional 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 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.

In 2015 CDC implemented the Bring Your Brave education and awareness social media campaign focusing on topics related to breast cancer in young women. This campaign addresses responds to aspects of the Education and Awareness Requires Learning Young Act (EARLY Act) legislation which directs CDC to address issues related to early onset breast cancer. This campaign educates young women (ages 15-44) and medical providers about breast health, breast cancer risk factors (including but not limited to BRCA gene mutation), and survivorship among young women.

The purpose of this project overall is to develop, implement, and launch this social media health communications campaign. This effort requires formative activities to develop and test educational materials and messages for a representative sampling of health professionals & young women living with or at risk for early onset breast cancer.

The proposed project activities are public health practice as the primary intention of this effort is to gain knowledge for the purpose of improving public health. The Bring Your Brave formative will help CDC identify optimal early onset breast cancer-related public health information and messages for a national social & digital media education campaign. This will help ascertain that messages are clear and compelling to the target audience(s), and are appropriate for the media proposed.

It is anticipated that concept testing of consumers and health care provider materials will be combined with the focus groups, IDIs, and web-testing to assess knowledge, behavior and attitudes related to early onset breast cancer and breast health. In-depth interviews will be conducted with health care providers from the primary care, oncological, and nursing communities. Focus group testing will take place in cities across the U.S. as deemed appropriate for the target audiences. Focus groups will be drawn from the target audience(s) using standard market research techniques and will represent geographic and demographic diversity to the extent necessary to assure appropriate audience representation. Web testing will be conducted on a representative population of the target population. As a result of these activities, Bring Your Brave will raise awareness of early onset breast cancer and the importance of breast health and breast cancer awareness.

CDC staff members will serve as COR and technical monitor providing the selected contractor with SME on the aforementioned topic. They will work with the contractor to develop a recruitment plan, moderator's guide and other testing tools. The communications contractor will conduct focus groups, in-depth interviews, and web testing sessions. All testing shall be upon direction the project COR.

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
Temeika Fairley - EPIDEMIOLOGIST staff member completing this form	03/04/2016	<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 (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u>
Jameka Blackmon - Deputy Associate Director for Po Team Lead	03/09/2016	<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 (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u> Moving forward. JRB
Cheryll Thomas - EPIDEMIOLOGIST Division ADS	03/09/2016	<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 (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u>
Joan Redmond Leonard - PUBLIC HEALTH ANALYST CUC ADS, Deputy ADS, or Human Subjects Contact	03/10/2016	<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 (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u>