Attachment 8

OHSR Determination and UCLA Institutional Review Board Approval

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

FAX: 301-435-3710 **Exempt: #:** 4470

To: Breen, Nancy
NCI
EPN/4005

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The California Health Interview Survey (CHIS) is a biennial population-based statewide local health survey (N`40-50,000 adults + adolescents + children). CHIS is administered by telephone in five languages to participants across the state of California. It is the only survey of its kind to provide statewide local estimates and estimates for small racial-ethnic groups with inadequate samples nationally. since 2001, the NCI had funded cancer control questions on CHIS that cover cancer risk factors and cancer screening behaviors

Original Request Received in OHSR on: 12/18/2008

Responsible NIH Research Investigator(s): Nancy Breen, PhD NCI

OHSR review of your request dated Mon, Dec 15, 2008 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. No further action is necessary.

☐ 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 Holden, JD _____ 12/22/2008
Signature Title Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

APPROVAL NOTICE

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
11000 Kinross Avenue, Suite 102
169407
www.oprs.ucla.edu

DATE: November 24, 2008

TO: E. Richard Brown, Ph.D.
Principal Investigator

FROM: Alison A. Moore, M.D., M.P.H.
Chair, South General Institutional Review Board

RE: UCLA IRB #G08-10-098-01
Approved by Full Committee Review
(Approval Period from 11/24/2008 **through** 11/17/2009)
California Health Interview Survey (2009)

Please be notified that the UCLA Institutional Review Board (UCLA IRB) has approved the above referenced research project involving human subjects in research. The UCLA's Federalwide Assurance (FWA) with the Department of Health and Human Services, Office for Human Research Protections is FWA00004642.

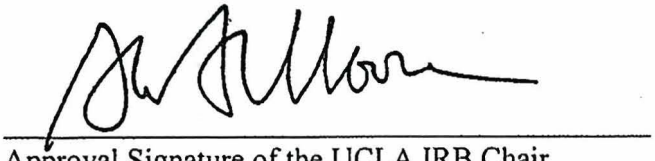
PLEASE COMPLY WITH THE FOLLOWING CODICIL(S) IMPOSED BY THE IRB:

1. **This Approval Notice is issued for administrative purposes only. No subjects may be contacted, recruited, or enrolled in the 2009 California Health Interview Survey. All related IRB-approved forms will be held on file until the AMENDED Certificate of Confidentiality for this study is received and acknowledged (through issuance of a revised approval notice) by the UCLA IRB.**

2. **Upon the expected enrollment of non-English speaking subjects or those who are not fluent in English, non-English recruitment materials and consent materials/scripts must be received and acknowledged by the UCLA IRB (through issuance of a revised approval notice) prior to implementation.**

3. **No subjects may be contacted, recruited or enrolled in this study until copies of the Westat IRB approval (CHIS 2009 data collection contractor) and the State of California Committee for the Protection of Human Subjects are received and acknowledged by the UCLA SGIRB.**

APPROVAL NOTICE
IRB #G08-10-098-01



Approval Signature of the UCLA IRB Chair

PRINCIPLES TO BE FOLLOWED BY PRINCIPAL INVESTIGATORS:

As the Principal Investigator, you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the UCLA IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved protocol.
2. Do not implement changes in the approved protocol or consent form without prior UCLA IRB approval (except in a life-threatening emergency, if necessary to safeguard the well-being of human subjects.)
3. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved UCLA-IRB stamped consent form.
4. Promptly report all undesirable and unintended, although not necessarily unexpected adverse reactions or events, that are the result of therapy or other intervention, within ten working days of occurrence. All fatal or life-threatening events must be reported to the UCLA IRB in writing within 2 working days after discovery.
5. In clinical medical research, any physician(s) caring for your research subjects must be fully aware of the protocol in which the subject is participating.
6. No subjects may be identified, contacted, recruited, or enrolled until the contract with the sponsor is finalized by the University.
7. Ensure that all individuals who will interact with subjects and/or have access to identifiable research data have completed the UCLA Protection of Human Research Subjects Certification.
8. Ensure that all individuals who will access subjects' medical records have completed the UCLA HIPAA Research Training Certification.
9. If non-UCLA sites or personnel are involved, follow all study-specific requirements and consent processes approved by the UCLA IRB.

FUNDING SOURCE(S):

According to the information provided in your application, the funding source(s) for this research project may include the following: extramural.