SAN DIEGO STATE UNIVERSITY

Graduate and Research Affairs
Division of Research Affairs
San Diego State University
5250 Campanile Drive
San Diego CA 92182-1933
Phone: 619-594-5938
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Convened Committee Approval

Reg: 45 CFR 46.111(a) – minimal risk

Submit Report of Progress by: **11/10/14**

December 11, 2013

Faculty Researcher: Gregory Talavera, M.D.
Department: Graduate School of Public Health
Contract/grant number: HHSN268201300005I
vIRB Number: 1586091

Re: *Hispanic Community Health Study/Study of Latinos (HCHS/SOL) San Diego Field Center Visit 2 Examination*

Dear Professor Talavera:

The above referenced protocol was reviewed and approved as expedited in accordance with SDSU's Assurance and federal requirements pertaining to human subjects protections within the Code of Federal Regulations (45 CFR 46). This approval 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, staff member or student). **This approval expires December 10, 2014.**

- The following approved consent form(s) have been uploaded to your protocol file within the vIRB system, within the Supporting Documents section:

San Diego Eng Renewal 11.22.2013 IRB FINAL.pdf	12/11/2013

For questions related to this correspondence, please contact the IRB office ((619) 594-6622 or e-mail irb@mail.sdsu.edu).

Sincerely,

Ramona Pérez
Chair, Institutional Review Board

Amy McDaniel
Research Affairs Analyst

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Important information for ALL expedited and Full Committee studies:

Report of Progress:
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.

The approved consent form has been uploaded to your protocol file within the vIRB system, within the Supporting Documents. This document bears the SDSU 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 document without prior review and approval of the IRB. You are required to keep signed copies of the consent document for three years after your project has been completed or terminated.

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 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.

Modifications:
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, please follow the necessary steps below:

Modification steps:

- Access the protocol via the Webportal (https://sunspot.sdsu.edu/pls/webapp/web_menu.login/)
- Protocol main page click on “Modifications” to enter a report

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- Once the report has been fill out completely, click "submit"
- Make sure to email the IRB (irb@mail.sdsu.edu) notifying them that a modification has been submitted.

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.

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) **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) **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.