PARTICIPANT INFORMED CONSENT FORM

Title of Study: Characterization of Arrhythmia Substrate to Ablate Persistent Atrial Fibrillation (COAST-AF): Randomized Clinical Trial

Local Site Principal Investigator (PI): Dr. George Veenhuyzen Phone 403-944-3385

Sponsor: Ottawa Heart Institute Research Corporation

Funding Agency: Heart and Stroke Foundation of Canada,Canadian Institute of Health Research (CIHR)

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form

**BACKGROUND/INTRODUCTION**

You are being asked to participate in this research study because you have an arrhythmia (abnormal heart rhythm), in which the top part of your heart beats irregularly and fast. In your case, this abnormal heart rhythm has lasted more than 3 months. This is called persistent atrial fibrillation (PeAF). Your doctor has discussed with you and recommended a catheter ablation to treat this condition.

Atrial fibrillation (AF) is a common abnormal heart rhythm and is associated with an increased risk of stroke, heart failure and death. Persistent AF is a complex arrhythmia and previous studies have shown that the standard ablation procedure for this rhythm is not successful in all patients. Some patients with AF also develop scar tissue in the atrium of the heart. Recent studies have shown that ablation of scar tissue during a catheter ablation is a promising strategy that may improve the results of this procedure.

A standard catheter ablation procedure includes obtaining information about the heart muscle in order to create a “map” of the upper chamber of your heart using special computer software and images from a MRI or CT scan.

This information allows the doctor to identify the areas of the heart muscle that are abnormal. Ablation eliminates the abnormal tissue by heating the tissue, therefore preventing the abnormal tissue from generating abnormal electrical activity that causes AF. The current standard ablation technique (known as “pulmonary vein isolation”, or “PVI”) does not specifically target all areas of abnormal or scarred heart muscle. This study will assign each participant to receive either a standard ablation or a standard ablation with additional ablation to the areas that are abnormal (scarred).

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to evaluate if a strategy of atrial scar ablation, in addition to the usual technique, will result in higher chance of success when compared to standard catheter ablation procedure with the usual technique.

# **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

This study is taking place at a number of sites across Canada. The entire study will run approximately 5 years. We estimate that 510 participants will be enrolled in the study, including up to 55 participants from the University of Calgary/Foothills.

# **WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?**

This study compares two treatment groups. You will be randomly assigned, similar to “flipping a coin,” to treatment arm 1 or arm 2 on the day of the ablation, using a computer system, before the procedure starts.

1) Control group: Standard catheter ablation technique for AF.

2) Experimental group: Catheter ablation of atrial scar tissue in addition to the standard catheter ablation technique for AF.

This study will be blinded, which means that you will not be told which treatment arm you are in. Your study team will know what treatment you receive. You may be told once the entire study is finished.

Each follow up visit will consist of:

* A review of your health and medications
* 3 Quality of Life questionnaires (12 and 18m visits only)
* Application of a Cardiostat ® ECG recorder: A wearable, long term cardiac monitoring device that is licensed by Health Canada. It weighs the same as an `AA`` battery and is 5 mm thick (about 3 stacked quarters). It is worn on your upper chest, and is designed to be invisible under your clothing. Two electrodes will be placed on your chest and they are kept in place using round medical adhesives.



The device records the electrical activity of your heart when you are doing your normal activities. You will be asked to remove the device after 14 days and return it using a pre-stamped envelope that you will be given. You will be given a CardioSTAT® instruction sheet/diary to complete and return in the mail with the device. You will be asked to write down in the diary any symptoms you may have during the 14 days.

**HOW LONG WILL I BE IN THE STUDY?**

Your participation in the study will last a minimum of 18 months, during which you will be telephoned or seen on the Foothills Hospital site at 3, 6, 12 and 18 months after the ablation. Additional follow-up visits will be done at 24 and at 36 months after your ablation.

If you experience arrhythmia symptoms we may ask you to return for a follow-up visit and to undergo ECG monitoring.

**WHAT ARE THE RISKS?**

The study treatments have risks, as most treatments do. However, there is always a chance of risks that we do not know about. The risks we know about are listed below.

Ablation:

Your doctor will review the risks of the ablation procedure before you sign the separate consent. The following risks are associated with the procedure:

* Bleeding or infection where the catheter enters the skin <2%
* Creation of a hole in your heart muscle which could require urgent drainage or surgery<1%
* Narrowing of the blood vessels that brings blood back to your heart causing permanent shortness of breath <1%
* Stroke <1%
* Damage to the esophagus, or food pipe, which lies right behind the heart causing small connection between the heart and the esophagus, called a fistula, this complication is almost always fatal <0.01%
* Injury to the phrenic nerve (the nerve to the diaphragm or breathing muscle) <4%

The catheter ablation technique that targets standard areas plus regions of atrial scar has not been shown to increase the overall risks of the procedure, however ablating additional areas may present a somewhat increased risk which has not been identified yet.

Ambulatory ECG Recorder:

The 14-day ECG recorder has round adhesives and electrodes which may produce a mild rash, but this is rare. In very rare cases, you may have an allergic reaction to the adhesives and electrodes.

Questionnaires :

You might find the interviews and questionnaires distressing or tiring. You might not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

ARE THERE ANY REPRODUCTIVE or BREASTFEEDING RISKS?

The catheter ablation procedure may be harmful to a fetus. For this reason, women who are pregnant will not be enrolled in this study. In addition, standard medications used to treat AF may be harmful to a fetus or breastfed child. In the event of pregnancy, or suspected pregnancy, you must tell your study doctor immediately. If you are breastfeeding or planning on breastfeeding, you must tell your study doctor immediately. Your study participation may be stopped in order to avoid unknown risks to you, the fetus or infant.

**WILL I BENEFIT IF I TAKE PART?**

You may not receive any direct benefit from your participation in this study. Your participation may allow researchers to help improve catheter ablation techniques for future patients with PeAF.

**DO I HAVE TO PARTICIPATE?**

No, you can choose not to participate in this study. If you choose not to participate, you will still have the catheter ablation as planned to treat your persistent atrial fibrillation. Your study doctor will discuss these options with you.

Your participation in the study may be stopped for any of the following reasons:

* The study doctor feels it is in your best interest.
* You need additional treatment that would interfere with the study.
* You do not follow the study staff’s instructions.
* You become pregnant.

**CAN I STOP BEING IN THE STUDY?**

You may withdraw from the study at any time without any impact on your current or future care at this institution.

* If you decide to stop your study treatment you should contact the study doctor or the study team first. They will discuss the related issues or possible safety concerns for you
* You may also choose to discontinue your participation in the study. However, a final visit(s) may need to be completed for your safety and well-being.
* If you withdraw your consent, the study team will no longer collect your personal health information for research purposes, unless it is needed for review of safety. Previously collected data may also be withdrawn upon request.

**WILL I BE PAID FOR MY PARTICIPATION?**

You will not be paid to participate in this research study. The cost of parking will be paid for any hospital visits related to the study.

**WILL MY PERSONAL INFORMATION BE PROTECTED?**

* If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. “Personal health information” is health information about you that could identify you because it includes information such as your name, address, telephone number, date of birth, new and existing medical records, or the types, dates and results of various tests and procedures.
* Information that identifies you will be released only if it is required by law.
* All information collected during your participation in this study will be identified with a unique study number (for example participant # AB01), and will not contain information that identifies you.
* Documents leaving the Foothills site will only contain the coded study number.
* A Master List provides the link between your identifying information and the coded study number. This list will only be available to Dr. Veenhuyzen and his staff and will not leave this site.
* The Master List and coded study records will be stored securely.

For audit purposes only, copies of your original medical records may be reviewed under the supervision of Dr. Veenhuyzen’s staff by representatives from the University of Ottawa Heart Institute Research Corporation (OHIRC), or the Conjoint Health Research Ethics Board

* You will not be identified in any publications or presentations resulting from this study
* Research records will be kept for 10 years, as required by the Sponsor.
* At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted

**IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?**

In the event that you suffer injury as a result of participating in this research, appropriate medical treatment will be provided. No compensation will be provided to you by the Ottawa Heart Research Institute Corporation, the University of Calgary, Alberta Health Services or the Researchers. The study doctor and the University of Calgary still have their legal and professional responsibilities. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

# **WHOM MAY I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?**

# The Research Team:

You may contact Jennifer McKeage, RN at 403-210-6047with any questions or concerns about the research or your participation in this study.

# Conjoint Health Research Ethics Board (CHREB):

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://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 access and search this web site at any time.

This research study can be found on the above listed website by using the clinical trial registration number: NCT03347227.

# **HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?**

After the completion of the study, you can receive information on the results obtained in the study upon request. Results will also be posted on the above clinicaltrials.gov website.

**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.

* You have a right to have all of your questions answered before deciding whether to take part.
* Your decision will not affect the standard medical care you receive
* If you decide to take part, you may leave the study at any time.

What are my responsibilities as a study participant?

* Ask your study doctor or study team if you have any questions or concerns.
* Tell your study doctor or study team if anything about your health has changed.
* Tell your study doctor or study team if you are or suspect you may be pregnant.
* Call the study doctor if you experience any side effects, even if you are unsure whether it has anything to do with this study.
* Return CardioStat ECG Recorder and diaries

Consent to Participate in Research

* I understand that I am being asked to participate in a research study about patient-tailored catheter ablation (CA) for persistent atrial fibrillation (PeAF).
* This study was explained to me by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* I have read, or someone has read to me, each page of this Participant Informed Consent Form.
* All of my questions have been answered to my satisfaction.
* If I decide that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
* I voluntarily agree to participate in this study.
* I will be given a copy of this signed Participant Informed Consent Form.

It is important that your personal doctor be aware you are in a research study, as you may be taking a treatment that could affect your health. With your permission, we will notify him/her that you are taking part in this study.

I consent to my personal doctor being notified that I am taking part in this study.

❑ YES ❑ NO Participant’s Initials\_\_\_\_\_\_\_\_\_\_\_

SIGNATURES

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Participant’s Printed Name Participant’s Signature Date

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Investigator/delegate Printed Name Investigator/delegate Signature Date

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Witness Printed Name Witness Signature Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.