OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX: 301-480-2198 **Exempt: #:** 5810

To: Hesse, Bradford
NCI
EPN 4068

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The Division of Cancer Control and Population Sciences, Behavior Research Program of the National Cancer Institute (NCI) is planning to conduct data collection for the Health Information National Trends Survey 4 (HINTS 4) over the course of three years starting in 2011. The purpose of HINTS is to assess the ways in which the general population uses communication channels to obtain information about health and cancer. The survey monitors the use of information resources while collecting information about respondents'

Original Request Received in OHSR on: 6/9/2011

Responsible NIH Research Investigator(s): Bradford Hesse, PhD NCI

OHSR review of your request dated Wed, Jun 1, 2011 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Note: Office Person SPC Admin Assist. CB

Charlotte Hpiden, JD — Acting Director, OHSR — 6/21/2011
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
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Memo

Date: November 11, 2010

To: Terisa Davis, Project Director

From: Kerry Levin; Chair, Westat IRB

Subject: **Expedited Approval of HINTS, Project 8861.01.04**
FWA 5551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **HINTS, Project 8861.01.04.** The Westat IRB reviews all studies involving research on human subjects. This study is sponsored by the National Cancer Institute.

The survey, that assesses the ways in which the general population uses communication channels to obtain information about health and cancer, may have several changes from the one conducted in 2008.

Westat will be responsible for the following activities:

- Mailings (Prenotification letter, thank you, and reminder post cards)
- Additional 5th mailing of Spanish materials
- Focus groups with eligible respondents (2 of these in Spanish)
- Cognitive testing:
  - Two rounds per modular instrument
  - Testing with a total of 100 English and 50 Spanish-speakers (total of 150 cog interviews)
- Field test to be conducted prior to first cycle of data collection
  - N=150
  - Conduct debriefing interviews with 20 of those that complete field test survey

Focus groups and cognitive tests will be either video or audio taped. Once notes are taken, tapes will be destroyed and names or identifiers will not be used in reports.

The data will be owned by NCI but will not be turned over until it has been de-identified.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. This study can be considered minimal risk and is approved under expedited authority. A waiver of informed consent is also approved (45 CFR 46 116d) as the research involves

no more than minimal risk, the waiver or alteration will not adversely affect the rights and welfare of the subjects, and the research could not practicably be carried out without the waiver or alteration.

When ready, submit protocols and consent forms for focus groups and cognitive testing to the IRB.
Prior to fielding, submit final letters and instruments to the IRB for review and approval.

As the Project Director you are responsible for the following:

- If you received a conditional approval, project activities (e.g., recruiting, enrolling) may not begin until your responses have been received by the IRB and final approval is granted.
- You are required to submit this study for a continuing review on or before November 11, **2011.**
- In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Nancy Weinfield