



APPROVAL

January 8, 2014

Neil Schneiderman
5665 Ponce de Leon Boulevard
Flipse Building
Coral Gables, FL 33146
305-284-6634
nschneid@miami.edu

Dear Dr. Neil Schneiderman:

On 1/8/2014, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Visit 2 of the Hispanic Community Health Study
Investigator:	Neil Schneiderman
IRB ID:	20131007
Funding:	National Heart, Lung, and Blood Institute, Funding Source ID: Contract #HHSN268201300004I
IND, IDE, or HDE:	None
Documents Reviewed:	<ul style="list-style-type: none"> • Anthropometry.pdf, Category: Questionnaire/Survey; • Family Cohesion.pdf, Category: Questionnaire/Survey; • Pregnancy Complications History.pdf, Category: Data Collection Sheet; • Tobacco Use Questionnaire.pdf, Category: Questionnaire/Survey; • Sitting Blood Pressure.pdf, Category: Data Collection Sheet; • Medication Use Survey.pdf, Category: Questionnaire/Survey; • Medical History Questionnaire.pdf, Category: Questionnaire/Survey; • BIOSPECIMEN COLLECTION FORM.pdf, Category: Data Collection Sheet; • Participant Feedback.pdf, Category: Questionnaire/Survey;

	<ul style="list-style-type: none"> • 20131007_ICF_UMMain_ENG.pdf, Category: Consent Form; • Chronic Stress.pdf, Category: Questionnaire/Survey; • Acculturation Questionnaire.pdf, Category: Questionnaire/Survey; • Participant Safety Screening Form.pdf, Category: Data Collection Sheet; • Alcohol Use Questionnaire.pdf, Category: Questionnaire/Survey; • Socio Economic_Occupation Questionnaire.pdf, Category: Questionnaire/Survey; • Health Care Questionnaire.pdf, Category: Questionnaire/Survey; • PHANTOM FORM.pdf, Category: Data Collection Sheet; • Personal Identifiers.pdf, Category: Data Collection Sheet; • V2 Invitation Miami.pdf, Category: Recruitment Materials; • AV_Consent.pdf, Category: Consent Form; • Reproductive and Medical History.pdf, Category: Data Collection Sheet; • Well-Being Questionnaire.pdf, Category: Questionnaire/Survey; • Social Support.pdf, Category: Questionnaire/Survey;
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The IRB approved the study from 1/8/2014 to 1/7/2015 inclusive. Before 1/7/2015 or within 45 days of the approval end date, whichever is earlier, you are to submit a completed Continuing Review to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 1/7/2015 approval of this study expires on that date.

To document consent, use the consent documents that were approved and stamped by the IRB. Go to the Documents tab to download them.

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system

Should you have any questions, please contact: Meghan Stein, IRB Regulatory Analyst,
(phone: 305-243-3195; email: m.stein@med.miami.edu)

Sincerely,

*[This is a representation of an electronic record
that was signed electronically and this page is
the manifestation of the electronic signature]*

Amanda Coltes-Rojas, MPH, CIP
Director
Regulatory Affairs & Educational Initiatives