Office for the Protection of Research Subjects Northwestern University 750 North Lake Shore Drive Suite 700 Chicago, Illinois 60611

### irb@northwestern.edu

Phone 312-503-9338



Fax 312-503-0555

9/27/2010

Dr. Martha Daviglus

Professor of Preventive Medicine and Medicine

**Preventive Medicine** 

680 N Lake Shore Dr, Suite 1102

Chicago, IL 60611

daviglus@northwestern.edu

IRB Project Number: CR2 STU00009660

Project Title: Hispanic Community Heal udy/Study of Latinos (HCHS/SOL)

**Project Sites:** 

Northwestern University (NU)

## Sponsor Information (Grant #, if applicable):

View National Heart, Lung, and Blood Institute

Submission Considered: Continuing Review Submission Number: CR2 STU00009660

**Review Type:** Full Review **Meeting Date:** 9/27/2010

Panel: Panel Q

**Status:** APPROVED **Approval Period:** (10/26/2010 - 10/25/2011)

Dear Dr. Daviglus,

The IRB considered and approved your submission referenced above through 10/25/2011. As Principal Investigator (P.I.), you have ultimate responsibility for the conduct of this study, the ethical performance

of the project, and the protection of the rights and welfare of human subjects. You are required to comply with all NU policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting unanticipated problems involving risks to subjects or others, or promptly reportable non-compliance in accordance with IRB guidelines.
- Submit a continuing review application 45 days prior to the expiration of IRB approval. If IRB reapproval is not obtained by the end of the approval period indicated above, all research related activities must stop and no new subjects may be enrolled.

# IRB approval includes the following:

## Written Consent Form/Consent Form and Authorization for Research:

Name

Addendum-consent-English-June7-2010

Addendum-consent-SPANISH-June7-2010

Main Consent English Language Clean 06-15-2010

Main Consent Spanish Language Clean 06-15-2010

Re Draw and Re Collection Lab Addendum English Clean 11-05-2009.doc

Re Draw and Re Collection Lab Addendum Spanish Clean 11-05-2009.doc

Stadiometer Consent Addendum English Clean 11-05-2009.doc

Stadiometer Consent Addendum SpanishClean 11-05-2009.doc

### **Protocol:**

Name

0623-011 Field Center Procedures Part 1 8-29-2008.pdf

0623-011 Field Center Procedures Part 2 8-29-2008.pdf

0623-011 Field Center Procedures Part 3 8-29-2008.pdf

0623-011 Protocol Part 1.pdf

0623-011 Protocol Part 2.pdf

## **Investigator Brochure:**

Non-FDA Brochures

There are no items to display

#### **Recruitment Materials:**

Name

0623-011 SRM Flyer 2 Spanish.pdf

0623-011 SRM Flyer 2.pdf

0623-011 SRM Flyer 3 Spanish.pdf

0623-011 SRM Flyer 3.pdf

0623-011 SRM Flyer Spanish.pdf

0623-011 SRM Flyer.pdf

0623-011 SRM Public Service Announcement.pdf

0623-011 SRM Subject Letter Spanish.pdf

0623-011 SRM Subject Letter.pdf

AFU Eng/Span Informational Letter-Updated on Letterhead 5/29/09

AFU Informational Letter-English Updated 5/26/09

AFU Informational Letter-English-Spanish

AFU informational Letter-Spanish Updated 5/26/09

**AFU Moving Card-English-Spanish** 

AFU Thank You Postcard-English-Spanish

Chicago SOL Newsletter-English

Chicago SOL Newsletter-Spanish

SOL follow-up recruitment card-side1

SOL Follow-up recruitment card-side2

## **Survey/Questionnaires:**

#### Name

0623-011 Alcohol Use Questionnaire Spanish.pdf

0623-011 Alcohol Use Questionnaire.pdf

0623-011 Ankle Arm Blood Pressure.pdf

0623-011 Anthropometry.pdf

0623-011 Audiometry Exam.pdf

0623-011 Biospecimen Collection Form.pdf

0623-011 Clinic Check Sheet.pdf

0623-011 Dietary Behavior Questionnaire Spanish.pdf

0623-011 Dietary Behavior Questionnaire.pdf

0623-011 Economic Questionnaire.pdf

0623-011 Health Care Use Spanish.pdf

0623-011 Health Care Use.pdf

0623-011 Health Survey.pdf

0623-011 Hearing Exam Questionnaire.pdf

0623-011 Hearing History Questionnaire.pdf

0623-011 Informed Consent Tracking.pdf

0623-011 Medical Family History Questionnaire Spanish.pdf

0623-011 Medical Family History Questionnaire.pdf

0623-011 Medication Use Questionnaire Spanish.pdf

0623-011 Medication Use Questionnaire.pdf

0623-011 Neurocognitive Assessment.pdf

0623-011 Occupation Classification and Exposures Questionnaire Spanish.pdf

0623-011 Occupation Classification and Exposures Questionnaire.pdf

0623-011 Oral Health Questionnaire Spanish.pdf

0623-011 Oral Health Questionnaire.pdf

0623-011 Otoscopy Exam.pdf

0623-011 Participant Safety Screening Form Spanish.pdf

0623-011 Participant Safety Screening Form.pdf

0623-011 Personal Identifiers.pdf

0623-011 Personal Information Questionnaire.pdf

0623-011 Phantom Form.pdf

0623-011 Physical Activity Questionnaire Spanish.pdf

0623-011 Physical Activity Questionnaire.pdf

0623-011 Respiratory Questionnaire Spanish.pdf

0623-011 Respiratory Questionnaire.pdf

0623-011 Sleep Questionnaire Spanish.pdf

0623-011 Sleep Questionnaire.pdf

0623-011 Social Network Index Questionnaire Spanish.pdf

0623-011 Social Network Index Questionnaire.pdf

0623-011 Sociocultural Questionnaire Spanish.pdf

0623-011 Sociocultural Questionnaire.pdf

0623-011 Tobacco Use Questionnaire Spanish.pdf

0623-011 Tobacco Use Questionnaire.pdf

0623-011 Tympanometry Exam.pdf

0623-011 Weight History Questionnaire Spanish.pdf

0623-011 Weight History Questionnaire.pdf

0623-011 Well-Being Questionnaire Spanish.pdf

0623-011 Well-Being Questionnaire.pdf

**AFU FPQ Response Card-English-Spanish** 

**AFU Informant Interview-English** 

**AFU Informant Interview-Spanish** 

AFU Informant interview-Spanish Updated 5/26/09

**AFU Interview Form-English** 

**AFU Interview Form-Spanish** 

AFU Interview Form-Spanish 5/26/09 Updated

**AFU Physician Questionnaire-English** 

**AFU Tracking Form** 

COM08RETAnnualFollowupYear205282010

COM08RETAnnualFollowupYear2Spanish03022010

Food Propensity Questionnaire-English-Version B

Food Propensity Questionnaire-Spanish-Version B

For more information regarding OPRS submissions and guidelines, please consult

http://www.northwestern.edu/research/OPRS/irb.

This Institution has an approved Federalwide Assurance with the Department of Health and Human Services: FWA00001549.

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Thanh-Huyen T. Vu, MD; PhD Department of Preventive Medicine

Northwestern University School of Medicine

680 N. Lake Shore Dr. Chicago, Ste. 1400, IL 60611

Tel: 312-908-6699 Fax: 312-908-9588

Email: huyenvu@northwestern.edu