Attachment 6

CHIS 2007 UCLA Institutional Review Board Approval

APPROVAL NOTICE

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
1401 Ueberroth Building
169407
www.oprs.ucla.edu

DATE: November 22, 2006

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 #G06-10-001-01
Approved by Full Committee Review
(Approval Period from 11/22/2006 **through** 11/21/2007)
California Health Interview Survey

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. **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.**

2. **This Approval Notice is issued for administrative purposes and for the anonymous pre-testing only. No subjects may be contacted, recruited, or enrolled expect for the anonymous pre-testing. All related IRB-approved forms will be held on file until the Certificate of Confidentiality for this study is received and acknowledged (through issuance of a revised approval notice) by the UCLA IRB.**

3. **This study is approved for use of non-emergency proxy informed consent as set forth in California Assembly Bill AB2328.**

4. **This approval is for conduct of the anonymous pretest only. Conduct of the pilot study and main survey may not begin until final versions of the survey for those activities have been reviewed and approved by the SGIRB.**

5. **This approval is for administrative purposes only. No subjects may be contacted or recruited until the IRB approval notices for the CHIS 2007 pretest have been received from Westat and the State Committee for the Protection of Human Subjects.**

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 five working days of occurrence. All fatal or life-threatening events or events requiring hospitalization must be reported to the UCLA IRB in writing within 48 hours 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):

APPROVAL NOTICE
IRB #G06-10-001-01

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

PI of Contract/Grant: E. Richard Brown
Funding Source: California Department of Health Services
Contract/Grant No: 05-45192
Contract/Grant Title: California Health Interview Survey

PI of Contract/Grant: E. Richard Brown
Funding Source: National Cancer Institute
Contract/Grant No: HHSN261200544000C:003
Contract/Grant Title: California Health Interview Survey

PI of Contract/Grant: E. Richard Brown
Funding Source: Blue Shield of California Foundation
Contract/Grant No: 1240193
Contract/Grant Title: California Health Interview Survey (CHIS) 2007 Violence Module