REVIEW OF SAFEGUARDS FOR HUMAN SUBJECTS

American Institutes for Research
1000 Thomas Jefferson Street, NW
Washington, DC 20007

Institutional Review Board
IRB00000436

Project number: 02600.008
Project Director/Proposal Author: Roger Levine
Project/Proposal title: **CDC Sickle Cell Messaging**

1. Type of review:

(Check one)
☒ Expedited review
☐ Full IRB review

(Check one)
☒ Initial review
☐ Scheduled re-review (e.g., annual)
☐ Requested re-review (e.g., new data collection component, research plan change)

2. Review determination:

After reviewing the above *project,* the Institutional Review Board (or member signing below) has determined the following:

☐ Determination of Exemption: the project is exempt from further IRB review because it does not constitute research or because it does not involve human subjects.

☐ Provisional Approval: the submitted *insert "project/study/proposal or other descriptive"* is approved pending development of the research plan (45CFR46.118), which must be reviewed before enrollment of subjects or collection of data can begin. Proposed date of review: __

☒ Conditional Approval: data collection on all pieces of the protocol may proceed and are approved **EXCEPT** the component that will obtain focus group input on extant sickle cell materials. This component can proceed only after submission of those extant materials to IRB for brief review/confirmation of content. **All other aspects of the focus group work are approved without exception.**

☐ Approval: approval of *insert "project/study/proposal or other descriptive"* is granted and data collection can proceed. In keeping with our Federalwide Assurance mandate, the IRB must conduct reviews at least annually for each project. This project will be reviewed again on *insert review date*.

☐ Approval Denied: approval of *insert "project/study/proposal or other descriptive"* is denied and data collection may not proceed for the following reasons:

3. Consent Procedures
The Institutional Review Board has determined that consent procedures:

☐ are not applicable to the project.

☐ must be reviewed on .

☒ **are approved as submitted.**

☐ are approved under the following conditions:

☐ are not approved for the following reasons:

4. Individually Identifiable Information Safeguards
The Institutional Review Board has determined that the safeguards planned for individually identifiable information:

☐ are not applicable to the project.

☐ must be reviewed on .

☒ **are approved as submitted.**

☐ are approved under the following conditions:

☐ are not approved for the following reasons:

5. Comments
On the basis of this review, the IRB has determined that the CDC Sickle Cell Messaging focus group activity with adolescent and adult sickle cell patients is approved on condition that the component of the focus group protocol dealing with review of extant materials requires review of those materials by the IRB. All other components of the focus group research are approved. The IRB has reviewed the accompanying materials for the submission and concludes that the risks to the participants are minimal (pending review of the extant messaging materials that will be reviewed during the focus groups). Consent/ assent procedures are appropriate, and waiver of signed consent (for adults) and waiver of signed assent (for adolescents) for telephone groups is also appropriate. Signed parental consent will still be obtained prior to telephone focus groups involving adolescents. Adequate protections have been assured for audio and videotapes, as well as any other data stemming from the focus groups; protections for the comfort and safety of the sickle cell patients participating in your focus groups is reflected in your application.

6. IRB Signature(s):

7/13/2011
Date

Susan K. Heil

Susan Heil
IRB Representative

Please keep in mind that any material changes made to the study or the study procedures require the submission of an updated IRB package.