Title: Exercise in Burn Survivors: Cooling Modalities

NCT Number: NCT04512976

Document Date: May 20, 2024

Title of Study: Cooling Approaches in Burn Survivors

Consent to be part of a Research Study to be conducted at
The University of Texas Southwestern Medical Center
Texas Health Resources

Key Information about this Study

The purpose of this study is to examine the beneficial effects of cooling approaches on internal body temperature regulation in burn survivors.

Burn survivors have a reduced capability to regulate their body temperature. Because of this, burn survivors have a higher risk for heat-related injuries. The use of cooling approaches is expected to reduce the elevation in body temperature during physical activity, and thus make such activity safer for burn survivors.

In this study you will be asked to complete four trials, where you will be exposed to different cooling approaches during light/moderate exercise. We will measure your body temperature and related variables that are important in body temperature regulation. This research will help healthcare professionals better understand the benefits of cooling approaches in burn survivors. We will also use data obtained from these trials to develop a smartphone application that will inform burn survivors whether it is safe for them to exercise when it is hot outside.

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 decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

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 Craig Crandall, PhD, Department of Internal Medicine at the University of Texas Southwestern Medical Center.

Funding

The National Institute of General Health, a federal agency that promotes scientific research, is funding this study. This organization is providing money to the University of Texas Southwestern Medical Center so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

Burn survivors are not able to regulate their body temperature very well due to reduced skin blood flow and sweating responses in the injured skin. We propose that this heat intolerance decreases the desire of burn survivors to have an active lifestyle. Thus, identifying effective approaches to reduce excessive elevations in internal body temperature during physical activity in burn survivors will assist in their full rehabilitation by removing heat intolerance as a barrier to participating in such activities. To that end, a primary objective of this project is to identify cooling approaches that are effective in burn survivors, thereby helping these individuals enjoy the health benefits of physical activity.

You are asked to participate in this research study of temperature control in burn survivors. This study needs to be done to better identify effective cooling approaches for this group.

The researchers hope to learn which cooling approach is best for burn survivors during physical activity.

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.

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

You are being asked to be a participant in this study because you are in good health, are between the ages of 18 and 65 years, and you either had a severe burn injury covering approximately 20% or more of your body or you have never had a burn injury (non-burned control subjects).

How many people are expected to take part in this study?
This study will enroll approximately 200 study participants, two-thirds of which will be burn survivors and one-third non-burned individuals.

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 5 visits with the researchers or study staff. The total time commitment for this study is approximately 22 hours.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated.

Screening Procedures

1. We will ask you to complete a medical history form.
2. If you are capable of becoming pregnant, we may perform a pregnancy test (from one urine sample).
3. We will measure your body height and mass.
4. We will measure your blood pressure.
5. We may perform a urinary drug screen
6. We will measure your heart rate and rhythm (12-lead electrocardiogram).
7. We may assess your body composition via dual-energy X-ray absorptiometry (DXA).
8. We will assess the percent of your skin surface burned – for burn survivors
9. You will perform a graded exercise test.
10. We will assess your heart function with an echocardiogram.

This visit will take approximately 4 hours.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Assignment to Study Groups –
There are three groups in this study, 1) non-burned individuals, 2) individuals with burns covering up to 40% of your body surface, and 3) individuals with burns cover greater than 40% of your body surface. You will be assigned to a group depending on the extent of your burn injury. You will then be assigned by chance (like flipping a coin) to complete one of the four trials (control, skin wetting only, fan only, and skin wetting plus a fan) first. The remaining trials will be completed in a random order as well.

Study Procedures - as a participant, you will undergo the following procedures:

Visit 1: Screening (see above)

Visits 2-5:
For each of these visits you will complete 60 minutes of light/moderate intensity exercise in an environmental chamber set to one of the following temperature conditions: ~24 °C (~75 °F), ~30 °C (~86 °F), or no higher than 40 °C (~104 °F). Whatever temperature condition you are first assigned to will be the same temperature that you will exercise for all the trials. All other procedures during these trials will be similar. Each visit will last approximately 4.5hours, though you will not be exposed to these conditions for this entire duration.

Prior to each visit we may ask you to swallow a pill that is used to measure internal body temperature. You will come to our laboratory; we will attach several recording devices to you, record some baseline measurements and then you will enter our environmental chamber (set to one the conditions mentioned above). You will then perform light to moderate treadmill or cycling exercise for 60 minutes. After this exercise bout, you will rest in the chamber for no more than 60 minutes. During this resting period, we will measure your heart function (echocardiogram). We will then cool the chamber (if it was heated) and remove the measuring devices that we attached to you.

The following measures and procedures may be performed during this study:

Procedure	**Description of Procedure**	**Duration of Procedure**
Exercise in a prescribed climate condition	You will enter an environmental chamber set to one of the previously mentioned temperatures and exercise for 60 minutes on a treadmill or stationary cycle.	You will perform a 60 min exercise bout during each of visits 2-5.
Urine sample	You will be asked to urinate into a cup from which we will assess the density of your urine, conduct a pregnancy test (if applicable), and/or assess for drug metabolites. There is no known significant risk with this measure.	You will be asked to urinate into a cup at the beginning of each visit.
Body mass	You will be asked to stand on a scale in a private room and record your nude body weight.	Each measurement will take about 30 seconds at the beginning and end of each visit.
Height	You will be asked to stand in front of a stadiometer.	During visit 1 this measurement will take about 30 seconds.

Arm blood pressure	Your blood pressure will be monitored using a cuff placed on your upper arm that is inflated and deflated periodically. You might feel mild temporary discomfort while the cuff is inflated.	We will measure blood pressure several times during each visit.
Heart rate and rhythm (electrocardiogram)	Sticky pads will be applied to your skin to measure the heart's electrical signals. You might feel mild temporary discomfort while the sticky pads are removed.	Heart rate and rhythm will be measured via 12-lead electrocardiogram during visit one (usually about 10 minutes). Heart rate and rhythm will be measured continuously via six-lead electrocardiogram during visits 2-4.
Dual-energy X-ray absorptiometry (DXA)	You will lay quietly on a scanning bed. During this time a device will move around to scan your body without contacting you. This scan provides information about how much muscle and fat your body contains.	Approximately 20 minutes during visit 1.
Graded exercise test	This test measures your body's ability to use oxygen. The test involves exercising on a stationary cycle or treadmill beginning at a light/easy workload and then increased to slightly harder workloads. You will breathe regular room air through a snorkel-like mouthpiece or facemask during this test, and air that you breathe out will be analyzed by a computer. During this test we will measure your blood pressure and heart rate.	Approximately 30 minutes during visit 1.
Internal temperature (temperature sensor pill)	In order to measure your internal body temperature, you will swallow a pill about the size of a large vitamin. The pill will pass though the gastrointestinal tract in typically 1 – 7 days.	Internal temperature will be measured throughout visits 2-5.
Internal temperature (via rectal thermometer)	The researcher will ask you to insert a single-use rectal thermometer to a pre-marked depth of approximately 10 to 15 cm (approximately 4 to 6 inches). You will insert and remove the thermometer in a private room.	Internal temperature will be measured throughout visits 2-5.
Internal temperature (via suppository pill)	If a rectal thermometer cannot be inserted, or you choose to decline inserting this thermometer, the researcher may ask you to insert a temperature sensor pill into your rectum (like a suppository). You will be provided with a lubricant and gloves to insert this pill. You will insert this pill in a private room.	Internal temperature will be measured throughout visits 2-5
Skin temperature	Skin temperature will be measured by taping temperature probes to your skin or using a thermal imaging camera.	Skin temperature will be measured throughout visits 2-5.
Local sweat rate	Local sweat rate is measured using small capsules placed on the arm. This approach involves supplying dry gas through the capsule to pick up any sweat secreted, which is then measured by a humidity sensor. The capsules will be taped to the skin.	Local sweat rate will be measured throughout visits 2-5.

Activated sweat glands	The number of activated sweat glands will be measured by placing a piece of paper embedded with iodine on your skin for a brief period (less than 1 minute).	Activated sweat glands will be obtained throughout visits 2-5.
Skin blood flow	Skin blood flow will be measured using laser Doppler devices. These devices use very low power laser light to detect the amount of blood circulating at the skin surface.	Skin blood flow will be measured throughout visits 2-5. After the exercise trial we may heat these sites to 111°F.
Thermal images of skin surface	Pictures of your skin surface will be taken using an infrared camera to get a global view of your skin temperature in different areas of your body.	These images will be obtained throughout visits 2-5.
Peripheral intravenous catheter and blood samples	To collect blood during the experiment (up to approximately 8 tablespoons per visit), a sterile catheter will be inserted into a superficial vein of one of your arms. This procedure allows for blood to be taken multiple times with the insertion of only one needle. We will measure several markers of stress and hydration. Finally, some coded samples may be stored in our freezer for future analysis of blood pressure-related hormones/biomarkers of interest.	The catheter will be placed at the beginning of visits 2-5 and removed prior to discharge. We will perform serial blood samples (up to 4).
Cardiac output (gas rebreathing)	The amount of blood being pumped by the heart will be measured by analyzing the air you breathe out. For this procedure, you will breathe a small amount of harmless gases (a mixture of oxygen, nitrous oxide, and sulfur hexafluoride) through a mouthpiece.	Each cardiac output measurement will last about 30 seconds. This procedure will be measured periodically during visits 2-5.
Metabolic rate	Metabolic rate will be measured by analyzing the gases that you breathe out through a mouthpiece or facemask, as well as the amount of air you pass through the mouthpiece (ventilation).	Metabolic rate will be measured during the entirety of the graded exercise test and periodically throughout visits 2-5.
Perceptual Questionnaires	You will be asked to complete a few questionnaires related to how you are feeling with respect to how hard it is to exercise and how hot you feel you are.	You will perform this procedure intermittently throughout visits 1-5.
Cooling Approaches	We will use one of the following cooling approaches while you exercise: none, skin wetting (apply water to your skin), fan (direct a fan at you), a combination of skin wetting and a fan.	We will apply one of these cooling approaches during each of visits 2-5.
Echocardiogram	Pictures of your heart will be taken with an ultrasound camera	This measure will take about 15 min and will be performed on your screening visit (day 1) and after each exercise trial.

Data Collection to Develop Smart Phone Application	Throughout the exercise bout we will obtain data that will help us identify the effectiveness of the cooling modality. De-identified data (that is data that is not connected with any one person) may be used to develop a smart phone application to assist burn survivors to perform physical activity more safely.	We will obtain such data during visits 1-5.

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.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. Any clinically relevant results of the research will be communicated to you. Clinically relevant means that the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable and it can be confirmed. In that case, we will attempt to notify you using the contact information you have provided.

If you do not want to be notified of any of these incidental findings, please initial below.

_____ Please do not notify me of any incidental findings obtained from this research.

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

Risks from the specific research procedures

There are risks to taking part in this research study. Side effects from this study will usually go away soon by the time you are discharged at the end of each visit. In some cases, side effects can be long lasting or may never go away.

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 your study doctor immediately, about any side effect that you have while taking part in the study.

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.

Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are life threatening or fatal (could cause death). The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

<u>Exercise in the climate chamber:</u>

- Exercise in the heat can result in high body temperature that can stress your heart and blood vessels. There is a risk of developing a heat-associated injury (heat exhaustion or heat stroke). However, we will monitor your internal temperature and vital signs (heart rate and blood pressure) closely in order to minimize this risk. Exercise will be stopped if your internal temperature reaches 103.1 °F, if you begin to feel light-headed or dizzy, or if you want to stop the test for any reason. Internal temperatures at or below 103.1°F are well tolerated by most people and do not cause harmful effects.

Peripheral intravenous catheter and blood samples:

Less Likely, some may be Serious

In 100 people, approximately (2 to 20 individuals) may have:

- You may have discomfort, bleeding, and/or bruising.
- You may feel dizzy or faint.

Rare and Serious

In 10,000 people, approximately (1 or less) may have:

- An infection, redness, or swelling
- The catheter perforating the vein or not being inserted into a blood vessel
- A blood clot or breakage of the catheter (very low risk)

Dual-energy X-ray absorptiometry (DXA):

- Being part of this study will expose you to radiation that you may not receive as part of your standard care. The radiation you receive for your everyday care outweighs risks the radiation poses because it allows your doctor to provide appropriate medical care. The extra radiation you receive from this study may not help you in this way. However, everyone is exposed daily to a background of radiation from the earth, outer space, the food we eat, and the air we breathe. Some people may be exposed to larger amounts of radiation (up to about 15 times more than this natural and background each year) because of their jobs working with radiation. Regulations limit the amount of radiation these workers can receive each year to make sure their risks are low. The added radiation dose you will receive from this study is less than the yearly regulatory limit set to protect radiation workers in the U.S.

Graded exercise test:

- Exercise rarely causes problems in healthy people, but in individuals with known or hidden heart disease, the test may cause chest pain, dizziness, or bouts of irregular heart rhythm. Exercise will be stopped immediately if there are any signs of excessive strain. There is no additional risk involved with completing the exercise test beyond that normally associated with exercise and hard physical effort. During intense training and/or testing, the risk of having a heart attack or even dying goes up slightly; however, the risk during an exercise test in a person with no history of heart disease is low.

Internal Temperature (temperature sensor pill):

- Although they are very rare, there are some risks associated with taking this pill. It is possible that you could inhale it into your lungs. The pill could also cause a perforation (tear), blockage or infection of the intestinal tract. The pill could become stuck in your intestinal tract and require endoscopy or surgery to remove it. You should not take this pill if you weigh less than 80 pounds, nor should you take this pill if you have or have had any gastrointestinal disease or surgery or if you have any implanted medical devices. You may not have a magnetic resonance imaging (MRI) procedure performed with this pill in your body.

Internal Temperature (rectal thermometer):

- Although it is very rare, it is possible that you could puncture your anus or rectum or get an infection.

Internal Temperature (suppository pill):

- You may feel some discomfort upon inserting the pill into your rectum. That discomfort will go away once your finger is removed from your rectum.
- The pill will come out upon defecation. In the very unlikely instance that the pill becomes stuck, endoscopy or surgery may be required to remove it.

- You should not insert the pill if you have hemorrhoids (internal or external), rectal bleeding, diarrhea, or fecal impact of the rectum.
- You may not have a magnetic resonance imaging (MRI) procedure performed with this pill in your body.

Iodine Embedded Paper:

- Though very rare, if you are allergic to iodine you may experience an itchy like rash where the iodine embedded paper is placed on your skin. Please tell the investigator if you suspect that you have an allergy to iodine.

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

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there risks related to withdrawing from the 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 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.

Reproductive Risks

Concerns for sexually active men and women: Women should not become pregnant and men should not father a baby while taking part in this study because we do not know how the study drugs/procedures could affect a man's sperm (for some drugs/procedures, the concern may be that the sperm might be affected and in some cases, drugs could being carried by the semen into the vagina and cause harm) or a fetus, if a woman becomes pregnant during the study. It is important that you talk to your study doctor about avoiding pregnancy during this study. If you think you might have become pregnant or if you believe your female partner has become pregnant while you are in this study, you must tell one of the study doctors right away so that management of the pregnancy and the possibility of stopping the study can be discussed.

If you are a woman who is pregnant or could be pregnant, you cannot take part in this study because we do not know how the heat-wave simulation might affect a developing fetus. We will do a pregnancy test before you start treatment to make sure you are not pregnant.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, or even at different times, 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?"

You may not receive any personal benefits from being in this study.

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

Payments – Will there be any payments for participation?

Individuals eligible to participate will be compensated at the rate of $35 per hour of time in the laboratory. For those who live outside of the area, a $40 per day meal allowance will be provided, as well as travel-related costs will be paid for airfare, ground transportation, and accommodations. An additional $25 per day ($100 in total) will be paid if you agree to have your internal temperature measured using the rectal thermometer (or suppository pill) and the temperature sensor pill that you swallow, assuming that you don't have any medical restrictions that would prohibit the use of these approaches. Where applicable, the compensation will be provided via a check in the mail within approximately six weeks of the final experimental visit completed.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

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.

Certificate of Confidentiality:

To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to

withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

How will my information and/or tissue samples be used?
With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information or tissue samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

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. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

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: Name, Address, Phone Number, Date of Birth
- Medical History: What medical conditions you have and information about them
- Physical Exam information (what we see during your physical examinations)
- Information that is collected during study testing

We will get this information by asking you, reviewing medical records in UTSW or THR electronic medical record, requesting medical records from your doctors or collecting this information through study procedures.

How will your PHI be shared?
Because this is a research study, we will be unable to 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, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- National Institutes of Health (NIH) and other U.S. and international governmental regulatory agencies involved in overseeing research.
- The Data Safety Monitoring Board is the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason
- The Research offices at Texas Health Resources and the University of Texas Southwestern Medical Center

- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

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 our laboratory at THR or UTSW 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 Craig Crandall, Institute for Exercise and Environmental Medicine, 7232 Greenville Avenue, Dallas, TX 75231. 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.
Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

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:
Research Nurse: Ileana Hill, BSN, RN can be reached at 214-345-6502 or IleanaHill@TexasHealth.org.

If primary is not available, contact 347-433-6522. This is a google voice number that multiple study team members receive updates for and can return your call promptly.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives 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 HRPP by calling the office at 214-648-3060.

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 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 FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM

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

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM