H-55723- FEASIBILITY OF THE "PASO A PASO" WEIGHT LOSS PROGRAM FOR MEXICAN & CENTRAL AMERICAN PATIENTS WITH METABOLIC-DYSFUNCTION ASSOCIATED STEATOTIC LIVER DISEASE (MASLD).

Concise and Focused Presentation

We are approaching you about this study because your doctor has diagnosed you with fatty liver disease. Weight loss is an important part of treating fatty liver disease. We have developed a weight loss program for Mexican and Central American patients with fatty liver disease (also known as metabolic dysfunction steatotic liver disease). The name of the weight loss program is "Step by Step: Journey to a Healthy Liver." The purpose of this study is to learn whether the program is acceptable to patients and feasible to participate in. If you decide to participate in this study, we will ask you to do the following:

1. We will ask you to participate in a 6-month weight loss program:
The program consists of 16 classes led by a health educator. Approximately 8 to 14 people who have fatty liver disease, like you, will attend the class. Each class is 1 hour long. During the class, the health educator will teach you about healthy eating and physical activity. The health educator will also help you change your habits by developing meal and exercise plans every week and teaching you strategies to stick to them. The purpose of the program's education and support is to help you lose weight.

We will offer the classes at 5 locations. We will ask you to come to 4 of the classes in-person; you may attend the other classes in person or through virtual (televideo) format. You can choose the location most convenient for you. You will be assigned to that location, along with other patients who also choose that location, for the duration of the program. The day and time of classes will be decided based what is most convenient for people in your group.

2. We will ask you to complete questionnaires and testing for the study at 4 time-points over 1 year: before you start the program, in the middle of the program, at the end of the program, and 6 months after the program ends. All questionnaires and testing will be done during your regular clinic visits, during program sessions, or over the phone; you will not have to make extra visits to the clinic. The testing includes questionnaires, measurement of your weight and muscle strength, fibroscan (ultrasound) of your liver.

3. We will record data about your medical history and testing from your medical records.

The total amount of time you will be in this study is 1 year.

This document describes the possible risks that are involved in this study. When you start making changes to your exercise and eating habits, there is the possibility of injury due to physical activity or discomfort due to changes in diet. If you have diabetes, there is possible risk of low blood sugar as well. The questionnaire may include some questions that make you feel upset or uncomfortable. Lastly, despite efforts to keep your information confidential, there is the possibility of unwanted disclosure accidentally.

There may be potential benefits for you. Participating in this weight loss program could lead to weight loss and better liver health. Participating in this program may also improve your knowledge of healthy

lifestyles that could benefit you and your family. However, you may not benefit at all from participating in this study.

Alternatives to participating in this study is to see a dietitian on your own, consider enrolling in other weight loss programs, or to talk to your physician about other methods of weight loss.

Your participation in this research study is voluntary. You can choose not to participate in this study research or you can decline the study at any time. Your decision will not affect the care you receive from any of your clinics in Harris Health System or Baylor College of Medicine. If you are interested in participating, follow reading below.

Background

Fatty liver disease (now known as Metabolic-Dysfunction Associated Steatotic Liver Disease (MASLD)) is a chronic liver disease. Patients with fatty liver disease are at risk for developing serious complications in the liver. These serious complications include cirrhosis, liver failure, and liver cancer.

Weight loss is extremely important for treating fatty liver disease. Weight loss improves fatty liver disease and can reverse the disease. Weight loss can prevent complications.

Many patients with fatty liver disease need extra support and guidance to lose weight. Therefore, with the help of patients, dietitians, and physical therapists, we have developed a weight loss program tailored for Mexican and Central American patients with fatty liver disease.

The purpose of this study is to learn whether the program is feasible for Mexican and Central American patients with fatty liver disease. In addition, we will look at whether the program improves weight loss, fatty liver disease, health knowledge, physical activity, diet, and family support for weight loss.

This research study is funded by National Institute of Health / National Institute on Minority Health and Health Disparities.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of this study is to learn whether the program is feasible for Mexican and Central American patients with fatty liver disease. In addition, we will also look at whether the program improves weight loss, fatty liver disease, physical activity, diet, and family support among patients.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos.

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WHAT WE ARE ASKING YOU TO DO:
This is a 1-year long study.
Being in the study involves two things: 1) participating in the 6-month long weight loss program and 2) completing research study testing.

DESCRIPTION OF THE 6-MONTH WEIGHT LOSS PROGRAM
The "Step by Step" Program consists of 16 group counseling classes scheduled over 6 months. During Months 1-2, the classes will be weekly. During Months 3-6, the classes will be scheduled for every-other-week.

We ask you to attend 4 of the sessions (week 1, week 2, week 13, and week 26) in-person. You can attend the rest of the program in-person OR through televideo.

We will offer the program at 5 locations. You can choose the location most convenient for you. You will be assigned to that location, along with other patients who also choose that location, for the duration of the program. The day and time of classes will be decided based what is most convenient for people in your group.

1) Vallbona Clinic (6630 DeMoss Drive Houston, TX 77074)
2) Casa de Amigos Health Center (1615 North Main Street, Houston, Texas 77009)
3) Baker Ripley Sharpstown-Gulfton (6500 Rookin Street, Houston, TX 77074)
4) McGovern-Stella Link Neighborhood Library (7405 Stella Link Rd, Houston, TX 77025)
5) Bayland Community Center (6400 Bissonnet St, Houston, TX 77074)

- The class includes 8 to 14 participants who, like you, who identify as Mexican or Central American and have MASLD. The classes are designed to teach and to support you in developing healthy eating and exercise habits to lose weight and are led by a trained health educator. The health educator will coach you to change your eating and physical activity habits over time; the educator will monitor your weight and work with you to make additional modifications tailored to your needs to lose weight if you are facing barriers to changing your habits. We will schedule the classes to maximize attendance among the group that you are part of.

- As part of the program, we will ask you to follow a specific meal plan, maintain a daily food and exercise log, and wear a pedometer.

DESCRIPTION OF RESEARCH STUDY TESTING
We would like to collect research data from you at 4 time points over 1 year:
- Baseline (before or at the beginning of the program)
- Mid-intervention (around Month 3 of the program)
- End-of-intervention (at the end of the 6 month program) and
- Post-intervention (6 months after completion of the program)

You can do all of the testing that we request of you during your regularly scheduled clinic visits, during

program sessions, online, or over the phone. You will not have to make extra visits to the clinic to complete the research testing.

Here are the specific tests that we request of you at each study time point.

Baseline study testing will include the below items.
1. Questionnaires that ask about diet, eating patterns, physical activity, alcohol, ability to change habits, social support, stress, depression, access to food, understanding of health information, and quality of life. You can do these questionnaires by phone, online, or during an upcoming clinic visit (if available). You can complete the testing in whatever way is convenient for you. The questionnaires will take approximately 60 minutes to complete.
2. Body weight and muscle strength measurement. These will be done during Program Week 1.
3. Fibroscan (ultrasound) of your liver. This will be done during a routine hepatology appointment within 3 months of starting the weight loss program. The ultrasound will take 10 minutes to complete.
4. Physical activity measurement with an actigraph. An actigraph is a small, lightweight device worn on the waist, similar to a fitness tracker. It is used to measure physical activity by tracking movement throughout the day. The device collects data about your activity levels, which helps us understand patterns in your physical activity. It is non-invasive, does not cause any discomfort, and does not require any special effort from you. You will be asked to wear the actigraph while you are awake for 7 days and return it to us.
5. We will review your medical records for the duration of the study. Records that we may review include diagnoses, progress notes, medications, lab or radiology findings, demographic information, and alcohol, drug and tobacco use. We will record your medical history and lab testing of your liver disease and metabolic conditions.

Mid-intervention study testing will include the below items:
1. Questionnaires that ask about how confident you feel about changing your habits. This will take 10 minutes to complete.
2. Body weight and muscle strength measurement. These will be done during Program Week 13.

End-of-intervention study testing will include the below items:
1. Questionnaires that ask about diet, eating patterns, physical activity, alcohol, ability to change habits, social support, stress, depression, understanding of health information, and quality of life. You can do these questionnaires by phone, online, or during an upcoming clinic visit (if available). You can complete the testing in whatever way is convenient for you. The questionnaires will take 20 minutes to complete.
2. Body weight and muscle strength measurement. These will be done during Program Week 26.
3. Fibroscan (ultrasound) of your liver. This will be done during a routine hepatology appointment within 1 month of completing the program. The ultrasound will take 10 minutes to complete.
4. Physical activity measurement with an actigraph.

Post-intervention study testing will take place approximately 6 months after you complete the program.

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The testing will include the below items:
1. Questionnaires that ask about diet, eating patterns, physical activity, alcohol, ability to change habits, social support, stress, depression, understanding of health information, and quality of life. You can do these questionnaires by phone, online, or during an upcoming clinic visit (if available). You can complete the testing in whatever way is convenient for you. The questionnaires will take 40 minutes to complete.
2. Body weight, muscle strength, and fibroscan (ultrasound) of your liver measurement. These will be done during a routine hepatology appointment within 1 month of this time point. These will take 10 minutes to complete.
3. We will review your medical records to obtain information about your medical history and record blood testing of your liver disease and metabolic conditions.

In addition to the above, we will record information from your food and exercise log and use the information to understand how participants' behaviors change over time.

IF YOU HAVE DIABETES:
We will let your diabetes doctor know that you will be in this study and participating in the weight loss program. Also, as part of the weight loss program, we will ask you to monitor your blood sugars and report any episodes of low blood sugar to either the health educator or any member of the research team. This is because when you make changes to your diet, physical activity, and lose weight, your blood sugars may drop. We will let your doctor know about low blood sugar episodes. Your doctor will advise advise you about any changes you may need to make to your diabetes medicines or doses prior to starting the weight loss program or to avoid low blood sugar episodes.

OPTIONAL RESEARCH STUDY TESTING
We also invite you to participate in optional research activities listed below. You can still participate in the main study even if you decline these optional items.

#1. Research Blood Samples
If you agree by signing the line below, we will also draw one additional tube of blood (10-20cc or 2-4 teaspoons) at two time points: at baseline and end-of-intervention. The blood sample collected from you would be stored in the Baylor College of Medicine Population Sciences Biorepository. The sampleswould be coded, which means that the samples will be labeled only with a study specific code and will not include any of your personal information (for example, your name, date of birth). The research blood samples will be used for two purposes. The first is to test inflammatory and fibrosis biomarkers that have been associated with your liver condition. The second is, as part of this study, your blood sample would be stored indefinitely for use in future Institutional Review Board (IRB)-approved research studies. These future studies may include testing if certain metabolic, inflammatory, and/or fibrosis biomarkers correlate with changes in diet, exercise, body weight, and/or liver disease. The same approved guidelines to assure patient confidentiality and privacy will be applied to any future approved research conducted by the Principal Investigator of this study. The

principal investigator of this study must obtain IRB approval prior to conducting any further testing on your sample unrelated to this research. Your blood samples would not be shared with any other research investigators.

You may still participate in the rest of the study without agreeing to this optional procedure. If you agree to have the additional blood drawn, please sign and date below.

_____Yes, I consent to the use of my blood samples for this study and to be stored for future testing.
_____No, I do not consent to use my blood samples for this study and to be stored for future testing.

#2. Interview

If you agree by signing the line below, we will contact you to complete one 30-minute phone interview to learn about your experience and opinion of the program. You can still participate in the main study even if you decline the interview. If you agree to the interview, then someone from our research team may contact you to participate in an interview when you complete the weight loss program or if you decide to leave the program early.

The interview will be conducted by someone from the research team. The interviewer will ask you questions about your experience with the weight loss program, the research study, and suggestions for improvement.

We will ask you for permission to record the interview. If you allow us to record the interview, we will transcribe the interview. The transcription would be done either by a 3rd party transcription service or, if you prefer, by someone from our research team. We will remove any information about your identity (for example, your name, where you live) from the recording. The recording and transcription will be stored in a secured server at Baylor College of Medicine. However, if you do not want the interview recorded, we will simply take notes during the interview

Even if you agree to this interview now, you can still change your mind and decline the interview if we contact you. You have the option to opt out or withdraw from this substudy, at any time and can still remain in the main study.

If you provide consent, there is the possibility you will not be contacted to participate in the interview.

If you want to participate in the interview you should mark the first box below and sign and date on the line provided. If you do not want to participate, you should mark the second box below and sign and date on the line provided. If at any time you want to stop participating you may do so without any penalty or loss of any benefits to which you are entitled.

__I wish to participate in the interview. I understand that I can change my mind at any time and can

decline the interview even when the research team contact me about scheduling or conducting the interview. I understand that taking part in this substudy is my choice.

__I do NOT wish to particpate in this interview. I understand my decision not to participate will not affect my treatment or future care or status at Baylor College of Medicine or with the Harris Health System.

Signature_____ Date_____

Clinically Relevant Research Results

We will give you the results of some testing that we do as part of this study. This is because it is important for your health. These are the test results that we will share with you:
-Body weight
-Fibroscan (liver ultrasound) results, which will give you information about severity of fat and fibrosis in your liver.

Some of the activities that you do as part of the weight loss program will provide information that is important for helping you make health changes in your diet and exercise routines. We plan to share, review, and discuss this information with you. Here is a list of the information that we will actively review with you throughout the 6-month weight loss program:
-Calorie count (which we will calculate using daily food logs that you will be asked to maintain as part of the program)
-Average amount of exercise you do every week (which we will calculate using the daily exercise log that you maintain as part of the program)
-Average step count (which we will calculate using a pedometer that you will be asked to wear as part of the program)

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Sharing and Future Research Studies with Identifiable Biospecimens

Information that identifies you may be removed from your identifiable biospecimens collected as part of this research, and after such removal, your biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District,

HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Photographs, videotapes, and/or audiotapes of you
- Identifiable biospecimens
- Questionnaire, Survey, and/or subject diary

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, Harris Health System: Casa de Amigos, and NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES and their representatives.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The 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 personnel of the United States Government that is used for auditing or evaluation of 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 researchers may not use the Certificate to withhold that information.

Information regarding study participation will be included in your medical records.

The Certificate of Confidentiality will not be used to prevent disclosure of child abuse, neglect, or harm to self or others to state or local authorities.

Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH

DISPARITIES and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, Data and Safety Monitoring Board, Community Center or Church, HCHD: Harris County Hospital District, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Harris Health System- Smith Clinic, and Harris Health System: Casa de Amigos may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Maya Balakrishnan, MD MPH
Mailing address: c/o Arlene Zamora; Ben Taub Hospital, 5th Floor; Office 5 PO 71-006; 1504 Taub Loop; Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

There are both risks and benefits to participating in this study. It is important that you think carefully about this when you make your decision.

When you make changes to your exercise and eating habits for weight loss, there is a possibility of injury due to physical activity or discomfort due to dietary changes. If you have diabetes, there is the risk of low blood sugars. Therefore, if you have diabetes, we will be monitoring how you feel and your blood sugars very closely. Also, we will be in close communication with your regular doctors to share information about your blood sugars while you are in the weight loss program so that they can best advise you about your diabetes medications and any changes, if required.

Some of the questions we ask you as part of this study's questionnaires or interview may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study.

If you agree to provide a research blood sample, then this involves a blood draw. There are minimal risks involved in the stick for blood draws. These include skin infection and small bruising where the blood is drawn. The risks of infection will be minimized by the use of aseptic (clean) technique.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits
The benefits of participating in this study may be: There is evidence that people with MASLD who are part of intensive weight loss programs, like this one, can lose weight and have improved liver health. There is also evidence that people who participate in weight loss programs could gain greater knowledge about their health conditions, healthy diets, and healthy exercise. Participating in this study can help doctors and study researchers learn things that could help other patients in the future.. However, you may receive no benefit from participating.

Alternatives
The following alternative procedures or treatments are available if you choose not to participate in this study: If you do not choose to participate in this study, there are other options for weight loss support. You can choose to see a dietitian on your own, engage in an exercise program on your own, or participate in any other lifestyle program or intervention available to you..

Subject Costs and Payments
You will not be asked to pay any costs related to this research.

We will compensate you for time and effort spent completing study visits. You will receive the following compensation for completing all study procedures at each time point: $50 for baseline, $20 for mid-intervention, $50 for end-of-intervention, and $20 for post-intervention follow-up assessments. This is a total of $140 for completing all the study assessments over 1 year. If you complete the optional interview, you will receive an additional $20 compensation.

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or legally authorized representative (LAR) reaches or exceeds $600 in a calendar year, Baylor College of Medicine will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, Baylor will collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email or text notification when payments are loaded to your ClinCard. Baylor College of Medicine and Greenphire

(ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

The College will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, Baylor will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, MAYA BALAKRISHNAN, and/or someone he/she appoints in his/her place 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 related to the research, you may speak with a member of the study staff: MAYA BALAKRISHNAN MD, MPH at 7138733503 anytime.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date