IRB Review - Office Use Only	IRB Date Stamp - Office Use Only	IRB Accession Number
Northwestern University Institutional Review Board IRB #: 0623-011 APPROVED: 08/17/2007	RECEIVED AUG 13 2007 OPRS	200708-1031 Office Use Only IRB Project Number: **0623-011**

Northwestern University – Office for the Protection of Research Subjects
REVISION SUBMISSION FORM

☐ **Please check if this is in response to a pending issue**
Name of IRB Staff who requested the change: ____

Please do not submit responses to pending issues on this form unless it has been requested by our office. Responses can be submitted electronically or in paper as a memo along with a cover memo to the person requesting the change.

For ease of submission, please submit your revisions electronically:

- Scan the documents (in PDF format), and e-mail them to irb@northwestern.edu.
- Use this format for the subject line of your message:
  " Protocol Revision [IRB#]"

You can also send or bring them to the appropriate OPRS office:

- Biomedical: OPRS, Rubloff, 7th Floor, 750 N. Lake Shore Drive, Chicago, IL 60611
- Social/Behavioral: OPRS, Hogan, G100-6th Floor, 2205 Tech Drive, Evanston, IL 60208.

HANDWRITTEN FORMS WILL NOT BE ACCEPTED.

1. Submission Date: 8/13/2007
2. Principal Investigator Name:Martha Daviglus MD, PhD
Phone:**(312) 908-7967** Fax:**(312) 908-9588** E-Mail :**daviglus@northwestern.edu**
3. Submission Prepared By: Karen Mancera Cuevas, MS
Phone: **(312) 908-9372** Fax: **(312) 908-2814** E-Mail:**k-mancera-cuevas@northwestern.edu**
4. Current Project Title: Hispanic Community Health Study (HCHS)

5. Type of Protocol
☒ **Biomedical** ☐ **Social/Behavior Science**

6. Revision Description:
This new revision was initiated by: ☒ Investigator ☐ Study Sponsor
Please check all applicable categories:
☐ Change in Authorized Research Personnel (please attach an updated personnel sheet found on our web-site)
☒ Revised Consent/Consent and Authorization for Research Form (Please specify the type of submission)
☒ Change in Protocol/Procedures (this includes inclusion/exclusion criteria, data collection, and recruitment)*
☐ Protocol Amendment # dated
☐ Revised Investigator's Brochure Version Date:
Does this new IB represent any changes to risks listed in the current approved consent form? ☐ YES ☐ NO
☐ New/Revised Subject Recruitment Materials (Please specify if this is new or a revision of previously approved material in Section 7).
Please check all applicable categories:
☐ Newspaper/ Printed Periodical ☐ Internet1 ☐ Brochure ☐ Poster ☐ TV/Radio
☐ Letter to a potential participant ☐ Scripts (for verbal contacts)2 ☐ Physician Letter
☐ Videotapes (only script needed) ☐ Other (Explain)
☐ Change in total number of subjects to be consented or cases/persons/records to be studied

[1] Provide a copy of the printed version
[2] Submit scripts for all verbal contacts (including what may be verbally discussed with media over the telephone)

☐ Change in Risks: Attach new version of consent Version Date:
☐ Change in Principal Investigator**
New Principal Investigator's Signature: _____ Date: _____
☐ Change in Title:* (Please indicate the new Protocol title in Section 7)
☐ Change in study site(s)*
☐ Change in HIPAA Compliance*
☐ Change in funding source(s)*
☒ Other:* Please specify: **HCHS OSMB Draft Charter, questionnaires**
Note: Revisions that may affect your HIPAA forms are marked with a *.

7. **Description of Changes**

Instructions:

- Refer to the Revision Guidelines on the IRB website for additional information.
- Fill in the current status of each item to be revised in the left column below.
- Fill in the proposed revisions in the right column. Include the rationale for each revision. When the protocol has been revised, provide page numbers for each revision.
- **To enable a prompt and accurate review, all changes to the protocol, consents, HIPAA documents or recruitment materials must be highlighted. Revisions without highlighted changes will be returned to the investigator without review.**
- Version dates on all materials should be updated accordingly.
- If additional space is required, attach an additional sheet.

Both Columns below must be completed.

PRESENT SITUATION	REVISION REQUESTED
The HCHS/SOL Coordinating Center has provided field centers with a template English-language consent form in which we incorporated NU IRB consent requirements, baseline questionnaires, and specific Manuals of Procedures for all exam components. Additionally, a draft charter for the OSMB (Observational Study Monitoring Board) has been developed by the coordinating center.This information is provided to the IRB to describe the general role outlined by the institute for the OSMB in monitoring the study.	The attached HCHS/SOL consent form, baseline questionnaires, specific Manuals of Procedures, and the OSMB Draft Charter are attached for IRB review and approval. The consent form will be translated to Spanish-language after we have received NU IRB approval of the English-language version.

VA ACOS Research and Development Name and Signature (If applicable) Date

MARTHA C. DARLING MD, PhD Martha Darling 8/13/07

Investigator's Name and Signature Date

Please check all applicable sites listed below to be copied on this submission:

☐ AIDS
☐ CRO
☐ GCRC
☐ NCCR

- ☐ RIC
- ☐ NMH
- ☐ VA
- ☐ Other:

NORTHWESTERN UNIVERSITY
Department of Preventive Medicine

CONSENT FORM
Study of Latinos (SOL)
Hispanic Community Health Study (HCHS)

INVESTIGATORS:
Principal Investigator, Martha L. Daviglus MD, PhD
Co-Principal Investigator, Kiang Liu, PhD
Co-Principal Investigator, Aida Giachello, PhD (University of Illinois at Chicago)
Project Coordinator, Karen Mancera Cuevas, MS

SPONSOR: National Institutes of Health

PURPOSE OF THE STUDY:

You are being asked to participate in SOL, a national health research study of Hispanics / Latinos. SOL is conducted by Northwestern University under a research contract from the National Institutes of Health (NIH). Before you give your consent to volunteer, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do in this study.

The purpose of SOL is to learn about the health of Latinos in the United States and to identify the factors that influence the health of the Latino population. You are one of 4,000 persons selected by chance from the residents of Chicago and asked to participate in this study. A total of 16,000 people from 4 cities across the nation (4,000 per city) will be included in the study. Your participation in SOL will last for as long as you agree to participate.

This research study is being done by Northwestern University in collaboration with the University of Illinois at Chicago (UIC). The clinical examination takes place at CommunityHealth, a clinic located at 2611 W. Chicago Ave, or at the Preventive Medicine clinic at 680 N. Lake Shore Dr., Suite 800 and lasts approximately 6 hours.

PROCEDURES:

If you agree to take part in SOL your visit to the clinic will include the following:

An **interview** with questions about your health, health care, occupation, diet, lifestyle, beliefs, and family medical history.

An **examination** to measure your height, weight, waist size, percent body fat, and blood pressures in your arms and ankles. You will also be asked to participate in the following procedures that are conducted by trained and certified SOL staff:

- A trained technician will draw some of your blood (up to 2.7 oz, which is 79 cubic centimeters or approximately 5 tablespoons) for blood tests that will include cholesterol and other blood fats, sugar levels, kidney function, liver function, tests for hepatitis, and other factors. Some of your blood will be stored for future studies.

- Because it is important that blood for these blood tests be collected while fasting, you were asked not to eat anything after 10 o'clock last night before your examination. After the fasting blood sample is drawn, you will be asked to complete a glucose tolerance test, which tests for possible diabetes. This involves drinking a high-sugar drink, consuming nothing else for two hours, and then having another 1/2 tablespoon of blood drawn. Besides the minor risks and discomfort of a second blood draw, there is a slight chance of stomach upset that occurs in about 1 person in 100. After the second blood draw, you will receive a snack. Results will indicate if you have diabetes, or are at risk of having diabetes. If you have diabetes or are being treated for high blood sugar you should not take the test. If you do not know if you have diabetes, a test with a tiny amount of blood from your fingertip (0.5 micrograms) using a lancing device will be done. The results will be ready in 15 seconds or less and will determine whether you should have the glucose tolerance test.

- While you are at the clinic you will be asked to provide a small amount of urine for tests of kidney function.

- Body tissues are made up of cells. Cells contain DNA, which is your unique genetic material that carries the instructions for your body's development and function. Some diseases can result from changes in a person's genetic material that cause cells to not work properly. Currently, researchers and doctors know some of the genetic changes that cause disease, but they do not know all of the genetic changes that cause disease.

  - You will be asked to permit genetic testing on the blood samples that will be collected and stored as part of SOL. Your blood samples may be used to isolate DNA and/or RNA (a substance related to DNA). Your blood, genetic material and other information you provide will be identified only by a number. Some of your blood and your genetic material will be stored for future studies by the SOL investigators and their collaborators for studies on conditions of the heart and blood vessels, lung and blood diseases, stroke, memory loss, deafness, cancer, obesity, diabetes, joint disease, bone loss, and other diseases and health conditions.

  - At times, researchers from private companies or other investigators that are not affiliated to SOL may request use of your DNA to develop diagnostic laboratory tests or treatments. Like other parts of this study, this is optional and you can choose not to allow your DNA samples to be given to private companies or other investigators by indicating this in the Consent section of the consent form. If you agree to allow your samples to be used in this

manner, neither your name nor other identifying information will be given to these researchers.

- An electrocardiogram (ECG) that measures whether your heartbeat is regular and your heart shows any signs of illness.

- A brief examination of your ears and a test of your hearing.

- A test of your lung function that requires you to blow hard into a machine, to find out how well your lungs are working. If the test results indicate that your breathing capacity may be reduced you will be asked to breathe in a medication that opens up the airways (Albuterol, which is routinely used by persons who have asthma), and then to repeat part of the test. If you have asthma you will be asked to take your own medication before the test.

- An examination of your teeth and gums conducted by a licensed dental hygienist. This exam will look for cavities and take measurements that indicate whether your gums are healthy.

Monitoring of Physical Activity: At the end of your examination visit at the SOL center you will be asked to wear a small, light-weight device similar to a watch that will automatically record your physical activity during your routine activities. You will be provided with instruction on how to use this monitor and how to return it to the clinic after seven days.

Sleep Study: You will be asked to wear a monitor on your forehead for one night to learn more about how sleep patterns influence health and disease. At the end of your exam visit you will be shown how to wear this monitor and how to return it to the clinic.

Repeat Interview: Four to six weeks after your visit to the clinic we will contact you to set up an appointment for a telephone interview that will last 40 minutes, to ask questions about your diet, very similar to the ones you answered during the examination visit.

Annual Contacts: After your initial examination at the clinic you will be contacted by telephone once a year to answer a brief questionnaire about your health, including whether you were hospitalized during that year. If we are unable to reach you at your current address we will contact the relatives or other individuals you identify or name to help locate you.

Follow-up Examination: It is anticipated that follow-up clinical exams will be done approximately every 4 to 8 years. If you choose to participate at that time, you will be asked to sign a new consent form.

Medical Record Review: If you are hospitalized or treated in an emergency department or urgent care center, we will request your signed permission at the time of annual contact for SOL personnel to obtain and review a copy of the hospital or outpatient records, emergency department/urgent care, cancer registry, and your

physician's medical records. We will use your signed medical release to obtain these records. You can cancel this authorization at any time by contacting the Study Manager listed at the end of this form. We are interested in diseases such as asthma and other lung disease, high blood pressure, heart diseases and diseases of the blood vessels, stroke, obesity, diabetes, kidney disease, cancer, and surgeries, interventions, and others. In the event of your death, information will be sought from your relatives or other sources, including coroner's report, medical records, (if your death takes place in a hospital or long term care facility), and information from the state health department. In all these instances, your social security number may be used to confirm your identity and assure that the correct records are reviewed.

New Information: If new knowledge about the conditions evaluated by SOL becomes available during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

Option for Additional Studies: You may be contacted to determine if you are interested in participating in other health-related studies done in collaboration with SOL. Only SOL personnel will be authorized to contact you on behalf of this study.

Ownership of Your Samples: Your DNA and blood samples belong to you. Your genetic material and samples will be stored at the SOL Central Laboratory. They will not be sold to any person, institution, or company and will not be used for cloning (creating body organs or tissues or fluids from genetic material). Information gained from research on your genetic material may be used for the development of diagnostic procedures or new treatments for major diseases. Neither you nor your heirs will benefit financially from discoveries made using the information and/or specimens that you provide. On the other hand, discoveries made using your genetic material could benefit other generations and humanity in the development of preventive measures and/or treatment for known diseases.

RESULTS:

A report on the results of your exams (with an additional copy to provide to your doctor if desired) will be mailed to you. You will also be given the option to authorize permission for your results to be sent directly to your doctor. It is recommended that you discuss any abnormal findings with your primary care physician. The results take a longer amount of time to report than your average medical exam, due to the process of data transmission and collection.

If your blood tests show that you have been infected with a hepatitis virus we will notify you, and we must also notify the Department of Health following guidelines for Notifiable Diseases or Conditions.

POTENTIAL RISKS AND DISCOMFORTS:

All of the examinations done by SOL are routinely included in standard health screenings and are considered safe. There are no known risks if you are, or may become, pregnant. However, some possible general discomforts may include headaches or feeling hungry, and fatigue or chills during a long exam.

A skilled technician will draw your blood. Minimal bruising, pain, or bleeding may occur as a result of the blood draw. No materials will be injected into your body; blood will only be withdrawn. The technician wears latex gloves when drawing blood. If you have a known latex allergy, inform the technician and he/she will use gloves made from another material.

There may be some discomfort from the repeated blood pressure measurements. You might experience some embarrassment or anxiety from answering some sensitive background questions. You may refuse to answer any questions that make you uncomfortable.

For the oral glucose tolerance test, besides the minor risks and discomfort of a second blood draw, there is a slight chance of stomach or bowel upset that occurs in about 1 person in 100.

If you have an artificial heart valve, a history of endocarditis (infection of a heart valve), were born with a serious heart condition, or have had a heart transplant, no measurements of gum disease will be made during your oral health examination to avoid a condition called infective endocarditis (infection of the heart valves). The oral health examination should cause no more discomfort than when a dentist examines your teeth and gums. If your gums normally bleed when touched, they may also bleed during the exam.

On rare occasions a person taking a lung function test may feel lightheaded or may faint. The primary risk involved is injury from falling. Participants asked to inhale the medication called Albuterol during lung function testing may notice an increase in heart rate (pulse) or feel jittery or shaky (tremors). In the unlikely event that during examination procedures you should require medical care, first aid will be available. If you have any concerns, a SOL staff person is available to talk with you.

You may also learn of a health or dental condition that you did not know you had, or that may require you to consult with a physician for further evaluation or treatment. If any clinically important medical problems are found, you may be obligated to provide this information to your insurance company or employer. However, no personal results will be released by SOL without your approval.

ANTICIPATED BENEFITS:

There may not be a direct benefit to you from being in this study. You will be given a report of all your results from this examination that may have medical value for diagnosis or treatment, including your blood pressure, blood cholesterol, blood sugar, kidney and liver function, body mass index, body composition percentages, urine protein level, hearing test, lung function test, oral examination and electrocardiogram. Since this is a research study, and the examination you receive is not a substitute for care you would receive from your health care provider, we do not make a diagnosis, provide treatment, or give medical advice. Instead, we will encourage you to share your results with your health care provider. If you do not have regular health care, or you are unable to afford such care, a SOL staff member will assist you in locating affordable health care.

ALTERNATIVES:
Your alternative is not to participate in SOL.

FINANCIAL INFORMATION:
There will be no costs to you for participating in this study. The tests done as part of this study are paid for by research grants. In the event that your physician decides that follow up clinical tests or treatments are necessary, payment must be provided by you or your third party payer, if applicable (for example, health insurance or Medicare). No special arrangements will be made by SOL for compensation or for payment of treatment solely because of your participation in this study. This does not waive any of your legal rights.

You will receive $50.00 payment for your participation to cover costs that you might incur the day of your clinic visit such as, but not limited to, loss of work, transportation (gas, tolls, parking, etc.), or child care.

RESEARCH-RELATED INJURY:
If any injuries or complications arise as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. Northwestern University will not pay for any care, lost wages, or provide other financial compensation.

SUBJECT'S RIGHTS:
If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study at any time. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefits to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your the quality of your medical care or your relationship with Northwestern University or UIC.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office for the Protection of Research Subjects. You can call them at **312-503-9338**.

If you decide to withdraw from the study the information collected about you may still be used in this study, unless you request that your records and test results obtained be removed from study files. You may also request that your DNA and blood samples be destroyed or that all identifiers be removed (including code numbers) from such samples. If you choose to withdraw your samples, you should call the Study Coordinator, Karen Mancera-Cuevas, MS, at **312-908-9372**. The investigators may decide to discontinue your participation without your permission because they may decide that staying in the study will not be beneficial for you, or the sponsor may stop the study.

CONFIDENTIALITY:

Protecting your privacy is a top priority for SOL. Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law. To ensure confidentiality, a code number will be assigned to you and information that may identify you. The code numbers will only be provided to qualified investigators in SOL. Files linking names and other identifying information to data and blood samples will be electronically saved and kept at Northwestern University using technology which prevents unauthorized individuals from seeing and understanding it. If your information is printed, it will be kept locked and accessible only to certified SOL personnel in Chicago. This SOL code number will not be used on any blood samples you provide. A label with a new security bar code number and the date the specimen is drawn will be the only information on the blood samples. The coded samples and records will be stored securely, separated from any files that can link your name to the code numbers. No other individuals will have access to the stored samples or information gained from your stored blood sample or genetic information. Your samples will be kept until no longer of scientific value.

When study results are published your name and any other potentially identifying information will not be revealed. You will be kept informed through periodic publications from SOL on any new findings from this study. Results from this study and from your records may be reviewed and photocopied by the Food and Drug Administration (FDA), other federal regulatory agencies such as the Office of Human Research Protection, and the Institutional Review Board of Northwestern University. To help insure your privacy, a Certificate of Confidentiality has been obtained from the National Heart, Lung, and Blood Institute for this study so that no agency can subpoena or compel the release of information about you collected in this study without your permission. The researchers can make disclosures of information only in very special cases (for example, if they think that a participant or someone else is in serious danger of harm).

NORTHWESTERN UNIVERSITY
Department of Preventive Medicine

CONSENT TO PARTICIPATE
Study of Latinos (SOL)
Hispanic Community Health Study (HCHS)

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this consent form to keep after you sign it.

If you do not wish to participate in any test mentioned above cross it out and print your initials next to it on this form or have the SOL staff mark this form according to your instructions. Please initial the appropriate place beside each statement shown below:

1) I _____ agree I _____ do not agree	to participate in the Study of Latinos (SOL) and the examinations described above.
2) I _____ agree I _____ do not agree	to donate blood and urine samples to be frozen, stored, and used for the tests described above and for other future SOL research.
3) I _____ agree I _____ do not agree	to allow the SOL staff to release the findings from examinations and non-genetic tests to my physician or clinic.
4) I _____ agree I _____ do not agree	to be contacted once a year by the SOL staff to answer questions about my health and to update my address.
5) I _____ agree I _____ do not agree	to provide a blood sample from which genetic material (DNA and RNA) can be extracted, stored and used for current and future studies by the SOL investigators and the investigators they work with.
6) I _____ agree I _____ do not agree	to have blood, genetic material (DNA/RNA) and other information I provided made available without my name or other identifying information to scientists that work with the SOL investigators, and other qualified researchers who have satisfied requirements for protection of confidentiality and privacy.
7) I _____ agree I _____ do not agree	to participate in genetic studies of factors that contribute to health and disease.

8) I _____ agree I _____ do not agree	to allow researchers from private companies to have access, in a way that cannot identify me, to my specimens, DNA/genetic data, and other information I provided to develop diagnostic laboratory tests or medical treatments that could benefit many people. I understand that that my DNA will not be sold to anyone and that neither I nor my heirs will benefit financially.
9) I _____ wish I _____ do not wish	to know my results if a genetic condition is identified that could have important health or medical treatment implications.

The stamp below indicates that Northwestern University has approved this consent form. My signature below indicates the following:

- That I have read the information in this document / it was read to me
- That I have had a chance to ask any questions I have about the study and that if I have additional questions, I have been told who to contact
- That I agree to be in the study
- That I have been told that I can change my mind and stop participating at any time
- That I have been given a copy of this consent form

Printed Name of Participant	Signature	Date
Printed Name of Person Obtaining Informed Consent	Signature	Date

Northwestern University
Institutional Review Board
IRB #: 0623-011
Approved to consent subjects
through: 10/25/2007