BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
The Heart Hospital Baylor Plano
CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: **Proposed Single Center Investigational Device Exemption: Feasibility of Endovascular Repair of Ascending Aortic Pathologies**

National Clinical Trial # NCT03322033

Investigational Device Exemption # G170196

PRINCIPAL INVESTIGATOR: William Brinkman, MD

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Introduction:

Before you say that you will be in this clinical trial (a kind of research study and referred to in this document as “this study”) you need to read this form. It is important for you to understand all the information in this form. This form will tell you what this study is about and how it will be done. It will tell you about some problems that might happen during this study. It will also tell you about the good things that might happen for you during this study. When you read and sign a paper like this to learn about a study it is called "informed consent." The people who are doing this study are giving you very important information about this study. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with one of the doctors or their staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have a disease or lesion in your ascending thoracic aorta (the main artery leading away from your heart).

You have a thoracic aortic dissection (a disease process where blood passes through or between the layers of the walls of the aorta, not within the aortic walls) or a retrograde thoracic dissection (a condition where there is a tear in the ascending aorta that begins at the artery farther away from the heart). If left untreated, any of these conditions can enlarge and rupture, causing injury or death.

Why Is This Study Being Done?

The purpose of this study is to find out what effects the use of a device known as a stent graft (a tube made of fabric and metal) has on you and others that have certain diseases in the ascending thoracic aorta (the main artery leaving the heart) in a small number of patients.

The standard operation of repairing a disease of the thoracic aorta requires a surgical cut in your chest to access to the aorta and replacing the diseased part of the aorta with a fabric tube known as a vascular graft. The surgical repair of the ascending aorta is considered major surgery.

A new method to treat ascending thoracic aortic diseases and the device used to treat it are being tested in this early feasibility study. An early feasibility study is a study that explores the new use of a device in a small number of patients. In this case, the device is called an endoluminal stent graft. The study is designed to get a clearer picture and a better understanding of the basic safety and function of this stent graft when it is used in the ascending aorta. Taking part in an early feasibility study may have unforeseeable risks because there is little data and experience on this device in its use for these diseases.

The new method to treat ascending thoracic aortic diseases is a procedure called endovascular stent graft repair. This type of procedure has been successful in treating abdominal and descending thoracic aortic diseases Endovascular repair involves small cuts in the femoral arteries (groins) where a catheter (a flexible hollow tube) with the device or stent graft inside of it is inserted and moved up to your thoracic aorta. The catheter is placed over the diseased part of the aorta where the device is released. After it is released, the stent graft expands within the blood vessel and creates a new pathway for the blood to flow. There will be no surgical cuts in your chest and your surgery, recovery and hospital stay will be shorter than the standard operation. It offers an alternative method of treatment that is less invasive, less expensive and less risky than standard operative repair.

What is the Status of the Devices Involved in This Study?

The Medtronic Thoracic Stent Graft System is approved by the US Food and Drug Administration for other treatments, but is not approved for the ascending disease in this study, so it is considered investigational in this study. The first version of the device used in this study was the Valiant Captivia PS-IDE Thoracic Stent Graft System. However, moving forward, the device being used for this trial will be the Valiant Navion Thoracic Stent Graft System, also referred to as the Medtronic Thoracic Stent Graft System.

The Valiant Navion™ thoracic stent graft system is composed of 2 main components: the implantable Valiant Navion thoracic stent graft and the disposable delivery system. The stent graft is placed into the delivery system. The loaded delivery system is inserted endoluminally through the femoral or iliac artery and tracked through the patient's vasculature to deliver the

stent graft to the target site. Upon placement, the stent graft self-expands to conform to the shape and size of the seal zones above and below the lesion.

How Many People Will Take Part In This Study?

About 20 people will take part at this location.

What Is Involved In This Study?

Before you begin the study...

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular medical care and may be done even if you do not join the study. If you have had some of them recently either at a hospital or in an outpatient setting, they may not need to be repeated. This will be up to your study doctor.

- CT Scan of your chest, abdomen and pelvis with and without contrast
- Physical exam

During the study...

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures at a clinic and/or at the hospital just before your procedure.

- Physical exam including your vital signs (temperature, heart rate, blood pressure and an evaluation of the pulses in your legs)
- A review of your demographic data (age, sex) and your medical history
- Blood tests (creatinine test to check kidney function); a urine pregnancy test will also be performed (if applicable)
- Heart and lung tests (echocardiogram -a test that uses sound waves to see how the heart is beating and pumping blood and electrocardiogram - ECG, recording of the heartbeat and pulmonary function test to see how the lungs are working)

You will have the following tests and procedures done during the surgery to implant the Medtronic Thoracic Stent Graft System. These are part of the regular care for your condition.

- Angiogram (x-ray) of your aorta and the arteries that branch from the aorta to evaluate the blood flow through these arteries and determine the exact location of your lesion
- Fluoroscopy and/or Intravascular Ultrasound/IVUS (x-rays taken from inside the arteries) to use as a guide for the accurate placement of the stent graft

In the event that your doctors are not able to insert/deploy the stent graft properly, you may have to undergo the standard open surgery to treat your condition.

After your procedure *and* before you are allowed to leave the hospital, you will have:

- Physical exam including your vital signs (temperature, heart rate, blood pressure and an evaluation of the pulses in your legs)
- CT scan of your chest to see how well the new stent graft is working.

When I am finished with the endovascular stent graft repair...

If you choose to take part in this study, you will be asked to undergo follow-up visits and diagnostic tests. These tests are part of the standard of care but are being performed more often than usual. At each visit you will have the following tests:

- Physical exam including your vital signs (heart rate, blood pressure and an evaluation of the pulses in your legs)
- Questions about any health-related complications you may be having
- CT scan of your chest to see how well the stent graft is working
- An echocardiogram at the 1 month, 12 months, and yearly visits to check your heart
- Chest x-ray (2 or 4 view)
- Additional tests as required by your doctor.

Your Responsibilities as a Research Subject:

Commitment: While you always have the right to change your mind and leave the study, you should enter this study only if you think you will want to be in it until it ends.

Visits: You agree to come for all study visits and to follow the instructions of the research doctor/staff, even if you stop the study medicine. In case it is not possible for you to attend a visit, we will contact you by phone or mail.

Problems: You will let the research doctor/staff know immediately if any problems occur while you are involved in this study. You will also let the research doctor/staff know if you have to go to an emergency room, doctor's office, or a hospital.

Medicines: You will let the research doctor/staff know about any changes in your prescription medicines, over-the-counter medicines, and all vitamins or supplements that you take, and will keep all study medicine and/or supplies out of the reach of others.

Women of child-bearing potential: You will let the research doctor/staff know immediately if you miss a period or think you may be pregnant.

Other studies: You will not take part in any other study at the same time you are in this study (unless you are given permission by both PI's).

How Long Will I Be In This Study?

You will be in the study for about 5 years. During the l2 months after you have had the device implanted you will return to see your doctor at least 3 times and then once a year after that up to about 5 years.

Your study doctor would like to keep track of your medical condition for the rest of your life. He would like to do this by scheduling a CT once a year to see how well your stent graft is working. Keeping in touch with you and checking on your condition every year helps him look at the long-term effects of the study.

All information collected from you during your taking part will be submitted to the Food and Drug Administration (FDA).

The researcher may decide to take you off the study if any of the following occur:

- He feels that it is in your medical best interest.
- Your condition worsens.
- New information becomes available.
- This study is stopped by the sponsor, Baylor Scott & White Research Institute (BSWRI).

You can stop taking part in this study at any time. However, if you decide to stop taking part in this study, we encourage you to talk to the researcher and your regular doctor first.

It is important to tell the study doctor if you are thinking about stopping so any risks from the Medtronic Thoracic Stent Graft System can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

If you stop being in this study, already collected data (information collected from and about you while you are in the study) may not be removed from the study database.

We will ask whether we can collect data from your routine medical care If you agree, we will handle this data the same as research data.

It is very important in clinical trials to know if subjects are alive and well by the end of the clinical trial. To do this, we ask the following things:

- ***Location and telephone number updates*:** At each visit, our staff will ask you if any of your contact information has changed. Please let us know of any changes at any time.
- ***Closest Relative or Friend*:** Please provide us with the name of a relative or friend whom we can contact in the event that you cannot make visits and we cannot reach you. We want to be able to ask this person information about your health status.

- ***Doctor*:** If we cannot reach you or one of the people you have listed above, we will contact your doctor to find out about your health.
- ***Public Registries*:** If you drop out of this study and we are unable to contact anyone with information about your health status, we will search Public Registries (such as the US Postal Service, Social Security, and social media) for information about you.
- ***Minimum information*:** We will not disclose any of your personally identifiable health information beyond the minimum required to confirm your health status.

What Are The Risks of This Study?

While on this study, you are at risk for these reactions, sometimes bad, which are listed below. You should discuss these with the researcher and/or your regular doctor. There also may be other reactions that we cannot predict. These unknown reactions could also be to your unborn child if you are pregnant or become pregnant while on this study. Other medicines may be given to make them less serious and uncomfortable.

Risks and reactions related to the Medtronic Thoracic Stent Graft System we are studying include:

Not all the risks associated with the use of this stent-graft are currently known. These risks include those which are:

<u>Likely</u>

- Bleeding during and/or after the procedure;
- Problems at the groin sites where the catheters are inserted including after the procedure are done which include:
    - Bleeding
    - Delayed wound healing
    - Wound separation
    - Wound drainage
    - Nerve injury, damage, irritation and / or pain
- Wound infection in 1 or both groins or deep in the tissue where the catheter was placed
- Pain caused by the implant procedure

<u>Less likely</u>

- New onset of pain or worsening of existing pain in buttocks and/or legs;
- Swelling of legs

<u>Rare but serious</u>

- Problems with your blood's ability to clot;

- Injury to the blood vessel wall including separation of layers of the vessel wall (may occur from the femoral vessels to the ascending aorta);
- Tearing or rupture of the blood vessel;
- Breaking apart of plaque within the blood vessel;
- Injury to your heart and/or heart valve;
- Irritation within the blood vessel;
- Transfusion reaction (a change in your body as a result of blood or blood products being given through a needle into your vein that may make you sick such as itchy bumps on your skin, fever, and shortness of breath);
- Allergic reaction from the contrast, medication(s) and/or stent graft material;
- Narrowing of the blood vessel;
- Rupture of the aneurysm/dissection;
- Partial rupture of the aneurysm/dissection;
- Enlargement of aneurysm/dissection or pseudoaneurysm (sometimes called a false aneurysm, occurs when a blood vessel is injured, and the blood is contained by the surrounding tissues);
- Local collection of blood or fluid under the skin causing swelling and/or discoloration;
- Movement of the stent from its original site;
- Blockage of blood flow through the stent-graft,
- Blockage of blood flow through a blood vessel near the aneurysm;
- The polyester graft material may break open;
- Failure to deliver the stent-graft to correct location;
- Stent deformity;
- The stent graft may twist or kink;
- The stent graft may fail to open;
- The balloon used to smooth the stent graft may break;
- Re-narrowing of the blood vessel;
- Temporary narrowing of the blood vessel;
- Ongoing leaking of blood through the graft material into the aneurysm;
- Ongoing leaking of blood into the aneurysm from one or more small vessels near the aneurysm;
- Kidney failure or insufficiency;
- Blood clots in the kidneys;
- Pneumonia and breathing problems such as lung congestion;
- Blood clots in the lungs;
- Failure of lungs to take in enough oxygen;
- Irregular heart beat;
- Chest discomfort or pain;
- Heart attack or fluid around the heart;

- Congestive heart failure (failure of the heart to adequately pump blood with resulting back-up of fluid in the veins);
- Catheter breakage;
- Breakage of the metal stent that could possibly cause a leak and may result in aneurysm growth and or rupture;
- Reaction to the medications or anesthesia;
- Decreased blood flow to the intestines;
- Bowel ischemia (temporary or permanent lack of blood flow to the intestines causing them to stop working); blockage of the bowel or death of the bowel;
- Impotence (inability of a male to have or maintain an erection);
- Nerve damage,
- Inability to tolerate food;
- Urinary tract infection;
- Infection of the stent graft causing fever;
- Staying in the hospital longer than 4 days;
- Surgery may be needed should something go wrong during the procedure;
- Failure of vital organs to function;
- Decreased blood flow to the spinal cord causing permanent or temporary paralysis (inability to move/use legs) with possible
- Inability to control bowel and bladder function;
- Change in brain function that may cause temporary weakness and/or awareness;
- Stroke from bleeding or from a clot that forms in the brain;
- Radiation injury or injury to cell life due to therapeutic radiation;
- Death

Reproductive Risks: Because the device and procedure used in this study could harm an unborn baby, you should not become pregnant while on this study. You should not nurse your baby while in this study. Ask about counseling and more information about preventing pregnancy. It is important you understand that you need to use birth control while on this study. If you are a woman of childbearing age, a pregnancy test (serum test) will be done before you are enrolled in this study and during your follow-up visits to insure you are not pregnant.

The lists stated above are reasonably foreseeable risks but there may not be information to fully predict the frequency and severity of these risks. Most of the complications can be treated with medication. Some complications could result in serious injury or death despite additional treatment. If a serious complication occurs, or if the device cannot be inserted properly, open surgery may be required to treat your condition. The decision to operate will be made by your doctor if your life is in danger. You also have the option of having the standard open procedure at a later time or having your condition managed medically

Radiation Risks:

If you take part in this study, you will receive several diagnostic imaging procedures that involve exposure to radiation. Some of these procedures are considered standard of care for someone with your condition, meaning that you would most likely receive those procedures as part of your standard medical care, whether or not you take part in this study. You may undergo the following "standard care" procedures:

- CT Scan of your chest, abdomen, and pelvis with and without contrast

Some of the diagnostic imaging procedures that you will receive are required by this research study and might not have part of your routine care if you were not taking part in this study. This means that you may receive additional radiation exposure as part of this study. You may undergo the following "research-related" procedures, in addition to any "standard care" procedures that would normally be part of the management of your disease:

- Angiogram (x-ray) of your aorta and the arteries
- Fluoroscopy and/or Intravascular Ultrasound/IVUS (x-rays taken from inside the arteries)
- CT scan of your chest after the procedure

You may be wondering if this amount of additional radiation exposure carries any additional risk of cancer in the future.

- The State and Federal government has established yearly limits of radiation exposure for people (radiation workers) who work around radiation every day. There has been no increased rate of cancer for radiation workers compared to others.
- If enrolled in this study, you may receive up to 5000 mrem from these diagnostic scans. For comparison, the annual radiation exposure limit for a radiation worker is 5000 mrem per year. That exposure level is considered to be very low risk and no adverse effects have been attributed to individuals at that limit
- At this level of radiation exposure, your increased risk of cancer due to the radiation is very low.
- Please also note that this is a long-term risk. That is, cancers that are known to be caused by radiation generally do not appear for 5 to 50 years after the exposure.
- If you have concerns about the radiation exposure associated with this study, please speak with your doctor.

If you have any questions about these or other risks, please ask the researcher.

Conflict of Interest

Your doctor may be an investigator in this study. If so, s/he is interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to take part in any research study offered by your doctor.

The people working on this study may be paid for their work on this research study from money provided by the company sponsoring this research study. The people working on this study may be paid for other work that is unrelated to this study, such as consulting with the sponsor company (BSWRI) or speaking at educational programs at the request of the sponsor company or other companies that may have an interest in this study.

Are There Benefits to Taking Part in This Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

What Other Options Are There?

Instead of being in this study, you have the following options:

- You may choose not to take part in this study.
- You may choose to receive treatment or care for your condition without taking part in this study.
- You may choose to receive the standard open surgery.
- You may choose to take part in another study.
- You may choose not to receive any treatment.

Please talk to your regular doctor about these and other options.

What About Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute (BSWRI) and your doctors and other health care providers and facilities that have provided services to you, which could include physicians that work for the Scott & White Clinic, HealthTexas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Scott & White Medical Center – Temple and other health care providers depending on where you have received care (collectively, "Your Health Care Providers") get your permission before giving any of your health information

to other people. There are people who need to review your information to make sure this study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to BSWRI and your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Board), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. This also includes the following groups of people who are working with Baylor Scott & White Research Institute: Medtronic, the manufacturer of the device, and M2S, the company that will provide 3D pictures from the CT scans. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and your Health Care Providers to release this information However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study

If you give permission to BSWRI and your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 2001 Bryan St, Suite 2200, Dallas, TX 75201. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and your Health Care Providers and make sure they are aware you are withdrawing your permission. If withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by your Health Care Providers before your Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed.

Unless permission is withdrawn, this permission will not expire at the end of this study.

A description of this clinical trial will be available on 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.

What Are the Costs?

Taking part in the study may lead to added costs to you or your insurance company. Someone within the billing department will work with you to get any pre-approvals necessary and inform you of any charges that you will need to pay. Your insurance company may ask us to provide a copy of this consent form.

You and/or your health insurance carrier will be billed for the cost of medical care during this research study, including the cost of the Study Device that you receive, Medtronic Thoracic Stent Graft System , and non-experimental accessory devices used during the procedure. This includes all research study-related medical care and standard care for your condition such as medical visits, procedures, and testing.

Medtronic, the manufacturer of the device, is providing funding to support BSWRI in the execution of this study. This money is to cover the cost of doing the study and pay for such things as study supplies, staff salaries, etc.

Will I Be Paid for Taking part in this Study?

You will not be paid for being in this study.

What if I am Injured or Become Ill While Taking part in this Study?

The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, there are some things that you need to know:

- The people doing the research project have not set funds aside to pay you money if you are hurt.
- Baylor Scott and White Health, Baylor Scott and White Research Institute and The Heart Hospital Baylor Plano have not set funds aside to pay you money if you are hurt.
- Medtronic has not set funds aside to pay you money if you are hurt.
- If you have an emergency illness during the project, the people working with you will provide emergency care. You or your insurance company may need to pay for the emergency care if that happens.
- You have not given up any of your legal rights by signing this form.

The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare program, has stated that payments by clinical trial sponsors for injuries related to a trial

are a form of liability insurance and must be reported to CMS. Under no circumstances will Medtronic be liable for any loss, damage, expense or consequential damages resulting from an injury not caused by a defect in the device or the negligence or willful misconduct of Medtronic. As a result, if Baylor Scott & White Research Institute pays any medical expenses to treat a trial-related injury, and if you are covered by Medicare, Baylor Scott & White Research Institute must report that payment to CMS. In order to do that, Baylor Scott & White Research Institute must have certain individually identifiable information about you, such as your name, date of birth, Social Security number, Medicare claim number, date of injury and a description of the injury.

What Are My Rights As a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave this study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Deciding not to be in this study, or leaving this study early, will not result in any penalty or loss of benefits that you would otherwise receive.

By signing below, you will be agreeing to allow the researchers to decide what to do with any surplus tissue (blood, biopsy sample, etc.) removed from your body during the research described above.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on this study must be careful not to carelessly harm you. If you are hurt during this study, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?

If you have concerns, complaints or questions about this study or have a research-related injury, contact the Principal Investigator, William Brinkman, MD at (469) 800-6200.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff contact the IRB Office at 214-820-2687.

Primary Care Doctor

Please indicate below whether you want us to notify your primary care doctor or your specialist of your taking part in this study:

_____ Yes, I want the study doctor to inform my primary care doctor/specialist of my taking part in this study

_____ No, I do not want the study doctor to inform my primary care doctor/specialist of my taking part in this study

_____ I do not have a primary care doctor/specialist

_____ The study doctor is my primary care doctor/specialist

PERMISSION TO OBTAIN INFORMATION FROM ADDITIONAL SOURCES

If the study site is unable to contact me after repeated attempts at any point during the study, I authorize the study site to contact my personal doctor and family member or friend to obtain information about how to contact me and to learn about changes in my health I also authorize the site to use public records to find information that can help them to contact me

Name of personal doctor: _____

Phone number: _____

Name of friend/family member: _____

Phone number: _____

Relationship: _____

_____ I do not wish to provide this information or allow these methods to be used to contact me.

Statement of Person Obtaining Consent:

I have explained to _____ the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part. I gave a copy of this consent to the subject.

_____ _____ _____

Signature of Person Obtaining Consent Date Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this study. You will be asked to give your written consent if you want to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about this study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I consent to take part as a subject in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

_____ _____ _____ AM/PM

Signature of Study Subject Date Time

_____ _____ _____ AM/PM

Signature of Family Member or Legal Representative Date Time

_____

Relationship to Subject