COVER PAGE

Official Study Title: Feasibility of Blood-flow Restriction Training Prehabilitation in Older Adults Awaiting Total Knee Replacement

NCT number: NCT06111690

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Concise Summary

You have been invited to part-take in this research study because you were diagnosed with knee osteoarthritis and are awaiting your first total knee replacement surgery. We are hoping to provide you with exercises preoperatively using a novel approach that uses a tight cuff placed on your thighs while you perform low resistance exercises for your legs. We will also be testing your thigh muscle strength, your ability to perform some activities of daily living such as sit-to-stand on a chair, climbing stairs and walking.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future**.** Patients with knee osteoarthritis have joint pain and often do not tolerate high resistance exercises that are necessary to improve muscle strength. Improving strength before surgery is very important for a successful postoperative recovery. The proposed low resistance exercise using blood flow restriction may be better tolerated by patients with knee osteoarthritis, but we need to know whether the patients will feel comfortable wearing a tight cuff on their thighs while performing the exercises.

For more information, please see the *Why is this Study being Done* section below.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?
Due to your knee osteoarthritis, it is very difficult for you to use the recommended exercise load to achieve muscle improvements before your surgery for knee replacement. In typical care, exercises are done either using low resistance that is not going to be effective in improving muscle strength OR using high resistance that might exacerbate your knee pain. Our exercise program uses a tight cuff around your thighs while you perform low resistance exercises that may be easier for you to perform and may prevent an increase in knee pain. The low resistance exercises performed with the cuff around your thighs reduces the blood flow into the muscles and, consequently, less oxygen to the muscle, which leads to improved strength.

Before you start the exercise sessions, for research purposes only, we will assess the strength of your thigh while kicking against a resistance and the muscle composition (i.e., size of your thigh muscle and amount of fat in the muscle) via CT Scan. Also, we will collect the equivalent of 2 tablespoons of your blood to analyze inflammatory markers and ask you to perform some tasks to assess your physical function. You will complete some questionnaires related to function and quality of life and wear an activity monitor on your wrist to track your daily number of steps for 7 days. To evaluate how comfortable you feel while exercising with a tight cuff around thighs, we will ask you about your discomfort level during the session.

For more information, please see the ***What will be done if you decide to be in the research*** section below.

3. How much time will I spend on the study?
It is expected that you spend around 2.5 hours for each session to complete the testing procedures that will take place 8 weeks before surgery, the week before surgery, and 8 weeks after surgery. Also, you will spend no more than 1 hour per exercise session that will occur 2-3 times a week for 6 weeks before surgery (12-18 sessions total).

***4.* Could taking part in the study help me and are there risks?**
If you complete all the proposed exercise sessions (x12), you may expect to see changes in your thigh strength as it was seen in other research studies in older adults. Amongst the testing procedures, you may experience temporary muscle soreness and fatigue in your thigh after the strength test. Participation in this research study involves exposure to radiation from full body DEXA scans. However, the amount of radiation exposure that you will receive is

from this study is considered to be low and comparable to everyday risks. Also, with blood drawing, there is a rare risk of bleeding and local infection, an infrequent risk of bruising, and a likely risk of discomfort.

During exercise sessions, the cuff used around your thighs may feel uncomfortable. When the cuff is pumped with air, you may feel tingly and soreness in the legs, and the legs may become discolored. After exercising, although not common, it is possible the skin may bruise at the site where the cuff was placed. Thigh muscle soreness and fatigue can also be expected after exercising.

For more information, please *see **How could you or others benefit from your taking part in this study*** section below. For details and a list of risks you should know about, please see the ***What are the risks of participation in the research*** section below.

5. What else should I consider before I make my decision?

Having to drive to our facility to participate in an exercise program 2-3 times per week may be cumbersome, however, all the research-related procedures described are free of cost to you.

Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.

Title of Study: Feasibility of Blood-flow Restriction Training Prehabilitation in Older Adults Awaiting Total Knee Replacement

Consent to be part of a Research Study
To be conducted at
University of Texas Health Science Center at San Antonio

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Gustavo J. Almeida, PT, PhD who is an Assistant Professor in the Department of Physical Therapy at UT Health San Antonio

Funding

The School of Health Professions Pilot Seed Grant Program at UT Health San Antonio and the San Antonio Older Americans Independence Center (OAIC) Mentored Career Development RL5 Scholar Program (Pepper Grant) NIH Funding are funding this study.

Purpose of this study – "Why is this study being done?"

Your knee osteoarthritis causes pain when you are doing exercises pushing against resistance, for example, weights. However, those exercises pushing against weights are necessary to improve muscle strength in your legs. If we are able to improve the strength of your legs and your physical function before surgery, chances are that you will have a successful postoperative recovery. However, we need to try exercises that may be more tolerable for you to obtain those muscle gains. Thus, we are proposing exercises to be done with a tight cuff around your thigh (B-Strong Cuff) while you perform them with very low weights, this is known as blood flow restriction training (BFRT). We hope that these exercises will be better tolerated by you, but we need to know whether you will feel comfortable wearing a tight cuff on your thighs while performing the exercises.

You are asked to participate in this research study that looks at the feasibility of wearing a pressure cuff placed around your thighs while you perform exercises to improve your thigh muscle strength and your physical function before you go to surgery.

The researchers hope to learn whether low resistance exercises using these tight cuffs around the thighs are well tolerated by individuals with knee osteoarthritis and also to determine whether there is an improvement in muscle strength and physical function before surgery.

This trial may be registered on www.ClinicalTrials.gov, a publicly available registry of clinical trials. 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.

Title of Study: Feasibility of Blood-flow Restriction Training Prehabilitation in Older Adults Awaiting Total Knee Replacement

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are 60 years and older and are awaiting your first total knee replacement due to osteoarthritis.

How many people are expected to take part in this study?
This study will enroll approximately 20 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 3 testing visits and 12-18 exercise sessions with the researchers or study staff.

It may be necessary for you to return to our research clinic for testing 8 weeks before your surgery, the week before your surgery, and 8 weeks after your surgery. You will also need to return to our research clinic for 12-18 exercise sessions (2-3 times a week for 6 weeks) in between the first and the second testing visits. The duration of your participation in our research study will be approximately 16 weeks (4 months).

Study Procedures – All procedures in this study will be for research purposes only. As a participant, you will undergo the following procedures:

Screening Procedures: Procedures to determine if you are eligible to take part in a research study are called "screening procedures". For this research study, after reading and signing this informed consent, the only screening procedure will be a review of the inclusion and exclusion criteria to be in the study and a measurement of your blood pressure. Also, to rule-out peripheral arterial disease, the evaluator will conduct an ankle-brachial index assessment to compare the blood pressure assessed at your ankle to the one at your arm. You must be within normal cut-off values (i.e., between 0.9 and 1.3) to be safe to participate in the study. These procedures will be done when you come for the first testing visit and it will take about 15-20 minutes.

Experimental Procedures: If you qualify to take part in this research study, you will undergo the research-related procedures listed below.

Testing Visit (approximately 2.5 hours)
1) This visit will first take place at the Barshop Institute. You will be asked to avoid strenuous physical activity 48 hours prior to testing.

a) Whole-body DXA scan to look at muscle composition of both thighs. DEXA scan is a noninvasive, painless medical test that uses low levels of ionizing radiation to measure bone density, body composition, and muscle mass. It uses special x-ray equipment to produce multiple images (pictures) of the inside of the body and a computer to join them together in cross-sectional views of the area being studied. The images can then be examined on a computer monitor. During this procedure you will be asked to lie on your back with the legs extended flat on the table. This procedure will take approximately 20 minutes to complete.

b) Study staff will escort you to the Physical Therapy Research Laboratory to complete the remaining of testing procedures:

b.1) Staff will ask questions about your medical history, current and past medical treatment, and your current and past medications. You will be asked to complete questionnaires that assess areas such as level of knee pain, education, work history, physical and mental health status, ability to do daily living tasks, physical function and physical activity (35 min).

b.2) You will undergo a brief examination including height, weight, and blood pressure (5 min).

b.3) A specialized technician will draw blood (approximately 2 tablespoons) from a vein in your arm for laboratory tests (5min). You will be asked to stop taking anti-inflammatory drugs, such as Ibuprofen, for 24h before the testing visit. However, you will be allowed to take your regular medications. The blood sample will be used to determine the amount of inflammation in your knee joints.

b.4) You will be asked to perform 6 tasks: stand on one leg for up to 30 seconds (3 times on each leg), walk a 4-meter walkway, sit to stand from a chair for 30 seconds, get up from a chair - walk 3 meters - turn around – walk back to and sit on the chair, climb up and down a flight of stairs (11 steps), and 6-minute walk test. The activities will be timed. These tests will take about 20 min.

b.5) You will be asked to participate in a thigh muscle strength test. You will sit on an isokinetic dynamometer to test the strength of your thigh muscles. Your knee will be comfortably bent and a force sensing pad will be secured to your ankle. You will be asked to kick as hard as possible against the sensing pad for 4 trials. However, you will not be able to move the sensing pad since it will be locked. This test will be performed in both legs and will take about 30 min.

b.5) You will also be asked to wear an activity monitor (Actigraph) on your wrist for 7 days to measure how active you are. Please note: we will ask you to use this monitor three times, before and after the BFRT training visits as well as 8 weeks after surgery. You will be instructed when and how to mail this device back to the study team after each time it is used.

After the testing visit, you will be scheduled to start your exercise program 2-3 times a week for 6 weeks. Exercise sessions will take place in the Physical Therapy Research Laboratory.

Training Visits (approximately 45 min)
You will complete 3 different exercises while wearing the B-Strong cuffs around the highest portion of both of your thighs (Figure). A study member trained in blood-flow restriction training will correctly size you for a B-Strong cuff. The cuff will also be used to find the pressure for complete blood flow restriction while you are standing using a Doppler ultrasound. For the initial training session, the B-Strong cuffs will then be inflated to 50% of the complete blood flow restriction pressure, and you will aim to complete 4 sets (30,15,15,15 repetitions) of sit-to-stand, leg extensions and leg curls, with 30 seconds rest in between sets. A study member will help you keep track of the repetitions and control the speed you are performing the exercises. At every session, the pressure in the B-Strong cuffs will be increased by 50 mmHg if it can be tolerated, until 80% of of the complete blood flow restriction pressure is achieved. A 10-minute warm-up on a stationary bike will be performed before each training session.

After each use, the B-Strong cuffs will be wiped down with a clean disinfectant wipe.


Figure. B-Strong cuffs for the legs

6-week Follow-up Testing Visit
After you complete 6 weeks of exercise (12-18 sessions), you will be scheduled for a follow-up visit following the same procedures described under “Testing Visit”.

Testing Visit 8 weeks after surgery

You will be tested following the same procedures described under "Testing Visit" 8 weeks after your surgery. Study staff will contact you to schedule your follow-up visit.

Final Follow Visit: This will be a phone call only to review the instructions to return the activity monitor and to check if you have any questions about the end of the study.

Future Use of Your Information or Biospecimens Collected as Part of Your Participation

Identifiers may be removed and the de-identified information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Your biospecimens, even if identifiers are removed, may be used for commercial profit and you would not share in this commercial profit.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – "What are the risks of participation in the research?"

The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study:

Risks from Radiation Exposure associated with DEXA scan:

Participation in this research study involves exposure to radiation from DEXA scan. The amount of radiation exposure that you will receive from these procedures is equivalent to a uniform whole body dose of 0.9 mrem (a unit of radiation exposure) which is considered a very small amount of radiation. For comparison, the average person in the United States receives about 300 mrem of radiation per year from natural sources, such as cosmic radiation and radon gas in the air. There is no known minimum level of radiation exposure that is recognized as being totally free of the risk of causing genetic defects (abnormal cells) or cancer. However, the probability of harm from such risk associated with the amount of radiation exposure that you will receive from this study is considered to be very low and comparable to the probability of harm from other everyday risks.

If you have had radiation (like x-rays) before, please tell us now. We want to make sure that the probability of harm from the amount of radiation you will be exposed to in this study continues to be low when combined with the radiation you have received within the past year.

Blood drawing - There is a not serious and less likely risk of bleeding and local infection. In 100 people, approximately one person may undergo such adverse event. There is also an infrequent risk of bruising, and a likely risk of discomfort. To minimize risk of infection, the needles used for this procedure are single use, pre-sterilized, individually packaged. Digital pressure will be applied post-venipuncture to decrease the risk of

bleeding and bruising. Sometimes anxiety related to the needle prick may give rise to a feeling of nausea, light-headedness (also described as giddiness), or drop in blood pressure.

Quadriceps Muscles Strength Testing and volitional exercise Training - There is a *serious and rare* risk of a strained thigh muscle from the maximal voluntary isometric thigh contraction, which could result in muscle pain and swelling for several days. In 100 people, approximately one person may experience such adverse event. Mild muscle soreness and discomfort are *not serious and likely* (in 100 people, approximately 25 people may experience such condition), which typically occur within 48 hours after testing and treatment but will usually resolve within 1-2 days after it starts. Rupture of the kneecap tendon or fracture of the kneecap is *serious and rare* (in 100 people, approximately one person may experience such adverse event). This risk will be minimized by excluding subjects with kneecap fracture, and rupture of quadriceps or kneecap tendons. Exacerbation of knee or hip pain and inflammation is *not serious and less likely* (in 100 people, approximately one person may experience such adverse event). Pain and swelling will be monitored before and after each training session by the investigators. If the exercises cause pain or swelling, the progression of the exercise program will be slowed and if needed you will be referred to your physician for evaluation. Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell the study personnel immediately about any side effect that you have while taking part in the study.

Physical Functional Assessment (self-selected gait speed, timed 5 chair rise, single leg stance time, timed-up and go test, stair ascend/descend test, and 6-minute walk test) – There is a *not serious and less likely* (in 100 people, approximately one person may experience such adverse event) chance of fall while performing the tasks described. The risk is further minimized by having the tester guarding the participant during all tests.

10-minute warm-up on a stationary bike - There is a *not serious and less likely* (in 100 people, approximately one person may experience such adverse event) chance of knee pain during the procedure. The risk is further minimized by adjusting the height of the seat on the bike to improve comfort.

Blood-flow Restriction Training – B-Strong cuff may be uncomfortable when placed at the highest part of the thigh. When the cuff is pumped with air, legs may feel tingly, be sore, and become discolored. Those are *not serious and less likely* to occur (in 100 people, approximately one person may experience such adverse event). There may be a *not serious and less likely* surface bruising after the study where the cuff was placed (in 100 people, approximately one person may experience such adverse event). These symptoms are normal, however a doppler ultrasound will be used to ensure blood flow is still going through the leg before starting exercise. Also, if in a rare situation you experience unbearable pain in your leg during exercises, the exercise instructor will be there to remove the cuff immediately.

Do not use this cuff if you have

- Existing and untreated deep vein thrombosis,
- Untreated hypertension,
- Sickle Cell Disease,
- Lymphedema (swelling around blocked lymph nodes) at the site of cuff use,
- Intravenous access at the cuff site of use
- Any on-going medical emergency

Risks related to completing questionnaires include those which are less likely (less than 5-20 subjects out of 100) and Not Serious which are being uncomfortable answering questions –If you feel uncomfortable answering questions, one of the investigators will speak with you to help clarify your doubts. Your responses will be kept confidential. You do not have to respond to any question that you do not feel comfortable answering. Rare (less than 5 subject out of 100) and Serious are breach of confidentiality- It is possible in a rare occurrence there may be a breach of confidentiality. However, the researchers have taken steps to minimize this risk such as keeping focus group audio recordings and materials in a secure, locked location.

For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?

No there are no risks from withdrawing from this study. If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures as described under "Testing Visit" at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them, nor will it affect your grades for not taking part or enrolling and then deciding to withdraw before completion.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is that you may be able to exercise with less pain in your knees as compared to regular exercises. Thus, you may get your thigh muscles stronger and improve your physical function. However, there is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

Preoperative exercises are not common, but you may choose to get treatment or care at other physical therapy clinics without being in the study.

Payments – Will there be any payments for participation?

The researchers will provide you with a MasterCard®. A $50 (fifty dollars) compensation will be automatically credited after completion of each Testing Visit, for a total of $150 (one hundred and fifty dollars). Your name, address, date of birth, and social security number will be shared with a third-party solely for the purposes of

compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

In addition to the compensation on the card, you may also elect to receive study-related messages (text and/or email). These messages will contain information confirming that money has been loaded onto your card. You may also receive reminder messages with information about your next appointment with researchers or study staff.

Please indicate your willingness to receive study-related messages:

- □ **Yes,** I would like to participate (please select the best method(s) for communication)
  - o Cell Phone (text messages)
  - o Email
- □ **No,** I choose not to participate

Costs – Will taking part in this study cost anything?

There are no costs to you for taking part in this study. All testing and exercise procedures will be performed at no cost to you. The researchers will provide the activity monitor free of charge for you to use during the first week of the study. At the end of your participation you must return the device to study staff.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Limits of Confidentiality
Even without your consent, suspected or known abuse or neglect of a child, disabled, or elder abuse, threatened violence to self or others or other local health reporting requirements will be reported to appropriate authorities.

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 whose it 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 study, you 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 this research study. In carrying out this research, the health information we will see and use about you will include: demographic information, such as your date of birth, height, weight and ethnicity and results from procedures conducted in this study.

We will get this information by asking you directly. This information will be entered in the physical activity monitor for initialization and into the dynamometer (strength testing machine) software. The purpose of this information is to be able to estimate accurately your physical activity and strength

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

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

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information 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, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the School of Health Professions (UTHSCSA) for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

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 but you will not be allowed to participate in the study. 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 and send your letter to:

Dr. Gustavo Almeida, PT, PhD
Department of Physical Therapy
7703 Floyd Curl Dr., MC 6247
San Antonio, TX 78229

If you tell the researchers to stop using your health information, your participation in the study will end and 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 receive your letter asking them to stop.

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.
You will only have access to your PHI until the end of the 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 until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Gustavo Almeida, PT, PhD, can be reached at 210-567-8755 or almeidag@uthscsa.edu

If primary is not available, contact:

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Deanna Wood, can be reached at 210-567-8750 or woodd1@uthscsa.edu

After hours, please contact:
Gustavo Almeida at 412-378-1951 or at almeidag@uthscsa.edu

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM
Printed Name of Witness	Signature of Witness	Date	Time AM PM

☐ *Check if consent and authorization obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. Have witness initial below.*

Declaration of witness: I was present for the entire consent process. ←(initials of witness)

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time AM PM

☐ Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____.
The specific means by which the subject communicated agreement to participate was: