UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: PROSPECTIVE ELIMINATION OF DISTAL CORONARY SINUS-LEFT ATRIAL CONNECTIONS FOR ATRIAL FIBRILLATION ABLATION TRIAL

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Why am I being asked to volunteer?

You are being invited to participate in a research study because you are planning to undergo atrial fibrillation ablation. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

What is the purpose of this research study?

Atrial fibrillation is a common heart rhythm problem that is often treated with catheter ablation. Catheter ablation, which is burning the abnormal muscle of your heart through wires, is one of the methods that has been used in the treatment of this disease. Unfortunately, repeated ablations are often needed. This study is to examine any benefit of targeting connections between the coronary sinus (a large vein in the heart) and left atrium during the first ablation procedure in addition to standard pulmonary vein isolation and non-pulmonary vein triggers elimination.

How long will I be in the study?

You are expected to participate the study for six months after the ablation procedure. The study will enroll one-hundred patients and end when all patients have completed all visits for six months. The expected study duration is two years.

What am I being asked to do?

If you decide to proceed, a randomized decision tool will assign you to the standard procedure, which is pulmonary vein isolation and non-pulmonary vein triggers elimination, or to the intervention, which is pulmonary vein isolation and non-pulmonary vein triggers, plus coronary sinus-left atrium connection elimination. The follow-up, which is standard of care will include a 30-day event monitor after discharge, regular clinic follow-up at 6 weeks, and 6 months after ablation with 12 lead electrocardiogram check-ups. In the last month, another 30-day event monitor will be set to detect the recurrence of atrial arrhythmias. Additionally, if you have symptoms of arrhythmia, 12 lead electrocardiogram will be checked. Anti-arrhythmia medication will be stopped 3 months after ablation.

What are the possible risks or discomforts?

The possible risks or discomforts are the same as standard atrial fibrillation ablation procedure, including: local pain at puncture site, bleeding, stroke, pulmonary vein stenosis (or narrowing of the veins that drain the lungs), injury to blood vessels, esophagus injury which may require surgery, nerve injury, which may cause shortness of breath, heart failure, cardiac perforation, cardiac tamponade (bleeding around the heart), or death.

Enrolling in this study may minimally increase the odds of injury to the vessels that supply blood to the heart muscle and risk of a heart attack as well as the other risks by prolonging the study duration.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you

to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

The procedure success may be improved due to additional coronary sinus-left atrium connection ablation. But it is also possible that you may not get any benefit from being in this research study.

What other choices do I have if I do not participate?

You do not have to participate in this study. If you do not participate, your care will not be affected.

Will I be paid for being in this study?

No. There is no compensation for enrollment in this study.

Will I have to pay for anything?

You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. The ablation will be billed to your insurance company. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance. There is no additional cost as a result of enrollment in this study.

- **What happens if I am injured from being in the study?**

If injured, we will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

- **When is the Study over? Can I leave the Study before it ends?**

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time

by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

▪ What information about me may be collected, used or shared with others?

Your information in the medical record, results of physical examinations, medical history, lab tests, or protected health information such as the following,

- Name, address, telephone number, date of birth
- Email address
- Personal and family medical history from the medical record
- Results from a physical examinations, tests or procedures from the medical record

▪ Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

▪ Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigators for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

▪ Who, outside of the School of Medicine, might receive my information?

- The Office of Human Research Protections

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

- **How long may the School of Medicine use or disclose my personal health information?**

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

You have given written authorization

The University of Pennsylvania's Institutional Review Board grants permission

As permitted by law

- **Can I change my mind about giving permission for use of my information?**

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required

by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

Electronic Medical Records and Research Results

- **What is an Electronic Medical Record and/or a Clinical Trial Management System?**

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, Information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.
Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of

this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date