

# **SOL Visit 2 Informed Consent Video**

## **Narration Script**

### English Version

Bienvenidos. Welcome back to our SOL Exam Center! Thank you for accepting our invitation to continue your participation in the Hispanic Community Health Study, Estudio de los Latinos, SOL. We are pleased to have this opportunity to tell you about the continuation of the study, and to give you all the information you need to make a well informed decision to continue to participate.

This study is done to understand what factors influence Hispanic health, and how to prevent and treat specific diseases in the future. The Hispanic Community Health Study, SOL, is funded by the National Heart, Lung, and Blood Institute (NHLBI) and other institutes and centers of the National Institutes of Health (NIH).

The Estudio de los Latinos includes 16,000 participants from four centers across the country. You are one of 4,000 residents from your city who participate in SOL. All persons who participated in Visit 1 of the SOL can now participate in Visit 2 of the study.

Our research team and staff want you to have a pleasant and productive experience at our SOL exam center, and will treat you with respect. We want you to feel at home, and we will look after your needs. We will answer all your questions, so please do not hesitate to ask our study staff any questions, or to mention any concerns that you may have.

Now we will tell you what will happen in the continuation of the SOL, and how long the study will last. We will tell you about the benefits and risks that result from participation in this study, and we will also describe how we will protect the information that you provide, as well as your privacy and confidentiality.

The process by which you learn all the important details about the study, and you then indicate your voluntary participation in all or some of its parts, is called Informed Consent. Giving consent means that you have read, or heard the information about this study, and you agree to participate.

The informed consent form is a document required by a Federal law concerning research, which you will be asked to review carefully today and sign. It is approved by an independent board to protect the rights and welfare of people

who participate in research. This board is called the Institutional Review Board, or IRB. If you continue to participate in the SOL you will always have access to the IRB at this university for any questions or concerns about this study, and its phone number and contact information will be provided to you in the informed consent form.

Now let's review the Informed Consent Form section by section:

The SOL staff will provide you with your copy of the Informed Consent Form. Please review it carefully and feel free to ask about anything that is not clear. After you examine the content of this form you will arrive at the section at the end of this form where you indicate agreement to participate in all, or some of the portions of the Study of Latinos. Your signature and that of a witness will document your choices.

As we go over this information with you, please remember that you have the option participate, or not participate, in any of the tests the study offers, and to answer, or not to answer any questions asked by the study. These are decisions that you make, and they do not affect your rights, your relation with this university, or the medical benefits you currently have.

This study involves a visit to the SOL Exam Center and a follow-up telephone call every year for at least three years after your examination. During the visit to the Exam Center we will ask about your health and medical history, about life style, any stress that you may experience, about access to medical care and medical insurance, and we will ask women about their pregnancies and complications they may have experienced during pregnancy.

We will also do some medical tests. A trained technician will draw about six tablespoons of blood from your arm. You were asked to fast this morning because this is needed for some blood tests. After your blood is drawn you will receive a snack or lunch. We will also collect a sample of urine to check your kidney function. The study does not test for drugs in the blood or urine, HIV, AID's or sexually transmitted diseases.

Other procedures include measuring your height, weight, your waist and hips, and we will measure your blood pressure.

We will also measure the size and function of your heart, using a test called echocardiography, which uses ultrasound to create an image of what is inside the human body. By using sound waves we can take moving pictures of the heart to get detailed information about the size and function of different parts of

the heart. Ultrasound is widely used in a number of medical exams and is safe. We will put some clear gel on your chest, and you will feel some mild pressure where the ultrasound wand is pressed against the skin. Once the images are recorded in the computer the gel will be wiped off your skin.

A summary of the results of your blood tests and other examinations will be provided to you after 6 weeks, and you may choose to give these results to your provider of medical care. Should a test result show that you should check this with your provider of medical care, we will let you know. If you do not have a provider of medical care we will try to assist you in finding one.

The SOL study personnel will continue to contact you once a year to learn about your health. That's why it is important for us to have up to date information about your address and telephone number.

If you experience a health event that required a visit to the emergency room, or a hospitalization, we will ask your permission to get copies of your medical records. Also, in case you die, your relatives or the person you designated will be contacted for permission to get a copy of the medical records.

The field of science that studies how characteristics are transmitted from one generation to another, such as from parents to children, is referred to as genetics. It can help us to understand what makes some persons develop health problems, while others seem to be protected. To study this, at Visit 1 we collected DNA and RNA – the material that defines our genetic code – from the blood the SOL participants who authorized this. No genetic material will be collected at Visit 2.

With your authorization, the DNA and RNA collected in Visit 1 was stored to do health research. These studies are not genetic tests to diagnose a health condition, or to determine if you will get a specific disease or not. The SOL will only use the blood from its participants to do research on how diseases develop, and how to protect the health of the population. Individual results of genetic studies will not be reported to you.

Other investigators who are not part of the SOL at this time could request permission to use your data, information, and stored samples for other studies, in a way that will not identify you. This will be done only if you authorize us to do so. On the informed consent form there are places for you to show your instructions to us on how the SOL should use your stored samples and genetic material. You also have the option to authorize outside investigators or

companies to use the blood and the information you provide to SOL. At all times, you have the option to withdraw an authorization by contacting staff of the SOL.

There is no charge to you for participating in this study. A benefit from your participation is receiving a summary report of the results of your medical tests, but please note that the procedures and blood tests performed during the clinic visit are not a substitute for medical care. This is a research project; we will not provide medical care for any of the conditions detected during the exam, but will refer you to a health care provider if you do not have one.

The long term benefit to you and to society from your participation is the knowledge that scientists will gain about Latino health. This may benefit the health of many generations of Hispanics, and of public health in general.

There are some risks associated with your participation in this project. A skilled technician will draw your blood. Minimal bruising, pain, or bleeding may occur as a result of the blood draw. Nothing will be inserted into your body, only blood will be taken out.

You may feel tired and hungry since you will be fasting, but this will be resolved after having a snack or lunch which we will provide. Also, you may not feel comfortable answering some questions, but you can choose not to answer them without having to explain why.

We will take precautions to avoid risk to you. The blood draws and some of the procedures may feel somewhat uncomfortable, but we want to assure you that our technicians have been carefully trained to make these procedures safe and comfortable. Before any tests are done we ask that you notify the staff of any medical conditions or surgery you experienced in the last six months. If you have diabetes, you do not need to do the diabetes test.

The tests and procedures performed in this study are considered safe for pregnant women and those who are nursing. Still, women who are pregnant are asked to schedule the exam visit 3 months after delivery.

All the information that you provide to this study is strictly confidential. That means that we will not share your information with anybody unless you give us written, signed permission. All the information, including questionnaires, stored blood, and test results will be secure and registered using number codes that do not mention your name, or any information that could potentially identify you.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. A federal law allows the NIH and other federal agencies to issue Certificates of Confidentiality to persons engaged in research for the purpose of protecting the privacy of research subjects.

The SOL investigators are committed to follow strict confidentiality and privacy practices to protect you, and, your information. Only a limited number of staff in the study is authorized to see the information that identifies you, so that they can contact you. To protect against anyone outside of this study getting access to our electronic database, your personal information is kept masked in such a way that you cannot be identified.

Investigators or companies who are authorized to access your information are expected to follow these best practices. Nevertheless, the SOL investigators cannot entirely guarantee that outside investigators will follow the same standards all the time.

Some people are concerned about losing their jobs or medical insurance if their employer or medical insurance company learns of their research results. We will not release any of the test results to your employer or an insurance company unless you instruct us in writing to do so.

If anyone should get your genetic information through other sources, the law protects you. The Genetic Information Notification Act (GINA) of 2008 protects people from discrimination by health insurers and employers on the basis of DNA information.

You will be asked to identify yourself with a photo ID, so that SOL staff can verify that only SOL participants take part in Visit 2. If you did not provide your Social Security Number in Visit 1 we will ask for this information at Visit 2, but this is entirely optional. We may need your social security number to get copies of your medical records and other medical documents, as explained earlier. We will not share your information with any law, government, financial, or health care agency. You may refuse to give your social security number and still participate in this study.

Your continued participation in SOL is very important to our understanding of Hispanic or Latino health. However, we want to make you aware that in the event you change your mind you can withdraw from the study, or modify your informed consent, at any time. In addition, to some extent, you can also ask in the future that your information be removed from our databases.

Before you make such a decision, we ask that you let us listen to your concerns and why you would like to withdraw your participation because hearing why, and your concerns, is also extremely helpful.

We want to stay in touch with you, and continue our partnership in the SOL in the future, as long as you would like to remain in our study. Please make sure that all your questions have been addressed before you fill out the last section of the Informed Consent Form.

Your signature on this document means that you have been informed of the study's purposes and activities, and, that you understood them completely.

We are very grateful for your continued willingness to participate in the SOL!

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