



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: 200-2007-20009/TBD

(Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 05/20/2014

Title of Project: Creation of a Marketing Campaign to Address Gaps in the Self-Management of Systemic Lupus Erythematosus (SLE)

Dates for project period:

Beginning: 08/27/2014

Ending: 09/01/2016

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: Charles Helmick

Contact information:

Division: DPH

Please indicate your role(s) in this project:

Project officer

Technical monitor

User ID: CGH1

Telephone: 770-488-5456

Principal investigator

Investigator

Scientific Ethics number: 12469

Mailstop: F78

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:

Generalizable knowledge will be created by conducting focus groups of people with Lupus and their providers to obtain patient experience and needs. The Contractor will be obtaining local IRB review and approval.

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

Surveillance

Program evaluation

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
Charles Helmick		12469

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.

The purpose of this task order is to develop multiple educational interventions tailored to address important sex- or race/ethnic-specific differences in the self-management of SLE. An environmental scan/situational analysis including available secondary audience research will be conducted focusing on the view of both people meeting classification criteria for SLE of research among these groups to develop concepts and channels that will be used to create materials and plans for sex-and race/ethnic specific educational campaigns to address any identified gaps.

Status of "research involving human subjects, no CDC investigators" is based on the CDC staff lead as a consultant to the contractor (the contractor will obtain local IRB approval).

Dr. Charles Helmick is the Project Officer for this task order and will be working with the contractor in obtaining OMB review and approval. CDC will not have access to the raw data.

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
Charles Helmick - MEDICAL OFFICER, IV staff member completing this form	05/27/2014	<input type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input checked="" 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 checked="" type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u> This second revision today edits the document to classify the CDC lead person (Helmick) as a consultant only, so no CDC IRB approval is needed. --Helmick

