The effects of low-dose analgesics on cardiovascular function (STU-2021-0579)
NCT04959812
8/18/2023

Title of Study: The effects of low-dose analgesics on cardiovascular function

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 research study is to determine whether a commonly used pain medication (sufentanil) affects a person's ability to tolerate a bleeding injury, simulated in the laboratory setting utilizing a lower-body negative pressure (LBNP) vacuum chamber.

Sufentanil is given to individuals (including soldiers) who need a pain medication for an injury. In combat settings, and in some non-combat settings, pain often accompanies a severe bleeding injury. It is important that the pain medication given to such an individual does not reduce their tolerance to the bleeding injury by adversely affecting the control of blood pressure. Therefore, we are studying how sufentanil affects your body's ability to tolerate a simulated hemorrhage injury by altering variables that control your blood pressure.

During this study, you will complete two experimental trials. During one trial, we will administer sufentanil once. During the other trial, we will give you a placebo (similar pill as sufentanil but does not have any drug in the pill). You will not know whether you are receiving the sufentanil pill or the placebo pill for these trials. During these visits, we will measure your nervous system activity, heart function, and blood vessel function. Total study duration is approximately 12 hours and will include 3 visits. If you are a healthy individual, between 18 and 45 years of age, you qualify to participate in this research study. Like all research studies, there are risks in participation, though the risks for this study (outlined below) are well controlled and are relatively minor.

This research will help doctors learn more about how sufentanil affects responses that control blood pressure during a bleeding injury. If you are interested in learning more about this study, please continue to read below.

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.

Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

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.

Title of Study: The effects of low-dose analgesics on cardiovascular function

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 Department of Defense 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?"

Pain management is an important component in the care of an injured soldier. Currently, the four pain medications available to a combat medic are morphine, fentanyl, ketamine, and sufentanil. Selection of the ideal pain medication is based on the type and level of distress of the soldier. Given that a bleeding injury on the battlefield is almost always associated with pain, it is important that the selected pain medication does not disrupt responses that are beneficial towards the maintenance of blood pressure and vital organ blood flow during a bleeding injury. The procedures outlined below will examine the effects of a recent FDA approved version of a pain medication called sufentanil (via pill placed under the tongue; sublingual) on tolerance to a simulated bleeding injury in humans. These data will be combined with similar data currently being collected using identical techniques but with morphine, fentanyl, and ketamine. Obtaining these data is an important step towards an understanding of the potential influence of commonly used pain medications on tolerance to a bleeding injury.

You are asked to participate in this research study on the effects of sufentanil on blood pressure control during a simulated bleeding condition. This study needs to be done so combat medics will know which pain medication is ideal to be given to an injured soldier.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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, between the ages of 18-45 years, and do not have any known specific risks for receiving sufentanil.

How many people are expected to take part in this study?

- This study will enroll approximately 60 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 visits with the researchers and study staff. The total time commitment for this study is approximately 12 hours (up to two hours for consent/screening and approximately five hours for each of the two experimental trials).

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 be able to 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. All of the procedures described below are for **research only**.

Screening Procedures (approximately 2 hours)

- If you are capable of becoming pregnant, a pregnancy test (from one urine sample) may also be done before you receive study treatment.
- You may also be asked to provide a urine sample for drug screening.
- We will measure your body height and mass.
- We will ask you to complete a medical history form.
- We will measure your blood pressure.
- We will measure your heart rate and rhythm (12-lead electrocardiogram).

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 (for example, if the urine drug screen comes back positive). We will inform you, and this information will not be shared with anyone outside of the study team.

Assignment to Study Groups

When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to complete either the sufentanil trial first or the placebo trial first. A placebo is an inactive, harmless substance that looks like the other study drugs.

If you are randomized to complete the sufentanil trial first, you will complete the placebo trial second. If you are randomized to complete the placebo trial first, you will complete the sufentanil trial second. These trials can last approximately five hours.

For either visit, neither you nor the researchers will know whether you are receiving sufentanil or the placebo. However, the study nurse and anesthesiologist will know if you are receiving sufentanil or placebo.

Study Procedures - as a participant, you will undergo the procedures outlined below.

Visit #1 - approximately two hours: Consent and Screening
Visit #2 - approximately five hours: First Experimental Visit
Visit #3 - approximately five hours: Second Experimental Visit

Visit #1

The following measures and procedures will be performed during visit #1 (see below for descriptions)

- Informed consent/discussion
- Urine sample (pregnancy and drug screening)
- Medical history
- Body height and mass
- Blood pressure (arm)
- Heart rate and rhythm (12-lead electrocardiogram)

Visits 2-3:

On visits 2 and 3, the procedures performed will be identical, with the exception that during one visit you will receive sufentanil (a commonly used pain medication) and during the other visit you will receive the placebo. The order of these visits will be randomized.

You will be instrumented and rest quietly by lying down. After a period of resting measurements, we will perform two tests (pressure algometry and a cold pressor test). You will then receive sufentanil or placebo followed by a rest period prior to initiation of the lower-body negative pressure (LBNP) test. After the LBNP test, there will be a rest period followed by a repeat of the pressure algometry and cold pressor tests.

The following measures and procedures may be performed during visits 2 and 3:

Procedure	**Description of Procedure**	**Duration of Procedure**
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 conduct a drug screening test. Drugs that your urine will be screened for include marijuana, cocaine, opiates (such as heroin, morphine, hydrocodone, oxycodone and methadone), barbiturates, benzodiazepines, and methamphetamines. If this drug test is positive for one or more of these agents, you will not be permitted to participate in the study. A positive drug test will not be indicated in your records and this information will remain confidential. 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 height and mass	You will be asked to stand on a scale. There is no known significant risk with this measure.	Each measurement will take about 30 seconds at the beginning of each visit.
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. There is no known significant risk with this measure.	We will measure blood pressure several times during each visit.
Limb blood flow	We will measure blood flow through an artery in one of your limbs using Doppler ultrasound. A small amount of gel will be placed on an ultrasound probe, with that probe placed on the upper limb. There is no known significant risk with this measure.	We will measure limb blood flow several times during visits 2 and 3.
Heart rate and rhythm (electrocardiogram)	Sticky pads will be applied to your skin to measure the heart's electrical signals. It is possible that a small amount of chest hair may need to be shaved to get the pads to stick. You might feel mild temporary discomfort while the sticky pads are removed. There is no known significant risk with this measure.	Heart rate and rhythm will be measured via 12-lead electrocardiogram during visit 1 (usually about 10 minutes). Heart rate and rhythm will be measured continuously via six-lead electrocardiogram during visits 2 and 3.
Finger blood pressure	Your blood pressure will be monitored using a cuff placed on your finger. You might feel mild temporary discomfort when the cuff is "on" (periodically inflating and deflating) for too long (over an hour or so). If you feel discomfort, let the researchers know and they can turn it "off" for a few minutes when there is a break in active data collection. There is no known significant risk with this measure.	This cuff will continuously record finger blood pressure throughout visits 2 and 3.
Lower-body negative pressure	This procedure causes fluid in your body to shift from your chest and upper body to your lower body. While lying on your back, you will be sealed in a box-like chamber from the waist down. Suction will be applied inside the box to your lower body. The level of suction will increase until the	This procedure will last no more than 30 minutes.

	researchers determine that the test is over, or you request to stop.	
Sufentanil administration	Sufentanil will be given by placing a pill under your tongue. The pill will rapidly dissolve while it is under your tongue	The pill will dissolve in about 1 minute
Placebo administration	A placebo pill will be given by placing a pill under your tongue. The pill is like the sufentanil pill, but it does not contain any sufentanil. The pill will rapidly dissolve while it is under your tongue. There is no known significant risk with this procedure.	The pill will dissolve in about 1 minute
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 hormones involved in blood pressure control.	The catheter will be placed at the beginning of the visit and removed prior to discharge. We will perform serial blood samples (up to five) throughout visits 2 and 3.
Nervous system recording (microneurography):	Nerve signals from the nerves in the arm will be measured. To locate the nerves, we use ultrasound imaging. When the nerve is located, we insert a small sterile needle (an electrode about the size of an acupuncture needle) through the skin. You may feel some slight discomfort during needle insertion. The recording needle is advanced into the nerve. When the tip of the needle enters the nerve, you may notice a tingling, pins and needles, cramping, or dull achy sensation. A second needle serves as a reference electrode and is inserted just under the skin, a couple of inches away from the nerve. Once the needles are in place it is extremely unlikely you will feel any discomfort. This method of recording nerve signals in human subjects has been used in over 3000 studies since 1979. We have performed over 300 recordings in our laboratory without any major complications. In rare cases, individuals may have tenderness, soreness, or numbness in the nerve recording area for a few days that subsides without treatment.	The microneurography needle will remain in position for the duration of visits two and three and will be removed at the end of the study (up to approximately five hours per visit, up to 10 hours total).
Tissue oxygen saturation	A small sensor will be placed on your skin in order to measure the amount of oxygen in your muscle or brain. There is no known significant risk with this measure.	The sensor will remain in place for the entire duration of visits 2 and 3 (up to approximately 5 hours per visit, up to 10 hours total).
Blood oxygen saturation	The amount of oxygen in your blood will be measured by pulse oximetry by placing a sensor on your finger. There is no known significant risk with this measure.	Oxygen saturation will be measured during the entire duration of visits 2 and 3 (up to approximately 5 hours per visit, up to 10 hours total).
Compensatory reserve indicator	A small cuff will be placed on one of your fingers to take measurements pertaining to the blood flow in your finger. There is no known significant risk with this measure.	The sensor will be used during visits 2 and 3 (up to

		approximately 5 hours per visit, up to 10 hours total).
Brain blood flow	A gel covered probe will be placed on the side of your forehead. Sound waves will be used to record blood flow inside your head. This procedure is similar to standard ultrasound tests done to examine the health of babies prior to birth. There is no known significant risk with this measure.	The sensor will remain in place for the entire duration of visits 2 and 3 (up to approximately 5 hours per visit, up to 10 hours total).
End tidal carbon dioxide	The amount of carbon dioxide that you exhale will be monitored from a nasal cannula (a plastic tube that fits behind your ears and two small, short prongs that are placed in your nostrils). There is no known significant risk with this measure.	The sensor will remain in place for the entire duration of visits 2 and 3 (up to approximately 5 hours per visit, up to 10 hours total)
Cold pressor test	You will place one hand up to the wrist in ice slurry water for a period of 2-3 min. You will report the pain that you are experiencing on a scale of 0 to 10, 0 being no pain and 10 being the worst imaginable pain. There is no known significant risk with this procedure.	This test will be performed twice during visits 2 and 3.
Pressure algometry	A digital algometer will be placed on your finger or thumb. Pressure to that area will increase until you first start to feel discomfort. There is no known significant risk with this measure.	This test will be performed twice during visits 2 and 3. Each test lasts approximately 30 seconds.

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. There are no plans to provide this information to you or your physician.

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 effects that you may have while taking part in the study.

The following section will describe the risks related to 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. Mild side effects are those that may be temporarily uncomfortable and go away shortly after the procedure and/or do not have the potential for any long-term adverse effects. 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 likely (many), less likely (few), or rarely (only one or two).

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

Lower-body negative pressure:

Likely

In 100 people, approximately (21 to 100 individuals) may have:

- Mild risk: Dizziness, lightheadedness, or nausea that will go away shortly (often immediately) after stopping lower-body negative pressure.
- Mild risk: Mild discomfort at the interface between the lower-body negative pressure device and your body that will go away immediately upon stopping lower-body negative pressure.

Sufentanil administration:

Likely

In 100 people, approximately (21 to 100 individuals) may have:

- Mild risk: Short-term disorientation and changes in vision or hearing
- Mild risk: Short-term tiredness, confusion, or nausea

Less Likely

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

- Mild risk: Short-term headaches, dizziness, vomiting, or low blood pressure

Rare

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

- Mild risk: Elevated or slowed heart rate
- Mild risk: Skin rash or excessive sweating
- Serious risk: Temporary difficulty breathing (very low risk)
- Serious risk: Addiction, abuse, and/or misuse of sufentanil (very low risk)

Peripheral intravenous catheter and blood samples:

Less Likely

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

- Mild risk: You may have discomfort, temporary bleeding, redness, mild swelling, and/or bruising.
- Mild risk: You may feel dizzy or faint.

Rare

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

- Serious risk: An infection
- Serious risk: A blood clot or breakage of the catheter (very low risk)

Nervous system recording (microneurography):

Consistent with published guidelines, we will limit the nerve search time to 60 minutes (though most nerve searches last less than 30 minutes). Also, we will not record from the same nerve within one 28-day period.

Likely

In 100 people, approximately (21 to 100 individuals) may have:

- Mild: Slight short-term discomfort during electrode insertion
- Mild: Slight short-term sensations of tingling, pins and needles, cramping, or dull achy

Rare
In 100 people, approximately (1 or less individuals) may have:

- Mild risk: Tenderness, soreness, or numbness near the nerve recording site for a few days that spontaneously resolves without treatment

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 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 be 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 sufentanil might affect a developing fetus. We will do a pregnancy test before you start treatment to make sure you are not pregnant.

Risks to babies who are being breastfed: Women who are breastfeeding cannot take part in this study because we do not know what effect the drugs/procedures might have on their breast milk.

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?"

The possible benefit of your participating in this study is related to research monitoring procedures (such as the assessment of blood pressure) which is likely to contribute to your well-being.

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

We hope the information gained from this research will lead to better treatment and management of individuals involved with traumatic injuries in the pre-hospital setting, e.g., traffic collisions or injured soldiers.

Alternative procedures– "What other options are there to participation in this study?"

Your participation is completely voluntary. You do not have to take part in this research.

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. This compensation will be provided via a check in the mail within approximately six weeks of the final experimental visit completion. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

If required, you will be reimbursed for your transportation to and from the research center (for example cab or bus fare). To receive reimbursement, you will need to turn in all your receipts to the research coordinator.

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.

Costs – Will taking part in this study cost anything?

There will be no costs to you in taking part of any of the procedures associated with this study.

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
- Screening information (information that is obtained during your screening visit)
- 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:

- 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.
- Department of Defense and other U.S. and international governmental regulatory agencies involved in overseeing research.
- A 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 Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- The Research offices at the University of Texas Southwestern Medical Center and Texas Health Resources.
- 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 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: Courtney Hakes, BSN, RN can be reached at 214-345-6502 or CourtneyHakes@TexasHealth.org.

If primary is not available, contact Craig Crandall, PhD at 972-522-8859.

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.

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

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	AM PM Time