CONSENT TO PARTICIPATE IN RESEARCH

PAN-ASIA UNITED STATES PREVENTION OF SUDDEN CARDIAC DEATH TRIAL (PAUSE-SCD): A Randomized Pilot Study

Lay Title: A study to examine the role of ICD and catheter ablation of ventricular tachycardia to prevent recurrent arrhythmias and death.

INTRODUCTION

Roderick Tung, MD and associates from the Heart Rhythm Center at the University of Chicago are conducting a research study.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

You are being asked to participate in a research study called the Pan-Asia United Stated Prevention of Sudden Cardiac Death Trial referred to as the PAUSE-SCD Trial which seeks to identify the effective way of treating ventricular tachycardia. The study was initiated by your physicians.

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this research study because you have or will need to have implantation of an Implantable Cardioverter Defibrillator (ICD) for your history or risk of life-threatening cardiac arrhythmias.

One type of arrhythmia that may result in sudden cardiac death is called ventricular tachycardia. Ventricular tachycardia (VT) is a rapid heartbeat that starts in the bottom chambers of the heart called the ventricles. This condition can be life-threatening because the ventricles are the main pumping chambers of the heart. The fast heartbeat is caused by electrical impulses that travel incorrectly in your heart. VT conditions are classified based on different criteria; monomorphic ventricular tachycardia (MMVT) is one type of VT. Some patients receive an ICD because of their past VT condition while other ICD patients do not have VT history, but may have a potential risk of developing MMVT. Ask your doctor about whether or not you have VT history or if you have potential risk of developing MMVT.

The current standard of care for VT includes the use of medicine called anti-arrhythmic drugs (AADs) and ICD therapy. These treatments are used to terminate the irregular heartbeats and bring your heart back to a normal rhythm. There is also a procedure called a catheter ablation that is approved for patients that have a history of VT. Catheter ablation is a procedure used to eliminate (damage or get rid of) the heart cells causing the arrhythmia. Your doctor has determined that you may benefit from an ablation procedure in addition to your ICD to treat your VT condition or risk of developing VT. This study aims to show that treating your VT condition

with catheter ablation, if performed before your receive ICD shock therapy, will likely reduce the need for ICD shocks in the future and lead to improved survival.

In addition, even if you experienced shock therapy from your ICD in the past 90 days, catheter ablation may lower the number of ICD shocks in the future and/or or the effects on your heart and your quality of life. Some studies have shown that for patients with an ICD and no history of VT, the chances of receiving an ICD shock following implant are approximately 18% within the first year (12 months) and 35% within the second year (24 months). In patients with prior VT episodes, the chances are 25% within the first year and 50% within the second year due to repeat VT episodes.

Study Purpose

The purpose of this study is to compare the effectiveness of routine medical therapy with ICD and routine medical therapy with ICD and catheter ablation to prevent ventricular tachycardia. The effectiveness to prevent or treat VT will be evaluated and information about your overall heart condition will be collected to see if there are improvements.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 180 people will participate in this study across up to 12 major academic centers in Asia. Regardless of whether you are randomized to receive the study ablation treatment or not, all patients who are in the study will be carefully monitored throughout the time they are in the study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:
If you decide to take part in this study you will be asked a series of questions related to your current medical condition. A physical exam and a medical history interview will be conducted by your physician.

Based on your answers, your doctor will decide if you qualify to take part in the PAUSE-SCD Trial. If your doctor determines that you qualify, and you decide to take part in this study, the following procedure(s) may be performed. These procedures are considered standard of care and your doctor will discuss each of these in detail with you before they are performed.

- Blood Tests: The study doctor or staff may order routine blood tests that are part of the standard of care for patients undergoing routine drug therapy or an ablation.

- Medication Review: The study doctor or staff will ask you about the medications that you take every day.

- 12 Lead ECG (electrocardiogram) Recording: This is a non-invasive test that records the rate and regularity of the heart rhythm (heartbeats). This test will take approximately 5 minutes.

- Trans-Thoracic Echocardiogram (TTE): The study doctor may ask you to have a TTE (ultrasound of your heart) if you have not had one within the last six (6) months. An echocardiogram is a test that uses sound waves to create a moving picture of the heart. This involves moving a wand on your chest while images are taken and displayed on a

monitor. If this test was done within 6 months before you are enrolled in this study, or if you will have or had a recent MRI or TEE test (described below), your doctor may decide you do not need the TTE. In particular circumstances, you may receive an additional TTE within 24 hours before the pacemaker implant procedure at your doctor's discretion.

- Computerized Tomography (CT) or Magnetic Resonance Imaging (MRI): If you haven't had a recent CT/MRI you may be required to complete one before an ablation procedure. This test records the structure and chambers of your heart. Depending on the area of the heart being studied and type of equipment, the test may take up to one hour or longer.

- NIPS (Non-Invasive Programmed Stimulation) test and/or EP (Electrophysiology) Study: If you received a new ICD (within 90 days) or will be receiving a new ICD, and your doctor has determined your VT records do not show MMVT, the doctor may perform a routine electrophysiology study (EP) or non-invasive programmed stimulation (NIPS) test to see if this type of VT can be induced. This test may be done at the same time you are receiving the ICD implant. This test will help determine if you are eligible to be randomized in the study.

- Trans-Esophageal Echocardiogram (TEE): The TEE is a sound wave picture of your heart that is taken using a probe that is placed down your throat and into your esophagus. Based on your medical history and current medical status, you will complete a TEE before an ablation procedure. The TEE will help your doctor determine if you have any blood clots or anything abnormal in the lower chambers of your heart. This is done by placing the echo probe into the esophagus while you are sedated.

- Pregnancy Test: A blood or urine pregnancy test will be done if you are a female, of child bearing potential, and if history of menstrual cycles cannot rule out pregnancy.

Even if you qualify to participate, your study doctor may decide to exclude you from the study if he or she determines, after the tests are complete or while in the procedure room, that you are not an eligible candidate.

Study Overview

Randomization:
In order to qualify for randomization, you will need one "documented" episode of monomorphic VT (MMVT). This can be from an ECG or induced during the NIPS test or EPS. If your doctor determines you do not meet this qualification, either from your VT records or from the NIPS test or EP study, you will not be eligible to be randomized in the study.

If you qualify for randomization, you will be assigned to one of two treatment groups by chance (as with a flip of a coin) to either a medication group or a medication plus ablation group. It is important to understand that neither you nor your physician will be able to decide to which group you are assigned. You will have a 50% chance of being assigned to either group.

Registry Group:
If you decline or are unable to undergo ICD implantation despite your treating physician's recommendation, you will not be eligible to be randomized in the study. However, you may be entered into a registry portion of the study if you choose catheter ablation as the primary therapy. You will follow-up for routine clinical care every 6 months to check on your overall status. No other study specific procedures will be performed.

Ablation Procedure:
Your doctor will discuss your ablation with you in detail prior to your procedure. You will have your ablation procedure performed in a special lab called the Electrophysiology Laboratory (EP Lab). On the day of your ablation procedure, you will first undergo the trans-esophageal echocardiogram (TEE) to look for blood clots in your heart. You will also be connected to electrodes that monitor your heart and additional electrodes that will be used for the ablation system.

There are two types of ablation techniques that can be used to treat your condition. Your doctor will discuss with you the type (s) of ablation that will be used in your ablation procedure.

Endocardial Ablation: Endocardial ablation uses heat to destroy abnormal tissue *inside* the heart and is the standard of care for both atrial and ventricular arrhythmias.

Epicardial Ablation: Epicardial ablation involves threading a wire beneath the rib cage to reach the *exterior* of the heart and is standard of care for both atrial and ventricular arrhythmias. About 30 percent of ventricular arrhythmias originate in tissue on the outside of the heart and cannot be treated effectively with only endocardial ablation.

The first part of the ablation procedure may involve a routine diagnostic electrophysiologic (EP) test to record the electrical activity of the heart and to find the area that is causing it to beat too fast. In this procedure, 4 to 8 catheters (long, narrow tubes) will be passed (threaded) under x-ray guidance through veins in the right and left legs and via a blood vessel in your neck into your heart.

The next part of the procedure uses the investigational catheter to apply radiofrequency energy to ablate the areas in the lower part of your heart (ventricles) that is responsible for your fast heartbeat. The doctor will electrically stimulate (pace) your heart to determine the path of electrical activity in your heart. Radiofrequency energy will then be applied once the target ablation area has been identified. Your heart will be “paced” again to determine if the electrical path has changed due to the treatment. This area in your heart will receive radiofrequency (RF) energy (“heat”) and the application of the heat will interrupt the electrical pathways that are traveling incorrectly in your heart. This procedure is performed under conscious sedation or general anesthesia.
The total estimated time for the ablation procedure is approximately 4-6 hours.

Study- Related Follow-Up Visits:
You will be required to return for follow-up study visits that follow routine standard or care procedure. The study team will use the data from the tests and procedures. It is very important that you keep your follow-up appointments so that your doctor can keep track of your progress.

<u>Pre-Discharge</u>
Before you are discharged from the hospital, the study doctor or staff will:
- Perform a 12- lead ECG.
- Check your ICD by connecting it to a programmer in the same way as a regular clinical check-up. You should not feel any discomfort during this procedure. It should take no longer than 15 minutes to gather information from your device.

<u>1 month Visit</u>
During your visit, the study doctor or staff will:
- Ask you about the medications that you take every day.
- Ask you about recent hospital visits, emergency room visits, or changes in your health.
- Check your ICD by connecting it to a programmer in the same way as a regular clinical check-up. You should not feel any discomfort during this procedure. It should take no

longer than 15 minutes to gather information from your device.

3 month Visit
During your visit, the study doctor or staff will:
- Ask you about the medications that you take every day.
- Ask you about recent hospital visits, emergency room visits, or changes in your health.
- Check your ICD by connecting it to a programmer in the same way as a regular clinical check-up. You should not feel any discomfort during this procedure. It should take no longer than 15 minutes to gather information from your device.

6 months Visit
During your visit, the study doctor or staff will:
- Ask you about the medications that you take every day.
- Ask you about recent hospital visits, emergency room visits, or changes in your health.
- Check your ICD by connecting it to a programmer in the same way as a regular clinical check-up. You should not feel any discomfort during this procedure. It should take no longer than 15 minutes to gather information from your device.

1 year Visit
During your visit, the study doctor or staff will:
- Ask you about the medications that you take every day.
- Ask you about recent hospital visits, emergency room visits, or changes in your health.
- Review the results of your Trans-Thoracic Echocardiogram (TTE).
- Check your ICD by connecting it to a programmer in the same way as a regular clinical check-up. You should not feel any discomfort during this procedure. It should take no longer than 15 minutes to gather information from your device.

1 ½ year Visit
During your visit, the study doctor or staff will:
- Ask you about the medications that you take every day.
- Ask you about recent hospital visits, emergency room visits, or changes in your health.
- Check your ICD by connecting it to a programmer in the same way as a regular clinical check-up. You should not feel any discomfort during this procedure. It should take no longer than 15 minutes to gather information from your device.

2 year Visit
During your visit, the study doctor or staff will:
- Ask you about the medications that you take every day.
- Ask you about recent hospital visits, emergency room visits, or changes in your health.
- Review the results of your Trans-Thoracic Echocardiogram (TTE).
- Check your ICD by connecting it to a programmer in the same way as a regular clinical check-up. You should not feel any discomfort during this procedure. It should take no longer than 15 minutes to gather information from your device.

HOW LONG WILL I BE IN THIS STUDY?

If you decide to take part in this study, your length of participation will be approximately 24 months from the time of randomization. If you are willing to have routine clinical follow-up every 6 months, your participation may extend to 5 years.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Risks related to ECG
The ECG is a noninvasive method of assessing the heart's function. Risks associated with the ECG are rare. Some people can have minor skin irritation or an allergic reaction from the sticky patches that are placed on the chest. The irritation should go away once the patches are removed.

Risks related to Trans-Thoracic Echocardiogram (TTE)
There are no known risks from a TTE. However, during the test the technician may have to press hard on your chest with the transducer. Tell the technician if you feel any pain or discomfort.

Risks related to the Trans-Esophageal Echocardiogram (TEE)
The risks with the trans-esophageal echocardiogram (TEE) are low (<1%) and include abnormal heart rhythms, temporary changes in blood pressure, temporary decrease in the oxygen levels of the blood, worsening of heart failure symptoms, spasm in the back of the throat, infection, bleeding and perforation.

Radiation Exposure: CT/MRI/Fluoroscopy
Since the radiation procedures are all standard of care, the amount of radiation you will receive is the same as that for similar patients who are not participating in this study. Therefore, you will not be exposed to any additional radiation by participating in this study.

Risks related to the Ablation Procedure
If you are randomized to the ablation group, there are a variety of risks or complications that can occur with the ablation procedure. Although the overall incidence rate (how often it occurs) of each risk is provided, these may be different at your medical center. These may be related to the insertion or placement of catheters, the use of medications, moving the catheters in the heart, or delivery of energy inside or on the outside of the heart.

The insertion of the catheters into your neck or leg veins or arteries can be accompanied by the following:

- The possibility of infection, bleeding, bruising, pain or blood clot formation under the skin. A blood clot can develop in one of your veins in the leg or even in the lungs. A vein or artery could be injured and may require surgery for repair.
- Since the neck vein catheter travels close to the lung, it is possible for the lung to be punctured causing it to collapse. If this occurs, a hollow tube may be inserted between the ribs to remove the air around the lung and help it re-expand.
- You could also develop a bladder or kidney infection, infection elsewhere in the blood, pneumonia or fluid in the lung.
- The possibility of air entering the blood stream.
- Medications given during the procedure could also have side effects.
- X-ray "contrast dye," used to visualize your heart and veins, may cause an allergic reaction resulting in a skin rash, difficulty breathing, or even cause lowering of blood pressure. This dye can also damage the kidneys. Although rare, the pumping ability of your heart may decrease or lung failure could occur.
- You may have an abnormal reaction to any anesthetic used during the procedure.
- The dye and anesthetic drug may produce an allergic response leading to a skin rash, a drop in blood pressure, or difficulty breathing. If this occurs, breathing can be supported by placement of a tube from the mouth into the upper airways of your lungs. A ventilator, or breathing

machine, then assists with the work of breathing and the procedure can be continued. In rare cases, pneumonia could develop.
- The blood thinner, heparin, or similar drug, which is used to prevent blood clot formation during the procedure, could cause bleeding anywhere in the body. While this is rare, such bleeding can be serious.
- There is a chance you may experience nausea or a visual migraine-like headache or see wavy lines in one or both eyes following the procedure.

Other procedure risks are related to positioning catheters within your heart:
- The most serious of these is heart muscle perforation by a catheter. In many cases the hole created by the catheter seals when the catheter is removed.
- In some cases, bleeding into the sac surrounding the heart could result in a drop in blood pressure.
- In such cases, a needle and catheter tube may be inserted from a position underneath the breastbone or between the ribs to drain this blood. In rare cases, open-heart surgery may be required.
- Moving the catheters within the heart could damage a heart valve, which could require surgical repair or replacement.
- A heart attack or stroke could also occur.
- An artery around the heart may spasm, develop a blood clot, or be damaged.
- There is also a possibility that the normal electrical system could be damaged, making a pacemaker necessary.
- The X-rays used to guide catheter placement could cause skin burns, or in the long run result in some form of cancer, or damage to your heart or lungs.
- If you already have a pacemaker, the wires positioned in the heart could be disturbed or the pacemaker damaged, making repair or replacement necessary.

The final group of risks has to do with the actual ablation:
- Cardiogenic shock: when the heart has been damaged so much that it is unable to supply enough blood to the organs of the body (<1%).
- Complete Heart Block: complete absence of conduction from the atria to the ventricles during a stable supraventricular rhythm (2%).
- New incessant VT/VF: new arrhythmias may occur as a result of damage to the heart's electrical system. It may be necessary to shock your heart to stop the rhythm (<1%).
- Acute Myocardial Infarction (MI): blocked blood supply to the heart that may cause damage to the heart muscle and affect how you feel and how well your heart can pump blood. This is often treated with drugs or may require surgical repair (1.5%).
- Stroke (also called Cardiovascular Accident or CVA): may cause an interruption in the blood supply to a part of the brain (~2-4%).
- Pericarditis: inflammation may occur in the outer lining of the heart (<1%).
- Cardiac perforation causing pleural effusion or tamponade: fluid build-up around the heart.
- A hole in your heart wall (*perforation*) could result in bleeding into the sac, called the pericardium, which surrounds your heart (*cardiac tamponade*). This may be treated by insertion of a needle, through your chest wall, into the sac and removal of the blood. This type of hole sometimes requires surgical repair (1.5%).
- Adverse effects on implantable pacemakers, cardioverters, and defibrillators. An example is dislodgement of ICD leads: (<1%).
- Coronary artery occlusion: a partial or complete block of blood flow in a coronary (heart) artery (<1%).
- Heart Valve injury (also called Valvular Damage/Insufficiency): an injury to a valve structure resulting in a loss and/or worsening of function (e.g., worsening of regurgitation score or

prolapse) (<1%).
- Acute Pulmonary edema: fluid accumulation (build-up) in the lungs (<1%).
- Pulmonary embolism: blockage of a pulmonary artery; a blood clot from a vein may get stuck in the lungs. This is usually treated with drugs (<1%).
- Vascular access complications: an obstruction or perforation or damage to the vascular
- (blood vessel) system (2%).
- Arterial/venous thrombus: clot formation in the artery or vein (1.5%).
- AV fistula: an abnormal passageway (such as a hole) between an artery and a vein; this may allow blood to go between the arteries and veins and not through the entire body. This may cause some part of the body to not receive the usual amount of blood. This may heal on its own, but may require surgical repair (1.5%).
- Catheter insertion site hematoma: bleeding or bruising from the site of catheter placement This may go away without treatment, but may require manual compression or surgical repair. If excessive bleeding at the site of the catheter placement continues, this could result in anemia requiring medical intervention (2%).
- Hemo-pneumothorax: bleeding in the chest (also called hemothorax); blood may leak into the chest cavity putting pressure on internal organs like your lungs (also called hemo-pneumothorax). This may be treated by using a needle or suction to remove the excess blood or it may require surgical repair. Pneumothorax may also occur when gas or air is present in the pleural (chest) cavity (<1%).
- Hypoxia: reduced oxygen supply to tissue (<1%).
- Infection, Localized or systemic: an infection may occur anywhere an incision or cut is made during the procedure (<1%).
- Peripheral venous thrombosis: blood clots in the vein (<1%).
- Phrenic nerve damage: damage to the nerve that controls the diaphragm and may affect your breathing. Symptoms may be temporary but in some cases can be permanent (respiratory arrest) (<1%).
- Pneumonia: infection of lungs or gathering of fluid in the lungs (<1%).
- Pseudoaneurysm: development of a false pouch in the vessel wall. This can be caused by movement of catheters in the blood vessels. This may heal on its own, but sometimes need surgical repair (<1%).
- Radiation injury resulting in dermatitis (skin burns): (<1%).
- Respiratory failure: damage to breathing that can be permanent (respiratory arrest) (<1%).
- Radiation exposure during the fluoroscopic imaging of the catheters during ablation: this may slightly increase the lifetime risk of developing a fatal malignancy or a genetic defect in offspring (<1%).
- Fluid overload: excessive fluid built up could result in pulmonary (lung) edema; congestive heart failure (CHF) may occur or may be exacerbated (worsened) due to delivery of sterile salt water (saline) during the procedure (these risks are specific to open irrigated ablation catheters) (1.5%).
- **Death**: End of Life (1%).

There are risks associated with an epicardial ablation if this is performed:
- RV puncture with no clinical consequence: a rupture or hole (perforation) in the right ventricular heart of no clinical significance (15%).
- Pericardial bleeding: blood in the pericardial sac (~7%).
- Hemoperitoneum: blood in the peritoneal cavity due to damage to abdominal vessel / organ
- (<1%).
- Coronary Artery Damage: see definition for Coronary Artery Occlusion above (~0.6%).
- Phrenic Nerve Damage: see definition for Phrenic Nerve Damage above (~0.6%).
- Pleural damage: see definition for Hemo-pneumothorax above (~1.5%).

- MI: see definition for acute myocardial infarction above (~0.6%).
- Tamponade: see definition for Cardiac Perforation above (~4%).
- Abdominal bleeding: uncontrolled bleeding in the abdomen (~ 0.5%).
- Pericarditis: see definition of Pericarditis above (~21%).

There may be other risks to you that are not known at this time.

Risks for Women of Childbearing Age
If you are pregnant or plan to become pregnant in the next 18 months, you should discuss your participation with your study doctor. Since the risk to an embryo or fetus is unknown at this time, patients who become pregnant while taking part in the study should contact the study doctor right away. Women of childbearing age will be asked to take a pregnancy test before the procedure.

Unknown risks and discomforts
The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
There is a possibility that your condition may be treated or not treated. There is no guarantee that you will receive any benefits from taking part in this study. The knowledge obtained from this study may advance medical science and have a benefit on other subjects with ventricular tachycardia.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, your doctor will discuss other options available to you. These include routine drug therapy and catheter ablation.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the researcher will ask you to return for a final close-out visit or evaluation. The data collected about you up to the point of withdrawal will remain part of the study and may not be removed from the study database.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be

physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:
If you receive medical care from a doctor other than your study doctor while taking part in this study, you agree that your medical records will be made available for the collection of data related to this study.

Federal law requires that personal health information that is created or obtained during this research cannot be used without your permission. Therefore you may not participate in this study unless you give permission to use and disclose your personal health information. By signing this consent form you are providing "authorization" to allow the study doctor and study staff to use your personal health information to conduct this study.

How information about you will be stored:
If you decide to take part in this study, the study doctor and study staff will keep your medical records and personal health information private to the extent allowed by federal, state, and local law. A special code (number combination) and your initials will be used to identify your personal health information. No personal health information about you, your illness, or your treatment will be made public.

People and agencies that will have access to your information:
Your personal health information will remain confidential and access to your medical records related to the study is only granted to those participating in the study enrollment and analysis.

How information about you will be shared:
Study data collected as part of your participation in this study will be shared with and sent to the University of Chicago for review and analysis. Only your special code and initials will be included with your study data. The University of Chicago will not receive and will not have access to any information that identifies you.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

[section left to the discretion of participating site/reviewing IRB or EC]

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your participation in this research study.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

Your doctor may decide to withdraw you from the study at any time without your consent. If it is felt to be in your best interest, or if the study is stopped, your doctor may withdraw you from this research. If you have a problem as described in the risks section, or if you become ill during the research, you may have to stop participating in the study, even if you would like to continue. Your study doctor will make this decision. Your study doctor or designee will discuss with you what follow-up is required if you decide to withdraw, or are withdrawn from the study before the study is finished.

RESEARCH FINANCIAL INTERESTS IN THE STUDY

There are no researcher financial interests in this study.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact any of the personnel below with any questions or concerns about the research or your participation in this study. You can also call the Page Operator at [page information] to reach the below investigator(s) 24 hours a day, 7 days week.

Principal Investigator: [site investigator name(s)]
[contact information]

[site/institution IRB or EC office]:
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the [IRB or EC office] by phone: [phone information]; by email: [email information] or mail: [mailing information].

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

[section left to the discretion of participating site/reviewing IRB or EC]

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from [institution name].
- If you decide to take part, you can leave the study at any time.
- If you decide to stop being in this study you should notify the research team right away.
- The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from [institution name].

You will be told of any important new information that is learned during the course of this research study that may affect your condition or your willingness to continue to take part in this study.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

The informed consent requirements in the regulations are not intended to preempt any applicable Federal, State, or local laws which required additional information to be disclosed for informed consent to be legally effective. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date