

Title: Ultrasonographic analysis of risks and complications in obesity and diabetes in Mexican Americans living in South Texas
HSC-SPH-11-0631

INFORMED CONSENT FOR RESEARCH STUDY
Copy to be provided to subject signing

INVITATION TO TAKE PART

You are being invited to take part in a research project called: **Ultrasonographic analysis of complications and risks of obesity and diabetes in Mexican Americans living in South Texas** conducted by the University of Texas Health Science Center at Houston - Brownsville Regional Campus in collaboration with the University of Texas Health Science Center San Antonio-Laredo & Harlingen Regional Campuses. Your decision to take part is voluntary and you may refuse to take part, or choose to stop taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services that are otherwise available to you. You may refuse to answer any questions asked or written on any forms. You are aware that you may ask questions at any time to the research staff. This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as Protocol Number HSC-SPH-11-0631.

Please take your time to make a decision, and discuss this proposal with your personal doctor, family members, and friends if you wish.

This study is sponsored by the University of Texas Health Science Center–Houston School of Public Health-Brownsville Regional Campus.

DESCRIPTION OF RESEARCH

The purpose of this study is to help scientists determine the evidence of the causes and progress of diseases of the heart, circulatory system, kidney, and liver using ultrasonography also eye problems using a camera and identify the problems that help to developed heart, circulatory system, kidney, liver and eye disease in Mexican Americans adults living in South Texas. Ultrasonography is a technique that uses sound waves to produce images.

You have been asked to take part because you have been a part of the large study of people of Mexican descent in South Texas and you are over 18 years of age.

PROCEDURES

If you choose to take part, the appointment will be made for you to have the ultrasound exams

In Brownsville at the Hispanic Health Research Center, Clinical Research Unit of the University of Texas Health Science Center at Houston-Brownsville Regional Campus at Valley Baptist Medical Center-Brownsville (Edelstein Professional Building), 800 West Jefferson Street, Suite 230.

In Harlingen at the Clinical Research Unit of the University of Texas Health Science Center San Antonio-Harlingen Regional Campus located at 2106 Treasure Hills Blvd. RAHC II Room 1.326.

In Laredo at the Clinical Research Unit of the University of Texas Health Science Center San Antonio-Laredo Regional Campus located at 1937 Bustamante St. Room 1.105.

The appointment will be made for these exams at a time that is convenient for you. You cannot eat or drink anything, except water, for at least 6 hours before the liver, elastography & brachial artery exams. An ultrasound of your neck will be performed, an echocardiogram, as well as measure the segmental vascular pressure. Using a digital camera some photographs/images will be taken of your retina, no pupil dilatation will be necessary. You will also be asked for a small sample of blood (about two teaspoons or 10 ml) taken from a vein to test your blood sugar, comprehensive metabolic panel and related factors if the previous results are over 3 months old.

These tests are not invasive and are generally not painful.

The **liver ultrasound** and **elastography** are not invasive tests and do not cause discomfort. You need to be fasting for at least 6 hours prior to the exam to maximize the distention of the organ and to increase the quality of the image or to prevent the liver reflection. Also, it is recommended to not smoke before the ultrasound. The smoke increase the air in the superior intestinal tract also can reduce the quality of the image. You will be asked to lie down facing up with your right arm above head and the right leg stretched, and then you will asked to change position and lay down on the side. Gel will be applied in the right side of your abdomen. The elastography will provide additional images to measure fatty changes in the liver, known as steatosis.

The **brachial ultrasound** is to measure the flexibility of the artery in the right upper arm. For this ultrasound you need to be fasting; no vitamins and no smoke will be allowed before the scan. Gel will be applied to the right upper arm. The brachial artery is a large artery that is in your upper arm. After blood pressure has been determined in the left arm, another narrow sleeve will be placed on the lower right arm. The ultrasound probe, a flat sensor, will be moved to various positions on the upper arm until the desired images are obtained. Ultrasound images will continue to be taken while the sleeve is inflated for 5 minutes and after the sleeve is deflated. You are going to be asked not to move your hand or fingers during those 5 minutes. Blood pressure will also be taken after the ultrasound test. Because this ultrasound test is for research purposes only, the results of the test will not be given to you or to your doctor unless the tests uncover a medical problem.

For the **carotid ultrasound**, not required to be fasting, you will be asked to lie down and have three adhesive patches attached to your chest. These adhesive patches will be used to obtain an electrocardiogram tracing to measure your heart rate throughout the test. You will be asked to turn your head halfway to the left. Gel will be applied to the right part of the neck and the ultrasound probe will be moved around until the required images are obtained. This will then be repeated on the left side of the neck. The ultrasound images will be used to measure the thickness of the arteries on the right and left sides of the neck that supply blood to the brain and to the face.

The **echocardiogram** is a safe and painless procedure. You can take your regular medication and fasting is not required. Wear a two piece outfit for the test. You may be asked to removed clothing and jewelry from the waist up. You will be given a short hospital gown. You will be asked to lay down on your left side with your left arm above your head during the exam. Small electrodes will be placed on your chest to monitor your heartbeat. A transducer, an instrument used to take the images (also known as a probe), coated with gel will be moved over your chest.

For the **segmental pressure vascular testing** fasting is not required. Wear shorts for the test. You will be asked to lie down facing up. Blood pressure cuffs will be placed on both arms and both legs, ankle, below the knee, above the knee, thigh, and feet as well as on big toes. The blood pressure cuffs will be connected to the Doppler one at a time. Blood pressure readings will be taken from both arms. Then, readings will be taken for the right foot and leg. Once the right side is complete, the process will be repeated on the left side.

The Doppler is an instrument that emits sounds waves into the body. The resulting waves produce an image that will be printed and interpreted. The images of these studies will be sent, without any identifying information to a reading center in Houston, where specialists will interpret them.

You will be asked to answer questions for the segmental pressure vascular testing. These questions ask about whether you are having difficulty walking. We would like to know how much difficulty you have walking. We will also ask about the condition and care of your feet. This will take approximately 15 minutes to complete.

Retinal imaging uses a camera to take the pictures, for this procedure fasting is not necessary. No eye drops will be used. You will be asked to sit and face a camera. You will place your chin on a chin rest and your forehead against a bar to keep your forehead steady. The light in the room will be turned off. You will need to keep your mouth closed, open your eyes as widely as you can, and stare straight ahead while the photos are taken.

TIME COMMITMENT

The brachial ultrasound will take about 15 minutes. The liver ultrasound/elastography and the segmental pressure vascular testing will take about 35 minutes each. The carotid ultrasound and echocardiogram will take about 1 hour each. The retinal imaging will take about 10 minutes. These studies will take additional time to any of the procedures being performed for the larger diabetes study. The total time it will take to do all the studies is 3 hours and 35 minutes. These studies will have no other appointments or follow-up after this one visit, unless some of the images are not measurable and will require to take them again. If your ultrasound tests results are abnormal, you will be recommended to see a cardiologist or primary physician of your choosing for further cardiovascular testing. In addition, if the results from the liver ultrasound are abnormal you will be recommended to see a gastroenterologist or primary physician.

BENEFITS

Taking part in this study may not lead to any immediate benefit for you or your family, but may lead to a better understanding of diabetes, its complications, and related diseases like heart disease, obesity, renal and liver disease and other complications. A better understanding may then help to prevent or lower the problems caused by these diseases.

RISKS AND/OR DISCOMFORTS

You have been told that all tests and exams will be carried out by trained personnel such as medical doctors, nurses or technicians, and that the risk to you is minimal you may have some discomfort from the ultrasound test or the blood pressure sleeve inflating around your arm. You may also have some mild discomfort from the three electrocardiogram leads (stickers) used to measure your heart rate. You can ask to stop the test at any time if the discomfort level becomes too much. This study will not interfere with your ongoing medical care with your regular doctor. Every effort will be made to protect your confidentiality as explained below, but there is a slight risk for possible loss of confidentiality.

ALTERNATIVES

You have the alternative to not take part in this study.

STUDY WITHDRAWAL

Taking part in the study is voluntary. If you decide to withdraw from the study any data collected before the request cannot be removed, This means that if you decide to withdraw from the study your data collected prior to withdrawal may still be used up to the point of withdrawal. The principal investigator may choose to stop the study at any time and your participation will also stop at that time.

CONFIDENTIALITY

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. There is always a possibility of loss of confidentiality during a research study. Every effort is made to prevent this by using a code number instead of your name and all research related data will be kept in a secure, locked cabinet, and only designated research staff will have access to these cabinets. The Institutional Review Board and the Food and Drug Administration (FDA) that have the responsibility of monitoring research may want to see study records, for research purposes only. The section below details the use and disclosure of your protected health information.

Information about how this study will use your Protected Health Information (PHI)

Taking part in the study will require the researchers to have and to use private information about you and your health. It will also be necessary for the researchers to permit other groups to see records that contain information about you and your health. The federal privacy regulations only permit the researchers to collect, use or share your identifiable health information if you give them your permission to do so.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out who the person is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this research study, will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for the study. In carrying out this research, the health information we will see and use about you will include:

- your medical history and blood work,
- pathology and results of medical tests,
- information from interviews or from questionnaires,
- demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information from the study procedures that will be done, by asking you, asking your doctor, and/or by looking at your chart at University of Texas Health Science Center at Houston.

How will your PHI be shared?

Because it is research, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in conducting and overseeing this research study including:

- The sponsor of the study.
- The members of the local research team and collaborators; and
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio and Houston, and other groups that oversee how research studies are carried out.

Parts of your PHI may be photocopied and sent to a sponsor or data coordinating center, as appropriate, or it may be transmitted electronically, such as by e-mail or fax.

Some groups receiving your PHI may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

In an effort to protect your privacy, whenever possible, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any transmission of your study records, and other study materials containing health information that are sent outside of University of Texas Health Science Center at Houston for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified. Your PHI will have identifiers if added to the Rio Grande Valley Information Exchange or the Texas Cancer Registry or to other providers as specified below.

Do you have to allow the use of your health information?

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing, by signing the opt-out form. If you tell the researchers to stop using your health information, the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they sign the form.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?

By signing this form, you agree to let us use and disclose your health information for purposes of the study. The permission to use your personal health information expires when the research ends and all required study monitoring is over.

Your Personal Information and Results:

The results will not be given to members of your family, your personal physician, or other third parties unless otherwise specified.

Authorization for the Use and Disclosure of Protected Health Information (PHI)

Sharing information with providers through Rio Grande Valley Health Information Exchange (RGV HIE) helps clinicians provide better care for patients by not duplicating tests and having more complete information about the patient’s medication and other treatment history

Participants may choose not to share information through the health information exchange. If you decide not to share information, you will be asked to sign an “opt out” form

“The ultimate goal and purpose of the Texas Cancer Registry (TCR) is to collect, maintain, and disseminate the highest quality cancer data that will contribute towards cancer prevention and control, improving diagnoses, treatment, survival, and quality of life for all cancer patients”.

I hereby authorize the University of Texas Health Science Center Houston to access and/or release the following information from the medical records of the participant identified above to the Rio Grande Valley Health Information Exchange, the Texas Cancer Registry, and the Centers for Disease Control and Prevention’s (CDC) National Center for Health Statistics. Please write Initials on each line, see below.

I understand I have the right to revoke this authorization in writing at any time except to the extent that action has been taken in reliance upon it. I understand that I may revoke this authorization by sending, via mail or facsimile, a written notice to the following individuals/organizations stating my intent to revoke this authorization.

___ **Rio Grande Valley Health Information Exchange**

1816 East Harrison Ave., Ste. A,
Harlingen, Texas 78550
Phone: 956-622-5801 Fax: 866-650-8035

___ **TDHS- Texas Cancer Registry**

Department of State Health Services
P.O. Box 149347
Austin, TX 78714-9347

___ **Centers for Disease Control and Prevention (CDC)**

National Center for Health Statistics
3311 Toledo Rd
Hyattsville, MD 20782-2064

___ **Other Known Health Provider**

The information to be released to the Principal Investigator will include (Please write initials on appropriate line)

- ___ Complete Clinical Records
- ___ Other _____

I understand that the University of Texas Health Science Center (UTHSCH) may not withhold or condition treatment based on my completion of this authorization form.

I understand that the records used and disclosed pursuant to this authorization form may include information relating to: drug or alcohol abuse, or mental or behavioral health or psychiatric care.

In the case of an adverse event related to or resulting from taking part in this study, I authorize the researchers listed above to access test, treatment and outcome information about the adverse even from the treating facility.

COSTS, REIMBURSEMENT, AND COMPENSATION

Your taking part in this study will not cost anything. You will not be paid for taking part in this study.

IN CASE OF INJURY

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any such injury

In Brownsville to Rocio Uribe at (956) 755-0695

In Harlingen to Ariana Garza at (956) 365-8686

In Laredo to (956) 523-7400

Also call the Committee for the Protection of Human Subjects at (713) 500-7943.

QUESTIONS

If you have questions please feel free to call the numbers listed above. The research staff will be glad to answer any questions regarding the study at any time.

SIGNATURES

Taking part in this study is your choice. You will not give up any of your legal rights by signing this consent. If you sign this form it means that you wish to take part in this research study. Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-7943. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject

Signature of Subject

Date

Time

Printed Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent

Date

Time

CPHS STATEMENT

This study (HSC-SPH-11-0631) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.