

HCHS/SOL V2 NIH APPROVED
ENGLISH INFORMED CONSENT ON DECEMBER 12, 2013

HCHS/SOL V2 consent- V12-27-13

This is the final Informed Consent for
HCHS/SOL Visit 2 approved by NIH on 12-27-2014

Note: Field centers should change only center specific information to personalize pertinent information for the center. Basic content of the consent should not be edited by any center. This is the final approved content for the consent as approved by the Project Office of NIH.

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0584). Do not return the completed form to this address.

OMB#: 0925-0585 Exp. xx/xx/xxxx

UNIVERSITY OF _____

School/Division _____

CONSENT (Permission) TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Visit 2 of the Hispanic Community Health Study/Study of Latinos

Principal Investigator:

Department/Division:

Email Address:

Phone Number:

Study Contact/Project Coordinator:

Study Contact/Project Coordinator Email Address:

Study Contact/Project Coordinator Phone Number:

SPONSOR: National Heart, Lung, and Blood Institute, National Institutes of Health

Please Read the Following Carefully

You are being asked to continue your participation in the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), a national health research study of Hispanic/Latinos. As part of this continuation you are asked to take part in the Visit 2 examination. This study is funded by the National Institutes of Health (NIH) under a research contract with the University of _____. This consent form contains important information to help you decide if you wish to continue in this study. Before you give your consent to be part of this study, please read the following and ask as many questions as necessary to be sure that you understand what your participation will involve.

Invitation to participate

- You are being invited to participate in the second in-person examination of the HCHS/SOL study, a health research project conducted by _____ University under a research contract from the National Institutes of Health (NIH).
- Your participation in this study is entirely voluntary.

What is the purpose of this study?

- HCHS/SOL is an ongoing study that includes approximately 16,400 participants from four centers across the country.
- You are one of 4,000 people selected by chance from the residents of _____ who enrolled to participate in this study.

- The purpose of this research study is to learn about the health of Hispanic/Latinos in the United States and to identify causes of certain chronic diseases in the Hispanic/Latino population.

Who is eligible to participate in this study?

- Persons who participated in Visit 1 of the HCHS/SOL can participate in Visit 2 of the study

What is involved?

- This research study is being done by the University of _____ with other universities elsewhere in the United States. The research examination will take place in the _____, located in the _____. This is the address of the _____ Field Center of the HCHS/SOL.
- This new HCHS/SOL clinical examination will last approximately 3 hours and 30 minutes. If you agree to participate, your HCHS/SOL visit will include interviews and the examination procedures listed below. Although all the procedures and activities performed in this study are safe for pregnant women and women who are nursing, women who are pregnant will be asked to schedule their exam three months after giving birth. If you do not wish to participate in an interview or test mentioned below, then cross it out and print your initials next to it, or have the HCHS/SOL staff mark the form according to your instructions.

1. Interviews will last about 2 hours, with questions about your health, health care, lifestyle, and medical history. You will be asked about your current medications and women will be asked about their health during pregnancies.

2. The physical examination will last about 50 minutes. You will be asked to participate in the following:

- **Height, weight, waist and hip size, and percent body fat measurements.** If you have an implanted device (such as a pacemaker or defibrillator) your weight will be measured using a non-electronic scale.
- **Blood Sampling.** A trained technician will draw samples of your blood (55 milliliters or approximately 4 tablespoons) for tests that will include cholesterol and other blood fats, glucose (sugar) level, kidney function and other factors. With your permission, some of your blood may be stored for future studies. **We will not test for HIV, AIDS or sexually transmitted diseases.** Because it is important that blood tests be collected while fasting, you were asked not to eat or drink anything except water after 10 o'clock the night before your

examination at the HCHS/SOL center. You were also asked not to smoke the morning of your examination at the HCHS/SOL center.

- Most of this blood sample will be taken early during the exam, while you are fasting. If you do not have diabetes, you will have a **glucose tolerance test (test of diabetes)** done. To do this test, you will be asked to drink a liquid with a high concentration of sugar. And two hours later, a small blood sample will be drawn to measure your blood glucose.
- The blood sample given by you **will be used for research only**. Your samples will be kept until no longer of scientific value or you tell us to destroy them. These samples are not available in the future for your personal use or clinical (diagnostic) purposes.
- Any present or future research on your blood samples must be **approved by an authorized Institutional Review Board (IRB)**, or in the case of international research it must adhere to the International Conference on Harmonization for Good Clinical Practice (ICH-GCP). If needed, you may be contacted in the future to request your informed consent and authorization to use your samples.
- **Urine sample to measure kidney function.** While you are at the clinic you will be asked to provide a small amount of urine. We will not test for illegal drugs in your urine. Your urine sample will be used only for research studies and some of your urine will be stored for future studies.
- **Echocardiogram:** If you are 45 years old or older and have not participated in the ECHO-SOL Ancillary Study, we will perform an Echocardiogram. This test may take 30 to 45 minutes. A trained technician will perform a test on your chest using sound waves to measure the ability of your heart to pump blood. A computer will pick up echoes of the sound waves from different parts of your heart and turn them into moving pictures of the heart that can be seen on a computer screen. This test is not being performed for the purposes of making a specific diagnosis and is not a substitute for an echocardiogram study ordered by your doctor. This test is not as extensive as a full echocardiogram like the one your doctor may order to diagnose a medical condition.
- The pictures that will be taken will be evaluated by investigators who will not be present at the time the tests are performed and who will not be familiar with you or your medical history. The test results will be sent to you, and with your permission can also be sent to your doctor or health care provider.
- **Genetic Research Tests:**

- DNA is material in our bodies that contains genes. RNA is another material that plays a role in the way genes work. If you gave your permission at the first exam visit, HCHS/SOL collected your DNA/RNA from your blood samples for research studies and long-term storage.
- The HCHS/SOL study examines your DNA and RNA to learn whether genes and gene products can help us understand the risk of diseases in adults, particularly heart disease, stroke, brain function, lung, and others. HCHS/SOL looks at specific genes and the entire sequence of DNA for their contribution to risk of disease. That means that **HCHS/SOL does not examine your DNA to diagnose diseases nor to do clinical genetic testing or genetic counseling**. Therefore the results of this research will not be reported to you, or to others who may request this information for clinical use. New knowledge may become available in the future to recommend that we contact you, to ask whether you would like to receive genetic research results.

What should be known about sharing of data and samples

In order for science to progress, researchers exchange scientific resources and information with strict precautions of confidentiality. We are asking for your permission to allow sharing of your data and samples, in a way that cannot be used to directly identify you, with researchers who are not part of the HCHS/SOL study.

- **Use of data and samples:**

- In addition to study information and genetic data, portions of samples of your blood, urine and DNA/RNA will be stored by HCHS/SOL and the National Institutes of Health for use by researchers.
- The National Institutes of Health will allow qualified researchers to analyze your samples after your identity has been removed. Researchers can qualify to use this data by proposing a research study approved by National Institutes of Health and by agreeing to protect your identity.
- Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to researchers not associated to the HCHS/SOL.

- **Commercial use of data and samples:**

- Researchers from private companies that develop diagnostic lab tests, or treatments for diseases, may request access to your study information or samples. These researchers will not have access to personal information that identifies you, such as your name, date of birth, address, etc.

- Your samples 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 your genetic material).
- Neither you nor your family would benefit financially from discoveries made using the information and/or specimens that you provide.
- HCHS/SOL data may lead to inventions or patents in which private companies, HCHS/SOL investigators or their universities may participate and may benefit.
- **Use of data and samples for genetic research:**
 - Detailed information about your DNA will be stored indefinitely at the National Institutes of Health, where investigators not associated to the HCHS/SOL may request access to it for research. This information and all of your other data will be used by researchers to look for genes that affect the risk of developing diseases and may lead to better methods for prevention and treatment for diseases such as diabetes.
 - The stored information is de-identified, which means that identifying information such as your name, date of birth, address, is removed. Access to this stored information will be controlled by the National Institutes of Health.
 - The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws, which might include Freedom of Information Act (FOIA) requests for de-identified information. This is explained on the following website: <http://www.nih.gov/icd/od/foia/efoia.htm>.
- **Certificate of Confidentiality:** To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.
- The Certificate cannot be used to resist a demand for information from an agency of the United States Government that is used for auditing or evaluation for Federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA).
- You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your Involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the study investigators may not use the Certificate to withhold that information.

- There is another exception: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent in incidents such as child abuse, and intent to harm yourself or others.

Who will have access to study data?

- The following institutions may have access to your data _____ University/Medical Center and the HCHS/SOL Coordinating Center at the University of North Carolina at Chapel Hill. The National Heart, Lung, and Blood Institute, NIH, and other institutions that are fund and collaborate with the HCHS/SOL may be given access to portions of your data without information that can identify you.
- The National Heart, Lung, and Blood Institute will obtain information from this epidemiological study under data collection authority Title 42 U.S.C. 285 b.

How will medical records help HCHS/SOL?

- If you are seen at an emergency room, urgent care or clinic, or admitted to a hospital, long term care facility or nursing home, we will ask that institution for your medical records so that HCHS/SOL can learn about your health. We will request your signed permission for HCHS/SOL staff to obtain and review a copy of the records from the hospital, clinic, emergency department/urgent care or cancer registry.
- We may request records from your doctor for certain office or clinic visits and we may request Medicare records to determine if you have been diagnosed with one of the diseases that HCHS/SOL is studying.
- To learn more about the health of Hispanic/Latina women we may request hospital records related to births and also birth certificates.
- We will use your signed medical release to obtain these records. You can cancel this authorization at any time by contacting the Project Coordinator or Clinic Manager listed at the top of this form.
- In the event of your death, information about the causes of death or events leading to death will be sought from your relatives or other sources, including the coroner's report, your medical records (if your death takes place in a hospital or long term care facility), and the state health department. If you have provided us your social security number it, may be used to confirm your identity in these instances to assure that the correct records are reviewed.

Will there be follow-up phone calls or communications from HCHS/SOL staff?

We will contact you by phone every 12 months and ask you about your health since the last contact. If you are unable to answer questions yourself, we may contact a person you have named who could answer questions for you. We may ask you to update this person's name during this interview. If in the future we do not have updated information to locate you, we will attempt to obtain that information from your contact(s), internet searches, public directories, social media or a visit to your last known address. If you provide your telephone number and or e-mail address, with your consent HCHS/SOL will use text messages and/or e-mail to send reminders of your annual follow up interview.

New scientific knowledge. If new scientific knowledge about the conditions evaluated by HCHS/SOL becomes available during the study that may affect whether you want to continue to take part, then you will be informed about such findings as soon as possible.

Option to participate in additional studies. You may be contacted to determine if you are interested in participating in other studies done in collaboration with HCHS/SOL. The studies may be related to your health or to laboratory information in the HCHS/SOL data, or ask for authorization to extend the study to children or other family members. Only HCHS/SOL personnel will be authorized to contact you on behalf of this study. You, of course, may choose at that time whether to take part in additional research.

What is the duration of the participation in HCHS/SOL? Your participation in HCHS/SOL is voluntary, and will be for as long as you agree while the study is active.

What will happen to stored blood, urine, cells and DNA samples? You have the ability to decide how your samples should be used. We will hold them until no longer needed or until you tell us to destroy them. Your blood, urine, cells and DNA samples will be identified only with a number code and sent to an HCHS/SOL laboratory for storage, or for detailed analysis. Some of your samples will be stored for an unlimited time, for future use in studies related to diseases or in other research projects that have been approved by HCHS/SOL.

Test results from this examination

A report on the results of your exams will be mailed to you by the HCHS/SOL research center. With your permission, we can also send the results to your physician. It is recommended that you discuss the findings with your primary care physician. If you do not have a personal health provider HCHS/SOL staff will provide you information on physicians and clinics in your community. Since this is a research study, any 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. Your health care provider is responsible for deciding any appropriate

medical follow-up, testing, or treatment based on your exam results. Results from genetic tests will not be reported. Because HCHS/SOL measures your test results at a research laboratory, the results take a longer amount of time to report than an average medical exam.

What are the potential risks and discomforts of participating?

All of the examinations and tests done by HCHS/SOL are considered safe and none involve X rays, or other types of radiation. However, some possible general discomforts may include headaches or feeling hungry, and fatigue or chills during a long exam. If you wear a medical device such as a pacemaker or another implanted device or if you had a mastectomy (surgery to remove one or both breasts) you should notify the HCHS/SOL staff at the start of your exam visit to ensure that certain tests are avoided or modified as needed.

- **Medical care during the examination:** In the unlikely event that during an examination procedure you should require medical care, first aid will be available.
- **Fasting:** There is a chance that your blood glucose (sugar) levels drop because you are fasting, especially if you have diabetes. You may feel cold sweats, blurry vision, rapid heart rate, shaking of the hands, dizziness, or fainting. These symptoms can be relieved by some fruit juice, a snack and/or lunch, which can be given after your blood is drawn. Of course, if necessary or requested, juice or a snack can be given earlier than planned.
- **Blood draw:** A skilled technician will draw your blood. Minimal bruising, pain, fainting, temporary bleeding or infection may occur as a result of the blood draw. No materials will be injected into your body. Blood will only be withdrawn.
- **Test for Diabetes (Glucose Tolerance Test):** The sweet liquid used for this test has a high concentration of sugar. After drinking it you may experience some stomach discomfort and fullness. These discomforts are temporary.
- **Interviews:** You might experience some embarrassment or anxiety from answering sensitive background questions. You may refuse to answer any questions that make you uncomfortable.
- **Echocardiography:** There are no known risks associated with ultrasound imaging of the heart. The ECG patches used during the study may cause minor irritation where they are placed on the skin.
- **Other risks and discomforts:** In addition to the risks and discomforts mentioned above, and how they can be decreased, there may be other adverse events associated with any of the procedures that are performed during this

examination which the investigators are not aware of. If you experience any other adverse event not mentioned above, it is extremely important that you make us aware of it.

- **A new health problem:** You may also learn of a health condition that you did not know you had or that may require you to consult with a physician for further evaluation and treatment. If any important medical problems are found, you may be asked by your insurance company or employer for this information. No personal medical results will be released by HCHS/SOL without your approval.
- **Data Sharing:** HCHS/SOL makes every effort to protect your identity and privacy, yet we cannot absolutely guarantee that information about you or your blood relatives will never become known. This is partly because of the possibility of matching your DNA sample with other DNA collections (such as those kept by law enforcement agencies). **However, researchers are strictly prohibited from attempting to identify you.**

What are the anticipated benefits of participating in HCHS/SOL?

- There will not be a direct benefit to you from being in this study. The information learned from this study will increase scientific knowledge about the causes of early heart disease, stroke, and memory loss, as well as other conditions.

What are the alternatives to participating?

Your alternative is not to participate in HCHS/SOL.

Will there be any financial benefit from participating? Will participating affect health insurance or the ability to get healthcare?

- There will be no costs to you for the tests performed by this study.
- 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 HCHS/SOL for compensation or for payment of treatment because of your participation in this study. This does not waive any of your legal rights.

Reimbursement

You will receive \$XX to reimburse expenses incurred by participating in the HCHS/SOL exam. [Center-specific: We will provide you with transportation to the research center in the study van. If you wish to drive yourself to the research center we will reimburse you for the cost of parking].

What if a research-related injury occurs?

If you believe that you have become ill or been injured from taking part in this study, treatment may be obtained through your regular doctor the treatment center or clinic of your choice. You may contact the researcher [Insert principal investigator name] at [Insert phone number] to talk to them about your illness or injury. You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. There are no plans for the University [insert name] to provide free medical care or to pay for research-related illnesses or injuries, or for the University [insert name] to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. By signing this form you will not give up any legal rights.

What are the rights of a HCHS/SOL participant?

- If you choose to be in this study you have the right to decide at any time whether or not you wish to continue or stop being in the study, not to answer some questions, or not to complete any of the HCHS/SOL exam components.
- If you decide to participate and then change your decision, you will have the right to withdraw from this study at any moment without negative consequences.

Giving and Withdrawing Consent

- Your decision of whether or not to participate in this study will not affect your current or future relations with the University of _____ [or _____ Medical Center]. If you decide to participate you are free to withdraw at any time without affecting those relationships. If you decide to leave the study, you may request that the Principal Investigator remove your records, test results, blood and urine samples, and DNA from the study, and it will be done so for all records and materials that are in the possession of HCHS/SOL. You also may withdraw your permission for anyone to use some of your health information (data and samples) at any time.

How will privacy and personal information be protected?

Protecting your privacy is a top priority for HCHS/SOL. Any information we obtain about you during this study will be treated as strictly confidential to the full extent permitted by applicable law.

- **Code numbers - not names:** To ensure confidentiality, a code number will be assigned to you and your medical information. Files with your name and other identifying information will be electronically saved separately from your medical information on a secure computer that can't be accessed by an unauthorized person. If your information is printed, it will be kept locked and accessible only to certified HCHS/SOL personnel at this HCHS/SOL field

center and the HCHS/SOL coordinating center. Only authorized HCHS/SOL personnel at these two locations will have access to your name and identifying information. HCHS/SOL will not share sensitive information with you via text message nor publish identifiable information on Internet sites.

- **What is the risk of being identified?** While we believe that the risks of being identified are very low and the benefits to science and the health of the community are large, there may be risks that we are not aware of at this time.
- The protected data developed for this project will not contain information that is used to identify you (such as your name, address, telephone number, or social security number), but it is possible that in the future people may develop ways to link your genetic or medical information back to you.
- To protect you, the **Genetic Information Nondiscrimination Act (GINA)** is a federal law passed in 2008 that makes it illegal to discriminate on matters of employment and health insurance in the U.S. based on genetic information. If you were identified by your genetic information however, this could potentially be used in ways that may cause you or your family distress, such as revealing that you (or a blood relative) carry a genetic disease, or by leading to the denial of employment or insurance for you (or a relative).
- **Publishing study results:** When study results are published your name and any other potentially identifying information will not be revealed. Results from this study and from your records may be reviewed and photocopied by the Office of Human Research Protection (OHRP) of the U.S Government or the Institutional Review Board of _____ University.

Can the relatives of the HCHS/SOL participants be involved in this research study or future studies? We may ask you if you will allow HCHS/SOL personnel to contact your relatives in the future, for health-related studies they may be interested in. They will be given the opportunity to agree or decline to participate.

Improving the quality of the information

We may ask you for authorization to audiotape some interviews for quality control purposes. Also, we may invite you to complete certain interviews or procedures if the information collected during a procedure is incomplete. Or, we may ask you to repeat certain interviews or procedures for quality control purposes. Repeating procedures is optional and will be shorter than the original visit. We will let you know how much time this will take when you are contacted.

Note: 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 HCHS/SOL staff mark this form according to your instructions.

IRB # _____ Approval Date: _____
Expiration Date: _____

(Stamp)

Whom to Contact

If at any time you have any questions about the study, you may contact <insert Principal Investigator name here> at <insert principal investigator telephone>.

In case of study-related injury, please contact <insert Principal Investigator name here> at <insert principal investigator telephone>.

If you have any questions relating to your rights as a research subject, please contact the University of _____ HUMAN SUBJECTS RESEARCH OFFICE (HSRO), at XXX-XXX-XXXX.

UNIVERSITY OF _____; Department / Division _____

CONSENT TO PARTICIPATE AND AUTHORIZATION
The Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

I will be given a copy this consent form after I sign it.

I have read or heard the above information, which is provided in Spanish and English, and have received answers to all my questions. I agree to participate in this HCHS/SOL examination and to allow researchers to collect, store and analyze my responses, measurements, blood, cells and urine samples now and in the future as specified below. I understand that if at any time I withdraw from this study, I will not suffer any penalty or lose any benefits to which I am entitled.

(Instructions: For each part of the statements below, please initial as to whether you agree or do not agree to participate and have your data or specimen used as described.)

1) Contact by HCHS/SOL staff:

I (agree/do not agree) to allow HCHS/SOL staff to contact me once a year to ask questions about my health and where I live.

_____ I agree _____ I do not agree

2) Release of my study results to a person I indicate:

I (agree/do not agree) to allow HCHS/SOL personnel to release my findings from exams and **non-genetic** tests to the physician, clinic or person that I designate.

_____ I agree _____ I do not agree

3) Use of my samples of blood, cells and urine by **HCHS/SOL**:

I (agree/do not agree) to allow **HCHS/SOL and investigators HCHS/SOL works with** to study my samples (blood, cells and urine) in current and future research.

_____ I agree _____ I do not agree

4) Use of my samples of blood, cells and urine by **other scientists**:

I (agree/do not agree) to allow **scientists not associated with HCHS/SOL** to study my samples (blood, cells and urine) in current and future research.

_____ I agree _____ I do not agree

5) Use of my samples of **genetic material** by **HCHS/SOL**:

I (agree/do not agree) to allow **HCHS/SOL and investigators they work with** to use my stored **genetic** material (DNA/RNA) for current and future research.

IRB # _____ Approval Date: _____
Expiration Date: _____

(Stamp)

_____ **I agree** _____ **I do not agree**

6) Use of my samples of **genetic material** by **other scientists**:

I (agree/do not agree) to allow scientists and specialized laboratories not associated with HCHS/SOL to study my de-identified stored **genetic** data, information, and samples.

_____ **I agree** _____ **I do not agree**

7) Use of my genetic and non-genetic information by **commercial or for-profit companies**:

I (agree/do not agree) to allow **commercial or for-profit companies that are not part of HCHS/SOL to use my de-identified stored genetic and non-genetic** information and samples to develop new diagnostic tests and medical treatments that may benefit people.

_____ **I agree** _____ **I do not agree**

8) Contact about future studies that may interest me:

I (agree/do not agree) to allow HCHS/SOL staff to contact me about my interest in participating in future health-related studies.

_____ **I agree** _____ **I do not agree**

9) Contact with my family members about studies that may interest them:

I (agree/do not agree) to allow HCHS/SOL personnel to contact my family members in the future for health-related studies. They will be given the opportunity to agree or decline participation.

_____ **I agree** _____ **I do not agree**

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

With my signature I also give permission for any hospital and/or health clinic where I have sought medical care to release any of my health records that HCHS/SOL needs and requests. This permission has no expiration date.

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