BAYLOR RESEARCH INSTITUTE
THE HEART HOSPITAL BAYLOR PLANO – PLANO, TX
BAYLOR JACK AND JANE HAMILTON HEART AND VASCULAR HOSPITAL – DALLAS, TX
BAYLOR ALL SAINTS MEDICAL CENTER – FORT WORTH, TX

PROJECT TITLE: **Left Atrial Appendage Closure with SentreHeart Lariat® Device**

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Introduction:

Before you say that you will be in this clinical trial (a kind of research 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 the clinical trial is about and how it will be done. It will tell you about some problems that might happen during the clinical trial. It will also tell you about the good things that might happen for you during the clinical trial. When you read a paper like this to learn about a clinical trial it is called "informed consent." The people who are doing this clinical trial are giving you very important information about the clinical trial. 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 atrial fibrillation or atrial flutter (conditions that cause your heart to beat abnormally) but are not able to take standard anticoagulation (blood thinners) and are scheduled to undergo left atrial appendage (a pocket of tissue connected to your heart) closure. Patients that have these conditions are at higher risk of having a stroke cause by blood clots that form in their left atrial appendage.

Why is this study being done?

This research study is being done to assess the outcomes of patients undergoing left atrial appendage ligation or closure with the SentreHeart Lariat® device as a stand-alone procedure.

What is the Status of the Devices involved in this study?

The SentreHeart Lariat® is a device that is approved by the FDA for soft tissue closure. Please note, the Lariat device is only available at our site to subjects taking part in the study.

How Many People Will Take Part In The Study?

About 50 people will take part in this study. This study is only being done by the hospitals listed on the first page.

What Is Involved In The Study?

If you agree to take part in this study, we will collect information about your medical history as well as information during your hospital stay and follow-up visits. Many of the procedures that are being done are considered a standard part of regular care for this condition and may be done even if you do not join the study. The treating physician may choose to perform some or all of the tests and or procedures listed in the protocol regardless of the patients taking part in the study (Blood work, CT, chest x-rays etc).

A. Screening Tests and Baseline Procedures

You will undergo the following routine tests and procedures:

- Review of your medical history
- Physical examination
- Blood tests (approximately 2-3 teaspoons)
- Computed Tomography (CT) angiograms with an x-ray dye (contrast media) to look at you heart to confirm that you are a candidate for closure of your left atrial appendage.

B. What happens at the time of Left Atrial Appendage Closure Procedure

The procedures will be performed in a cardiac operating room (OR) under general anesthesia (you will be given medicine to make you sleep and stop you from feeling pain), using x-rays to place the SentreHeart Lariat®. You will be exposed to x-rays for about 30 minutes.

At the time of the procedure, a small catheter (thin flexible tube) will be inserted through the arteries in your groin leading to your heart and advanced into your left atrial appendage; using this catheter and x-ray dye, the Lariat Suture is guided into position and cinched/tightened over the outside of the left atrial appendage.

A surgical team will be on standby in case of complications. The procedures will be done in the OR hybrid room. For the first 10 cases there will be an OR team and surgeon on standby. After the first 10 cases, the doctor will re-evaluate if a full team needs to remain on standby or if only a surgeon will need to be standby.

C. Hospital Discharge

You will undergo the following routine tests before leaving the hospital:

- Medicine list will be collected
- Electrocardiogram “EKG”- a test that checks for problems with the electrical activity of your heart
- Chest X-ray which will take about 15 minutes

D. Follow Up Visits at 7, 90 and 180 days

- You will have a physical exam and your cardiac medicines will be reviewed
- Chest X-Ray
- At the time of your 180 day visit, you will have either a computed tomography (CT) angiograms with an x-ray dye (contrast media) or a Transesophageal echocardiogram (TEE) to look at you heart to confirm that you left atrial appendage is closed. A TEE requires a tube placed in the esophagus (food pipe) to be able to look at the heart. The TEE requires anesthesia. Both procedures take about takes about 45 minutes.

How Long Will I Be In The Study?

You will be in the study for up to 210 days.

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

- He/She feels that it is in your medical best interest.

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

What Are The Risks of The Study?

You are at risk for these bad reactions when you have a left atrial appendage closure with the SentreHeart Lariat®. You should discuss these with the researcher and/or your regular doctor. There also may be other bad reactions that we cannot predict. Other drugs may be given to make them less serious and uncomfortable. Many bad reactions go away quickly, but in some cases can be serious or long lasting and permanent.

Risks and bad reactions related to left atrial appendage closure with the SentreHeart Lariat® are:

- Pericardial Effusion (bleeding into the heart sac)
- Cardiac Tamponade (bleeding into the heart sac)
- Device Embolization (the device moves to an unintended location)
- Atrioventricular Fistula (a hole between chambers of the heart)
- Cardiac Perforation (a hole in the heart)
- Thrombus (clot formation)
- Bleeding (loss of blood)
- Bruising/Hematoma (blood accumulation)
- Arrhythmia (irregular heart beat)
- Pseudoaneurysm (is a dilated artery or blood vessel)Valvular Damage (injury to one of the heart valves)
- Stroke
- Conversion to Surgery

- Hypotension – unusually low blood pressure
- Death

Radiation Risks:

If you take part in this study, you will receive several diagnostic imaging procedures that involve exposure to radiation. Most of these procedures are considered standard of care for someone with your condition. This means that you would most likely receive many of these procedures as part of your standard medical care, whether or not you take part in this study. Over the course of this study, you may be exposed to x-rays from:

- Standard of care procedures (you would have likely had even if you were not in this research study)
  - CT angiograph at screening
  - X-ray fluoroscopy guidance during Left Atrial Appendage Closure Procedure
  - Chest x-ray prior to hospital release
- Research only procedures
  - CT angiogram (or TEE) at 180 days post-procedure
  - Chest x-rays at follow up visit at 7, 90 and 180 days

You may be wondering if this amount of 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 you enroll in this study, during each year you take part, the additional research-only scans you receive will expose you to approximately 1/2 of the amount of radiation allowed for a radiation worker per year.
- At this level of radiation exposure, it is expected that your increased risk of cancer due to the radiation is very low.
- Please 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.

Conflict of Interest

Your doctor may be an investigator in this research 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.

If you have additional questions about these risks, ask the researcher.

Are There Benefits to Taking Part in The Study?

Left atrial appendage closure with the use of SentreHeart Lariat® may reduce your risk of stroke. Information learned from this study may help in the management of patients with atrial

fibrillation and atrial flutter who are at elevated bleeding risk with the use of any oral anticoagulation therapy.

The possible benefits of taking part in the study are the same as Left atrial appendage closure with the use of SentreHeart Lariat® without being in the study.

What Other Options Are There?

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

- You may choose to undergo Left atrial appendage closure without taking part in the study
- You can choose to have nothing done

Please talk to your regular doctor about this 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 the 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 Research Institute and Cardiopulmonary Research Science and Technology Institute 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 the 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 Baylor Research Institute to give other people information about your health as needed for the research project. These groups include people who work for Baylor Research Institute (including the Institutional Review Board), the U.S. Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection. 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 be notes written by your doctor from your medical record or notes written by your doctor asking for tests to be done on you. Other information may include your procedure reports.

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 us 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 the research study.

If you give permission to Baylor Research Institute to give other people information about your health and the other people are not part of the group that must obey this 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 Baylor Research Institute in writing at 3310 Live Oak, Suite 501, Dallas, TX 75204. If you decide to do this, it will not apply to information that was given before you withdrew your permission and you will no longer be able to take part in the 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 the study is completed.

Unless permission is withdrawn, this permission will not expire at the end of the 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. You or your insurance company will pay for the items or services that are part of this study. If you have insurance, the hospital will submit claims to your insurance for items and services that are part of this study. Please ask about any expected added costs or insurance problems.

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 Health Care System, Baylor Research Institute and The Heart Hospital Baylor Plano have 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.

What are My Rights As a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the 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 the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

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 the project must be careful not to carelessly harm you. If you are hurt during this project, 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 the study or have a research-related injury, contact J. Brian DeVille at 469-800-4540.

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 Lawrence R. Schiller, M.D., IRB Chair, at 214-820-2687.

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Statement of Person Obtaining Consent:

I have explained to _____ the purpose of the research project, 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.

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the 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 research project 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 the research project, 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 the research 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 agree to give my consent to take part as a subject in this research project.

_____	_____	_____
Signature of Subject	Date	Time

_____	_____	_____
Legally Authorized Representative (if Applicable)	Date	Time

_____
Printed Name of Legally Authorized Representative