Informed Consent Form for Participation in a Research Study

**Study Title**: *The Fourth Left Atrial Appendage Occlusion Study: (LAAOS-4)*

**Sponsor:**  *Hamilton Health Sciences Corporation through its Population Health*

*Research Institute (PHRI)*

**Study Doctor**: **Dr. Allan Skanes**

 University Hospital, London Health Science Centre

 339 Windermere Road

 London, Ontario, Canada N6A 5A5

**Emergency Contact Number** (24 hours / 7 days a week):

Present to your local emergency department. Let them know you are participating in the LAAOS-4 study and to contact the EP attending physician at LHSC.

Non-Emergency contact numbers are noted at the end of this document.

INTRODUCTION

You are being invited to participate in a clinical trial (a type of study that involves research). You are invited to participate in this trial because you are taking anticoagulant medications, have atrial fibrillation and have been identified as being at an increased risk of stroke*.* 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. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

London Health Sciences Centre Hospital is receiving reimbursement from the Hamilton Health Sciences Corporation through its Population Health Research Institute (PHRI) Research Fund.

If you would like additional information about the funding for this study, or about the role of the doctor in charge of this study, please speak to the study staff or the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Atrial fibrillation is a common heart condition that happens when the top two chambers of the heart, called the atria, beat too fast and with an irregular rhythm (fibrillation). This condition can decrease the heart’s pumping capacity, which can cause blood cells to pool and stick together, forming clots in a small pouch on the heart called the left atrial appendage. If a clot escapes from the appendage and gets into your arteries, it may block the blood supply to your brain and cause a stroke. Atrial fibrillation is associated with a 3-5 times increased risk of stroke.

 

Research studies have found that the risk of stroke can be reduced by taking medications called “oral anticoagulants” (often known as blood thinners), that help to prevent blood clots. Studies have also found that the risk of stroke can be reduced by closing off the left atrial appendage with a device permanently implanted into the heart, or by removing the appendage during heart surgery.

WHY IS THIS STUDY BEING DONE?

The purpose of the LAAOS-4 study is to determine if closure of the left atrial appendage using a closure device called the WATCHMAN FLX™ or FLX PROTM, in addition to taking oral anticoagulant medications, is more effective at reducing strokes and blood clots in your body, than taking oral anticoagulant medications on their own.

The WATCHMAN FLXTM and FLX PROTM devices (shown below) are manufactured by Boston Scientific Corporation. It is a permanent parachute-shaped implant about the size of a quarter, designed to close the left atrial appendage in the heart in an effort to reduce the risk of stroke by preventing blood clots from forming in the left atrial appendage. The device is made of a metallic frame that is then covered with a thin layer of fabric. It is extremely lightweight and compact, and uses materials that are common to many medical devices. The device is available in five different sizes. If you are randomized to receive a WATCHMAN FLXTM or FLX PROTM device, testing will be done to determine what size will be best for you.



WATCHMAN FLX™ device

The WATCHMAN FLX TM device has been approved for use by the U.S Food and Drug Administration (FDA), Health Canada, the European Medicines Agency (EMA) and other regulatory authorities internationally to prevent blood clots from forming in the left atrial appendage. There is a second FDA-approved WATCHMAN FLXTM device in use in the USA and in Canada, the WATCHMAN FLX PROTM, and both the FLX and FLX PRO models are used in the LAAOS-4 study in the USA and in Canada.

Although the WATCHMAN FLXTM and FLX PROTM LEFT ATRIAL APPENDAGE CLOSURE devices are approved for use in Canada, LAAOS-4 is currently studying the combination of device implantation with continuation of anti-coagulation medication therapy after the procedure. The continuation of oral anti-coagulants therapy after implantation of the device is not commercially approved by Health Canada. The WATCHMAN FLXTM and FLX PROTM LEFT ATRIAL APPENDAGE CLOSURE devices used in the LAAOS-4 study in Canada will only be used at the direction of Qualified Investigators who are approved to lead the study at the respective research hospital site.

This research study is funded by Boston Scientific Corporation, the manufacturer of the device. Boston Scientific Corporation (the Funder) is providing the money for this study to Hamilton Health Sciences Corporation through its Population Health Research Institute (PHRI) (the Sponsor) who designed the study.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. Other options (in addition to the standard or usual treatment described above) may include, but are not limited to:

* no therapy at this time
* other research studies may be available if you do not take part in this study

Please talk to your usual doctor or the study doctorabout the known benefits and risks of these other options before you decide to take part in this study. Your usual doctoror the study doctor can also discuss with you what will happen if you decide not to undertake any treatment at this time.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 4000 people will take part in this study, from research sites located in North America and other countries internationally.

WHAT WILL HAPPEN DURING THIS STUDY?

ASSIGNMENT TO A GROUP

If you decide to participate then 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 group. Neither you, the study staff, nor the study doctors can choose what group you will be in. You will be told which group you are in.

WHAT IS THE STUDY INTERVENTION?

The comparison being tested in this study is whether or not having a WATCHMAN FLXTM or FLX PROTM device implanted will help in preventing strokes and blood clots in people taking anticoagulant medication, compared to people taking anticoagulant medication without a device.

Group 1 - Intervention (Device and Anticoagulation group): If you are randomized to this group you will have a WATCHMAN FLXTM or FLX PROTM device implanted, AND continue to take anticoagulant medications prescribed by your doctor.

Group 2 -Standard (Anticoagulation group): If you are randomized to this group you will continue to take anticoagulant medications prescribed by your doctor.

WHAT ARE THE STUDY PROCEDURES?

If you decide to take part in this study, you will be asked to sign and date this informed consent form. You will then be required to undergo the following assessments. Information at each visit will be collected through in-person visits; telephone calls or video/virtual call with you or a family member; or from your medical records. We may also send you a letter/email with study results after the study has been completed and all data analyzed.

Baseline Procedures

When you are first enrolled into the study, your study doctor and the study team will check your health by looking at your medical records, by checking the medications you are taking, and by asking you to answer some questions about your health. The study team will collect standard physical measurements (e.g., may include height, weight, and similar items). You will also be asked to answer questions, including standard questionnaires, about your health, cognitive (brain) function, and your quality of life.

For your safety, please check with the study doctor before starting, stopping, or changing your current medications or supplements at any time during the study.

Randomization

Once you are assessed and confirmed to be eligible to be randomized in the study, the study team will use the central randomization system at the Population Health Research Institute to determine which study group you have been assigned to.

If you are randomized to the Device and Anticoagulation Group (a 50% chance) you will be scheduled for a WATCHMAN FLXTM or FLX PROTM device implantation within a target of 15 calendar days. Your doctor may adjust your medications or ask you to start taking antibiotics. Your doctor may also schedule imaging (photos that are similar to x-rays) to be taken of your heart (often called “cardiac computerized tomography” or “cardiac CT”), to be conducted prior to having the device implantation procedure. Everything required of you prior to the procedure will be discussed with you by the study doctor.

If you are randomized to the Anticoagulation Group (a 50% chance) you will not have the device implanted, and will not require imaging (photos) of your heart as part of the research study. You will continue on your anticoagulation medications for the duration of the trial as directed by the study doctor.

DEVICE and ANTICOAGULATION Group

On the day of the device implantation procedure your doctor will review your health status and answer any questions you may have. The doctor will use cardiac ultrasound imaging (which is looking at images or pictures of your heart) to help guide the device implant procedure. This imaging may be called either a “transesophageal echocardiogram (TEE)” or an “intra-cardiac ultrasound (ICE)”. Your doctor will discuss the recommended option with you prior to the procedure. TEE is performed by inserting an ultrasound probe into your mouth and advancing it into your esophagus (food tube) to take pictures of your heart from inside your chest. The probe takes pictures using sound waves. ICE is performed by inserting a flexible tube (ultrasound catheter) through the blood vessel in your groin and directing it through your blood vessel to your heart to take pictures from inside your heart.

To place the WATCHMAN FLXTM or FLX PROTM device into your left atrial appendage, the study doctor will insert a flexible tube (catheter) through a vein in your groin and direct it into your heart. Once the tube is in the correct position, your study doctor will take pictures of your heart in order to measure your appendage. These measurements will determine which size WATCHMAN FLX TM or FLX PROTM device to use. The device will then be guided to your heart through this same tube. After the device is put in place, additional heart measurements and pictures will be taken by TEE or ICE to make sure the device is in the correct position. Once your study doctor is satisfied, the device will be released and left permanently in your heart. This procedure takes about one hour. You may need to stay in the hospital 1-2 days after the procedure to recover and be monitored.

After the implantation procedure you will return for follow-up exams so your study doctor can check your health status and the status of the device with additional cardiac images. Your doctor will tell you what the timing and assessments for this follow up will be.

ANTICOAGULATION Group

If you are assigned to the Anticoagulation Group, you will continue treatment with oral anticoagulant medications for the duration of the trial as directed by the study doctor.

For the purposes of your safety and this research, it is very important that you attend each study visit no matter which group you are in.

Questionnaires

You will be provided with cognitive function questionnaires before you begin the study, at the 24 month visit, and at the end of study visit. You will also be asked to answer questions 45 days after randomization, every 6 months, and at the end of study visit about your health. The purpose of the questionnaires is to understand how the study intervention affects your brain health and your quality of life. Each questionnaire will take about 5-10 minutes to complete.

People who have a stroke during the study will also be contacted about 3 months after the stroke occurred to ask about health status and recovery progress.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

* Tell the study doctor about your current medical conditions, and any significant health events
* Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbal supplements, and check with the study doctor before starting, stopping, or changing any of these. This is for your safety as these may interact with the intervention you receive on this study.
* Tell the study doctor if you are thinking about participating in another research study
* Tell the study doctor if you become pregnant while participating on this study

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

This study should take about 6 years to complete. Participation in the study is expected to last an average of 51 months (4.25 years), but this period may be shorter or longer for an individual participant, depending on whether they were enrolled early or later on in the international recruitment process to reach 4000 participants.

You will have a study visit 45 days after randomization. You will then be asked to have contact with your clinic (either in person, via video or virtual call, or by telephone) every 6 months until study end.

You may be seen more often if the study doctor determines that this is necessary.

No matter which group you are randomized to, we would like to keep track of your health for the duration of the study. We would do this by having someone from this centre call you to see how you are doing if you are not able to come into the clinic. If something should happen to your health and we need to get information regarding your medical condition, we may contact your health care provider, next of kin or another provider/facility where you may have been treated.

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 be asked questions about your experience with the study intervention, and to have laboratory tests and physical examinations considered necessary to safely stop your study involvement.

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.

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no new information will be collected or sent to the sponsor after you withdraw your permission.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

* New information shows that the study intervention is no longer in your best interest
* The study doctor no longer feels this is the best option for you
* The Sponsor decides to stop the study
* The Regulatory Authority/ies (for example, Health Canada) or research ethics board withdraw permission for this study to continue
* If you plan to or become pregnant

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form.

If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

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, who will watch you closely to see if you have side effects. When possible, other medicine will be given to you to make side effects less serious and more tolerable. Many side effects go away quickly, but in some cases be serious, long-lasting, permanent, or may even cause death.

The implant procedure and the WATCHMAN FLXTM or FLX PROTM device itself has potential risks. The most common risk (more than 20% of patients) is minor bruising under the skin of the groin where the vein is accessed to insert the device. Less common complications (in the range of 3-20% of patients) include irregular heartbeats, allergic reaction to the contrast dye, anesthesia risks, chest pain/discomfort, low blood pressure, damage to your blood vessels, bleeding, fainting (vasovagal reactions), bleeding or pain at the groin puncture site, non-healing of the hole in the heart wall between the atria from the implant procedure, reduced red blood cell count requiring transfusion.

Uncommon complications (less than 3% of patients) may include an accidental hole punctured or erosion in your heart which could cause blood to collect in the sack around the heart (this could require a procedure to drain the excess blood or surgery to repair the tear), blood clotting within blood vessels or in the heart, air bubbles in the blood stream, abnormal connection between an artery and a vein (AV fistula), heart attack, infection, stroke, collection of blood around a vessel puncture site (pseudoaneurysm), blood clot in the vessels of the lung (pulmonary embolism), fluid in or around your lungs, kidney dysfunction or failure, damage to the valves in your heart, heart failure, bleeding requiring transfusion, misplacement, fracture or dislodgment of the device, inability to remove the device (if necessary), bleeding, device infection, allergic reaction to the implant materials, scarring or clotted veins or chronic irritation from the device in the heart that could lead to erosion or death, and potential blood clots on the device when taking an anticoagulant.

All efforts will be made to minimize risks. There is a risk of dislodgement or migration of the device in your heart if it does not fit properly, which could lead to another procedure or major surgery to remove the device.

Additionally, there are risks associated with imaging tests required to insert the WATCHMAN FLXTM or FLX PROTM device. If a trans-esophageal echo (TEE) is done, risks include problems with breathing or heart rhythm, infection of the heart valves, and bleeding or tear of the esophagus (food pipe). If intra-cardiac echocardiography (ICE) is used, risks remain similar to the overall procedure to insert the WATCHMAN FLXTM or FLX PROTM device. If a Cardiac CT scan is used to image the heart, there’s some exposure to x-ray radiation, however the levels of radiation are considered safe for adults.

You and your study doctor should carefully discuss in detail all of the possible risks involved with this study before you volunteer to participate. By agreeing to volunteer in this study you agree that you have read, understood, and accepted the potential risks involved with this study.

There may also be additional risks or side effects which are unknown at this time.

WHAT ARE THE REPRODUCTIVE RISKS?

If you become pregnant while you are in this study, you should immediately notify the study doctor. The study doctor will ask if you are willing to provide information about the pregnancy as part of this study. You may choose not to give consent for the collection of this information or may withdraw consent at any time without giving a reason. This will not impact your participation on the study and will not result in any penalty or affect your current or future health care.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There may or may not be any direct benefits to you if you decide to take part in this study. However, previous studies have found that the risk of stroke can be reduced by closing off the left atrial appendage with a device permanently implanted into the heart. Therefore, there could be less chance of stroke or blood clots in your body.

Your participation in this study is also expected to add to the medical knowledge about the use of this device in people with atrial fibrillation and at increased risk of stroke.

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 centre 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/clinical study 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.

* Hamilton Health Sciences Corporation through its Population Health Research Institute, the Sponsor of this study
* The research ethics board who oversees the ethical conduct of this study
* This institution and affiliated sites, to oversee the conduct of research at this location
* The monitors for this study
* The Quality Assurance and Education Officers from Lawson Health Research Institute (Lawson) may audit this research study for quality assurance purposes
* Health Canada (because they oversee the use of the WATCHMAN FLXTM and FLX PROTM device in Canada)
* U.S. Food and Drug Administration (because they oversee the use of the WATCHMAN FLXTM and FLX PROTM device in the United States)

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your disclose identifiers e.g., participant code, initials, sex, and date of birth.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is required.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

This study does not require that an autopsy be performed. However, if an autopsy is performed for other reasons, and a copy of the report is provided to the study doctor, this report will be sent to the study sponsor as part of the study data collected for this trial. This report may contain other health information that is not required for study purposes.

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. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of the study intervention.

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.

Any information, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data, that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

The Sponsor of this study will share your study data, in pseudonymized form (personal information is replaced with artificial identifiers to prevent your identification) with Boston Scientific Corporation, the manufacturer of the study product and collaborator of the Sponsor, a medical device company that is located in the United States and is considered a data controller. Boston Scientific may use the pseudonymized study data that it receives about you for the purposes of internal development and analysis of the study product and for submission to Regulatory Authorities. The legal basis for the processing of your pseudonymized data is Boston Scientific’s legitimate interest in collecting regulatory evidence and conduct internal analysis for product development, as well as the need to conduct scientific research. Boston Scientific will retain your pseudonymized data as needed to perform the purposes mentioned above, and as necessary to comply with our legal obligations and to resolve disputes. The Sponsor of this study may additionally share your study data, in coded form, with Regulatory Authorities at the request of Boston Scientific.

Because this study also falls under U.S. regulations, in the event of an investigation of the study, the US Food and Drug Administration (US FDA) may need to copy and take away records that contain your personal information. If possible, the study doctor will inform you and confirm your consent at that time. By signing this consent form you are agreeing to this release of information. You should be aware that privacy protections may differ in other countries.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider may be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss this with the study team.

WILL information about this study BE available online?

A description of this clinical trial will be available on <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 search this Web site at any time.

WHAT IS THE COST TO PARTICIPANTS?

The WATCHMAN FLXTM or FLX PROTM device will be supplied at no charge while you take part in this study.

The costs of your medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study. In the case of research-related side effects or injury, medical care will be provided by your doctor or you will be referred for appropriate medical care.

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. The results of this study will be available on the clinical trial registry (see the “Will information about this study be available online” section for more details).

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, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor, 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.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may find out that you have another medical condition.

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

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 is in charge of the study at this institution. That person is: Dr. Allan Skanes, Study Doctor, London Health Sciences Centre, 519-663-3746.

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905-521-2100 ext. 42013.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036

SIGNATURES

By signing this consent form, please ensure that the following statements are correct and accurate.

* All of my questions have been answered,
* I understand the information within this informed consent form,
* I allow access to medical records and related personal health information as explained in this consent form,
* I do not give up any legal rights by signing this consent form,
* I understand that my family doctor/health care provider may be informed of study participation
* I agree to take part in this study.

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Signature of Participant PRINTED NAME Date

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Signature of Person Conducting PRINTED NAME & ROLE Date

the Consent Discussion

The following attestation must be provided if the participant is unable to read or requires an oral translation:

**If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:**

[ ]  The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

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PRINT NAME Signature Date

of Interpreter

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Language

[ ]  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.

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PRINT NAME Signature Date

of Witness

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Relationship to Participant