UNIVERSITY OF OTTAWA
HEART INSTITUTE
INSTITUT DE CARDIOLOGIE
DE L'UNIVERSITÉ D'OTTAWA

Main Informed Consent Form for Participation in a Research Study

Title of Study: Left Atrial imaging prior to Cardioversion: Leveraging computed tomography to rule Out Thrombus. (LA CLOT)

OHSN-REB Number: 20190117-01H

Principal Investigator (PI): Dr. Benjamin Chow, (613) 696-7286

Sponsor: Ottawa Heart Institute Research Corporation

INTRODUCTION

You are being invited to participate in this research study because you will be undergoing a cardioversion for Atrial Fibrillation or Atrial Flutter. Your doctor will either order a cardiac computed tomography (CCT) or transesophageal echocardiography (TEE) to look at presence of blood clots in your heart and condition of the blood vessels.

This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Atrial fibrillation and flutter are an irregular and often rapid heart rate that can increase your risk of stroke, heart failure and other heart-related complications. Atrial fibrillation and flutter can lead to blood clots forming in the heart that may circulate to other organs and lead to blocked blood vessels and resulting in complications. Tests such as TEE and CCT are performed to see the presence or absence of blood clots.

TEE is the standard technique for the detection of blood clots forming in the heart. TEE uses ultrasound to create images of your heart with a specialized probe which is inserted into the esophagus. Once it is in the esophagus, the ultrasound probe rests closer to the heart. This provides information about how large the heart is, how well it contracts, how the valves function and if there are any blood clots.

CCT is a Computed Tomography- scan that is done specifically to look at blood vessels within the body. Intravenous contrast in administered and images are taken when the contrast is thought to be passing through the vessels around the heart. It is a non-invasive way of gaining more information about the vessels around the heart.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare risk versus benefit balance and cost-effectiveness of CCT versus TEE.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting the medical care, education, or other services to which you are entitled or are presently receiving at this hospital. If you are not in the study, your doctor will order the test to be performed before your cardioversion as per normal standard of care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is estimated that 100 participants will be enrolled in the study from the University of Ottawa Heart Institute (UOHI) and the Ottawa Hospital (TOH) emergency department.

WHAT WILL HAPPEN DURING THIS STUDY?

Patients presenting to the UOHI or TOH that are scheduled to undergo a cardioversion will be invited to participate.

If you decide to participate, you will be "randomized' into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either the CCT arm or the TEE arm. Patients will not be asked what arm they prefer to be assigned to. Patients in both arms will undergo testing as per clinical routine and reports will be issued immediately.

CCT arm:

- The CT nurse will collect information such as your height, weight, medical history, blood pressure and heart rate. An intravenous (IV) catheter, a thin plastic tube will be inserted in a vein in your arm. During the test, electrocardiogram (ECG) sticky patches connected to wires are put on your skin to record the electrical activity of the heart.
- You will be asked to lie flat on the examination table with your arms above your head for the duration of the test which is approximately 30 to 45 minutes. The CT machine will take pictures of your heart. During the test, you will be asked to hold your breath for a few seconds and lie very still.
- After initial pictures of your heart are taken, IV contrast dye (Omnipaque dye) will be injected through your IV to obtain clear pictures of your heart and arteries.

TEE arm:

- Specially trained doctors perform TEE. It's done in a hospital or a clinic and lasts 30 to 60 minutes.
- A technician sprays your throat with a medicine to numb it and suppress the gag reflex. You'll lie on a table.
- A nurse puts an IV (intravenous line) in your arm and gives you a mild sedative (medicine) to help you stay calm.
- During the test, electrocardiogram (ECG) sticky patches connected to wires are put on your skin to record the electrical activity of the heart.
- The doctor then gently guides a thin, flexible tube (probe) through your mouth and down your throat and asks you to swallow as it goes down.
- A transducer on the end of the probe sends sound waves to your heart and collects the echoes that bounce back. These echoes become pictures that show up on a video screen. This part of the test takes 10 to 15 minutes.
- When the doctor is finished taking pictures, the probe, IV and electrodes are removed, and nurses watch you until you are fully awake.

You will be asked to answer Quality of Life questionnaires before your cardioversion procedure and at the time of your hospital discharge. At 30 days after your cardioversion procedure, you will be contacted for a follow up phone call and asked to answer the same Quality of Life questionnaires. At the same time, your electronic charts will be reviewed by the research staff for any potential that might have taken place within 30 days of your procedure.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

It is important to remember the following things during this study:

- Ask your study coordinator if you have any questions or concerns.
- Tell your study coordinator if anything about your health has changed.
- Follow your study doctor's instructions in preparation for the imaging scan:

1. TEE arm:
   - Inform your study doctor if you have had an allergic reaction to any sedative medication in the past.
   - If your procedure is in the morning, you will be asked to refrain from eating or drinking after midnight, before the procedure. Otherwise, you will be asked not to eat or drink anything at least 6 hours before your procedure.
   - If you need to take any medicine before the test, you will be advised to take them with small sips of water.

2. CCT arm:
   - Inform your study doctor if you have had an allergic reaction to dye injection in the past.
   - If you are a female of child-bearing age, you will be asked to take a pregnancy test (showing no pregnancy) before booking your scan. Inform your study doctor if you plan to get pregnant.

- If you breastfeed, you will be asked to pump 48 hours' worth of milk in advance to your scan in preparation to discard your breast milk for the 48 hours after the dye injection.
- You will be asked to stop any marijuana products for 24 hours before your scan. If you take metformin-based medication, you will be asked to skip the morning dosage. All other medications can be taken as normal.
- You will be advised to have a glass of water as the last thing before coming for your scan.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The entire study will last approximately 2 years. Your participation in this study will last about 2 months.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the study doctor know. However, this would also mean that you withdraw from the study.

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. Any information collected prior to withdrawing participation will be used for the study.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation on the study may be stopped early, and without your consent, for reasons such as:

- You are unable to complete all required study procedures
- The study doctor no longer feels this is the best option for you
- The Ottawa Health Science Network Research Ethics Board withdraw permission for this study to continue
- The Sponsor (Ottawa Heart Institute Research Ethics Corporation) decides to stop the study.
- If you plan to or become pregnant

If you are removed from this study, the study doctor will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. You should discuss these with the study doctor.

If you are assigned to the TEE arm, the risks and side effects will be explained to you as part of your standard care; however, they would include:

- Damage to the esophagus, including bleeding or tear
- Reaction to medication used to relax patients during the procedure, including nausea
- Sore throat after the procedure.

If you are assigned to the CCT arm, related risks would include:

- IV Contrast Dye Risks:

When the IV contrast dye is being given, mild allergic reactions, such as itching, and hives occur occasionally (13%). These reactions may pass without treatment or respond quickly to medication. You may develop a metallic taste in your mouth and have a warm feeling with the IV contrast dye. This sensation is normal and will last about one minute. Very rarely (less than 0.5%) more severe reactions such as breathing difficulty, swelling of the throat or swelling of other body parts can occur.

- Intravenous risks:

An intravenous may cause minor bleeding, bruising, redness, or swelling at the site. Less often it may lead to an infection.

- Radiation Risks:

The additional amount of radiation you will receive from participating in this research study is about the same amount a person would receive naturally, while living in Ontario for 3.3-5.9 years. The risk is considered to be minimal and there are no expected consequences associated with this exposure.

IS THERE A CONCERN WITH PREGNANCY OR BREASTFEEDING?

If you are pregnant, you cannot participate in this study as the imaging procedures used in this study may be harmful to the fetus. For this reason, women must not become pregnant. In the event of pregnancy, or suspected pregnancy, you must tell your study doctor immediately and the study scan will not be completed.

If you are a nursing mother, you will be asked to wait 24-48 hours after receiving an injection of dye used for the CCT scan before resuming breastfeeding.

If you are a woman of childbearing potential, you will have a blood pregnancy test to ensure you are not pregnant before the study begins.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive any direct benefit from your participation in this study. Your participation may allow the researchers to evaluate CCT as an alternative to TEE which may expedite cardioversions and may improve patient care. This may benefit future patients.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study.

Records identifying you at this center will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study in Ontario
- Ottawa Heart Institute Research Corporation, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant ID, sex, and partial date of birth (month and year).

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

In the event of a study-related injury or illness, you will be provided with appropriate medical treatment and care. Financial compensation for lost wages, disability or discomfort due to an injury or illness is not generally available.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the study doctor or Ottawa Heart Institute Research Corporation (OHIRC) for compensation, nor does this form relieve the study doctor /OHIRC or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

Dr. Benjamin Chow	(613) 696 - 7286
Principal Investigator Name	Telephone

If you have any questions about your rights as a participant or about ethical issues related to the study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board Chairperson at 613-798-5555, extension 16719.

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SIGNATURES

- All my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to my medical records as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree, to take part in this study.

Signature of Participant	Printed Name	Date

Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date

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Participant Assistance

Complete the following declaration only if the participant is <u>unable to read</u>:

- The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

Signature of Impartial Witness	Printed Name	Date

Complete the following declaration only if the participant has <u>limited proficiency in the language in which the consent form is written and interpretation was provided</u> as follows:

- The informed consent discussion was interpreted by an interpreter and attests that this study as set out in the consent form is accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and in additional discussion arising from this process.

Signature of Interpreter	Printed Name	Date