

From: Amy McDaniel [mailto:amcdanie@mail.sdsu.edu]
Sent: Wednesday, February 06, 2008 4:47 PM
To: gtalaver@mail.sdsu.edu
Cc: jelder@mail.sdsu.edu; awards@foundation.sdsu.edu
Subject: Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

vIRB Number: 3677

Contract Number: G00006784

Title: Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

Dear Dr. Talavera and Professor Elder:

The referenced protocol was reviewed and approved in accordance with SDSU's Assurance and federal requirements pertaining to human subjects protections within the Code of Federal Regulations (45 CFR 46; 21 CFR 50). This review is valid through **August 21, 2008**, and applies to the conditions and procedures described in your protocol. Please notify the IRB office if your status as an SDSU-affiliate changes while conducting this research study (you are no longer an SDSU faculty member). **Provide the Spanish-translated Informed Consent Document, Inform Consent Cover Letter, In-Person Recruitment Script, Phone Recruitment Script, Scheduling Clinic Visit Script, and Brochure.**

The approved consent form(s) has been uploaded to your protocol file within the vIRB system, within the Supporting Documentsµ section. This document bears the IRB's stamp of approval. Please print a copy of this stamped form to use when documenting informed consent from research participants. Changes may not be made to the consent document(s) without prior review and approval of the IRB. You are required to keep signed copies of the consent document(s) for three years after your project has been completed or terminated.

Please note the following:

a) For studies requiring consent translation: The SDSU Institutional Review Board (IRB) does not verify the accuracy of the translated document. IRB approval of this document for use in subject recruitment is based on your assurance that the translated document reflects the content of the IRB approved English version of the document.

b) Approval is contingent upon the completion of the SDSU human subjects tutorial (found at: <http://www-rohan.sdsu.edu/~gra/login.php>) by all members of the research team. This certification must be renewed every 2 years.

For questions related to this correspondence, please contact the IRB office ((619) 594-6622 or e-mail irb@mail.sdsu.edu). To access IRB review application materials, SDSU's Assurance, the 45 CFR 46, the Belmont Report, and/or any other relevant policies and guidelines related to the involvement of human subjects in research, please visit the IRB web site at <http://gra.sdsu.edu/research.php>.

Sincerely,

Jeanne F. Nichols, Chair
SDSU Institutional Review Board

Wendy Bracken
Human Research Protection Program Coordinator

Amy McDaniel
Regulatory Compliance Analyst

Choya Washington
Regulatory Compliance Analyst