SAN DIEGO STATE UNIVERSITY

Graduate and Research Affairs
Division of Research Affairs
San Diego State University
5500 Campanile Drive
San Diego CA 92182-8220
Phone: 619-594-5938
Fax: 619-594-4109

Submit your report of progress by 5/3/2012

June 3, 2011

Faculty Researcher: Greg Talavera, MD, MPH
Department: Public Health
Title: Hispanic Community Health Study/Study of Latinos (HCHS/SOL)
vIRB Number: 3677
Grants/Contracts: *NIH* G00006784
Regulatory Determinations
Modification: Expedited per 45 CFR 46.110(b)(2), Minor Modification
Continuation: Expedited per 45 CFR 46.110, Category 9

Dear Professor Talavera:

The SDSU Institutional Review Board approved the project referenced for continuation and modification on June 2, 2011, 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). The approval for continuation applies to the recruitment of human subjects and collection/analysis of data based on procedures described in your protocol and the information you provided within your report of progress. The modification approval is valid for revisions to the protocol [*procedure to document informed consent details over time, use of participant safety screening form, use of informant/alternate respondents*]. Approval carries with it the understanding that you will contact the IRB to obtain authorization to implement any proposed changes to the protocols, to document a change in your affiliation with SDSU (student, faculty or staff), and/or to report the completion of study recruitment, data collection and data analysis. **Project approval expires June 3, 2012.**

Please note your expiration date. To request continued recruitment, data collection and/or data analyses, a Report of Progress must be submitted prior to the expiration date of your study. A lapse in approval requires that all research with human subjects be suspended until approval is obtained and may result in a temporary hold on funds, if your study is funded. The investigator will be out of compliance with federal regulation and university policy if human subjects continue to be involved in this project without a valid IRB approval.

As the consent document has been modified, please note that a final version of the consent form **(Talavera_SOL_3677_San Diego Eng IC Renewal FINAL v2 5-5-2011_stamped.pdf; Talavera_SOL_3677_San Diego Span version FINAL Renewal v2 5-5-2011_stamped.pdf)** has been uploaded to your protocol file within the vIRB system, within the "Supporting Documents" section. This document bears the IRB's stamp of approval. Print a copy of this stamped form to use when documenting informed consent from research participants. Changes may not be made to the consent documents without prior review and approval of the IRB. You are required to keep signed copies of the consent documents for three years after your project has been completed or terminated.

SAN DIEGO STATE UNIVERSITY

Graduate and Research Affairs
Division of Research Affairs
San Diego State University
5500 Campanile Drive
San Diego CA 92182-8220
Phone: 619-594-5938
Fax: 619-594-4109

Please note the following:

a) **As this study requires 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) If recruitment will take place through an outside agency or organization, confirm with that institution that you have permission to conduct the study prior to initiation of any study activities.

c) 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.

d) **If any changes to your study are planned**, you must submit a modification request and receive IRB approval prior to the implementation of study changes. To submit a modification request, access the protocol via the WebPortal, on the protocol Main Page, you will need to click on "Modifications" under Protocol Maintenance and enter a report. Once you have filled in your responses on the report form, click "submit".

REQUIREMENTS!

- To document your modification in detail, access your currently approved protocol in the "Full Document Viewer." Copy and paste the document into Word and use "track changes" to document revisions to your protocol. Save the file (Name_Modification_Date) and upload it to your protocol file. When approved by the IRB, this document will be the current version of your approved protocol.
- **If a change to the approved consent form(s) or other uploaded document(s) is being requested,** changes must be documented using the "track changes" feature in Word. Upload the revised form to your vIRB protocol file. This form will be reviewed by the IRB. If you do not have a copy of your approved consent form in a Word format, request a copy from the IRB office.

e) **The SDSU IRB requires investigators to report any problems that arise during the course of an IRB approved research study.** *Serious* adverse events or unanticipated problems that are life-threatening or have resulted in serious injury or death must be reported to the IRB **immediately** whenever possible or within at least 48 hours from the onset of the incident. All other problems must be reported to the SDSU IRB within 5 days. **To complete and submit an adverse event report, go to the Protocol Main Menu**, click on "Adverse Events" under "Protocol Maintenance" and follow the instructions. For more information and consultation, contact the IRB office directly via Email at: IRB@mail.sdsu.edu or telephone: 619-594-6622, Monday through Friday from 8:00AM to 4:00PM.

f) **To submit a request to extend IRB approval**, log in to your WebPortal account and access the protocol. On the protocol Main Page, click on "Progress Reports" under Protocol Maintenance

SAN DIEGO STATE UNIVERSITY

Graduate and Research Affairs
Division of Research Affairs
San Diego State University
5500 Campanile Drive
San Diego CA 92182-8220
Phone: 619-594-5938
Fax: 619-594-4109

and enter a report. Once you have filled in your responses on the report form, click "submit". You should receive an automated email verifying IRB receipt of your Report of Progress.

REQUIREMENT! Within the description box of the Report of Progress form, indicate which, if any, consent form(s) you are requesting to renew. Refer to the Consent Form Development section of the protocol and provide the IRB with the specific file names and date(s) of upload of the consent document(s) you are requesting to renew.

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 Nichols
Chair, Institutional Review Board

Brianne Larsen-Mongeon
Regulatory Compliance Analyst

Amy McDaniel
Regulatory Compliance Analyst

Choya Washington
Regulatory Compliance Analyst