Hispanic Community Health Study / Study of Latinos

[INSERT INSTITUTION Name]

Informed Consent

You are being asked to participate in the Hispanic Community Health Study / Study of Latinos (HCHS / SOL), a national health research study of Hispanics / Latinos. HCHS / SOL is conducted by the University of [_____] 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.

Background

The purpose of HCHS / 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 [_____] and asked to participate in this study. This is part of a larger study including a total of 16,000 people from 4 cities across the nation (4,000 per city). Your participation in HCHS / SOL will last for as long as you agree to participate.

Investigators

This research study is being done by the University of [_____] in collaboration with [community partners] and other universities elsewhere in the United States. The research examination takes place at the HCHS / SOL examination center located at [_____] and will take approximately 6 hours.

What happens in this research study

If you agree to take part in HCHS/SOL your visit to the study field center will include the following:

I**nterviews** that will last approximately 3 hours and 40 minutes with questions about your health, health care, occupation, diet, lifestyle, beliefs, and family medical history. It is anticipated that an exam at the SOL center will be done approximately every 4 to 8 years. If you participate at that time you will be asked to sign a new consent form.

Several **examinations** lasting approximately 2 hours and 45 minutes in total to measure the following:

- Your height, weight, waist size, percent body fat and blood pressures in your arms and ankles.
- 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 are asked not to eat or drink anything except water after 10 o'clock the night before your examination at the SOL center. You are also asked not smoke the morning of your examination at the SOL center.

- 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.

- While you are at the SOL examination center you will be asked to provide a small amount of urine for other 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 make-up that contributes to cells not working properly. Currently, researchers and doctors know some of the genetic changes that can cause disease, but they do not know all of the genetic changes that can cause disease.

    - You will be asked to permit genetic testing on the blood samples that will be collected and stored as part of HCHS / 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 HCHS / 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 HCHS / SOL may request the 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 this 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, as would be done by a specialist in an ear clinic.

- 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 in advance of the test.

- An examination of your teeth and gums conducted by a licensed dental care professional. 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 HCHS / SOL center you will be asked to wear a small, light-weight item similar to a watch that will automatically record your level of 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 HCHS / SOL center 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 HCHS / SOL center.

Result of your tests
With your permission, a letter summarizing test results that have value for medical diagnosis or treatment will be sent to you and to your physician or clinic. Results from genetic tests will be reported only if they are clinically significant and if treatment for these findings is known. If you do not wish to have your study results sent to your provider of health care you will be able to designate another person who should be informed of your test results.

Repeat Interview
Four to six weeks after your visit to the HCHS / SOL examination center 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 HCHS / SOL center 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.

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 HCHS / 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 conditions such as asthma and other lung disease, high blood pressure, heart diseases and diseases of the blood vessels, stroke, obesity, diabetes, kidney disease, cancer, surgeries, interventions, and others. In the event of your death, we will seek information 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.

Risks and Discomforts

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

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 and you might experience some embarrassment or anxiety from answering any sensitive background questions. You may refuse to answer any questions that make you uncomfortable.

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 have to provide this information to your insurance company or employer. However, no personal results will be released by HCHS / SOL without your approval. If you do not have a personal health provider, the HCHS / SOL clinic staff will assist you in getting a referral to the appropriate medical or dental professional.

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.

If you have an artificial heart valve, a history of endocarditis (infection of a heart valve), were born with a serious heart condition or 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 a little 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, used 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 HCHS / SOL staff person is available to talk with you.

Benefits
There may or 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 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 summary report of results with your health care provider and, with your permission, results will be sent to her/him. Should you not have regular health care, or be unable to afford such care, HCHS / SOL will assist you in locating affordable health care.

Costs
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. If the examination uncovers any medical problems that require medical diagnosis or treatment, you will be so advised and that information will be provided to the physician or clinic that you choose. 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 solely because of your participation in this study. This does not waive any of your legal rights.

Ownership of your samples
Your DNA and blood samples belong to you. Your genetic material and samples will be stored at the HCHS / 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 your 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.

Research-related injury
If any 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. [Institution] will not pay for any care, lost wages, or provide other financial compensation. However, if you feel you have a claim that you wish to file against the [Institution], please contact [_____] at xxx-xxx-xxxx to obtain the appropriate claim forms.

Compensation
You will not receive payment for your participation. Costs that you might incur the day of your participation such as but not limited to, loss of work and transportation (gas, tolls, parking, etc.) will be reimbursed up to $XX. Child care will / will not be made available by the HCHS / SOL examination center during your visit.

Right to Refuse or Withdraw
Taking part in this study is voluntary. You have the right to refuse to take part in this study and you may decide not to answer any of the questions or complete any of the examinations. If you decide to be in the study and then change your mind, you can withdraw from the research without penalty. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. If you choose to take part, you have the right to stop at any time.

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 HCHS / SOL examination center at xxx-xxx-xxxx and ask for the Study Manager. Your decision to stop your participation will have no effect on the quality of your medical care. The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Confidentiality
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. 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 HCHS / SOL. Files linking names and other identifying information to data and blood samples will be electronically saved on a secure computer 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 HCHS / SOL personnel. This HCHS / 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 unauthorized 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 HCHS / SOL on any important 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 the University of [_____]. To help

assure 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).

New Information
If new knowledge about the conditions evaluated by HCHS / 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.

Alternative
Your alternative is not to participate in HCHS / SOL

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 HCHS / SOL. Only HCHS / SOL personnel will be authorized to contact you on behalf of this study.

Hispanic Community Health Study / Study of Latinos

[Insert Institution Name]

Consent to Participate

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 form to keep. If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact [name] at xxx-xxx-xxxx. You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of [_____] University at xxx-xxx-xxxx.

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. Please check the appropriate box beside each statement shown below:

	Yes	No
1) I agree to participate in the Hispanic Community Health Study / Study of Latinos (HCHS / SOL) and the examinations described above.		

	Yes	No
2) I agree to allow the HCHS / SOL staff to release the findings from examinations and non-genetic tests to my physician or clinic.		

	Yes	No
3) I agree to be contacted once a year by the HCHS / SOL staff to answer questions about my health and to update my address.		

	Yes	No
4) I 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 **HCHS / SOL investigators and the investigators they work with**.		

5) I agree to participate in genetic studies of factors that contribute to health and disease except those listed below:

_____
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	Yes	No
6) I 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 HCHS / SOL investigators, and other qualified researchers** who have satisfied requirements for protection of confidentiality and privacy.		

7) I agree to allow **researchers from private companies** to have access to my DNA and 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.	**Yes**	**No**

8) If a genetic condition is identified that could have important health or medical treatment implications for me or my relatives, I would like to have HCHS / SOL to notify me, and with my permission, to notify my physician.	**Yes**	**No**

The stamp below indicates that the [Institution] has approved this consent form. My signature below indicates the following:

- That I have read the information in this document or that it was read to me
- That I have had a chance to ask any questions I have about the study
- 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

_____	_____	_____
Name of participant	Signature of participant	Date
_____	_____	_____
Name of witness	Signature of witness	Date
_____	_____	_____
Name of investigator	Signature of investigator	Date