INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Hamilton Health Sciences Corporation through its Population Health Research Institute (PHRI) / "The Fourth Left Atrial Appendage Occlusion Study"**
Principal Investigator: (Study Doctor)	**Steven Messe, MD**
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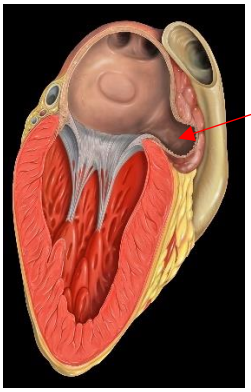
INFORMATION

You are being invited to take part in a research study called The Fourth Left Atrial Appendage Occlusion Study: (LAAOS-4). Taking part in this study is completely voluntary. This document explains the purpose of the study and the study requirements and activities. Please ask questions about anything that is not clear. The study doctor or team member will discuss the study with you and answer your questions. Before you decide whether to participate, you need to understand what the study is for, what risks you might take and what benefits you might receive, so please read this information carefully and take as much time as you like to think about it. Please feel free to discuss this with your family, your friends or other health care providers. If you decide to participate you will be given a signed copy of this information and consent form to take home with you.

ATRIAL FIBRILLATION

Atrial fibrillation is a common heart condition that happens when the top two chambers of the heart, 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.



Left atrial appendage
(Source: Wikipedia.org)

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.

PURPOSE OF THIS RESEARCH STUDY

The purpose of the LAAOS-4 study is to determine if closure of the left atrial appendage using a closure device called the WATCHMAN™, 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.

DEVICE INFORMATION

The WATCHMAN™ Device (shown below) is manufactured by Boston Scientific Corporation. The Device is made of materials that are common to many medical devices. The device is available in five different sizes. If you are randomized to receive a WATCHMAN™ Device, testing will be done to determine what size will be best for you.

WATCHMAN™ Device

The WATCHMAN™ 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. There are currently two FDA-approved WATCHMAN™ devices in use in the USA, the WATCHMAN FLX and the WATCHMAN FLX PRO, and both can be used in the LAAOS-4 study.

This research study is funded by Boston Scientific Corporation, the manufacturer of the device.

In the USA, the cost of the WATCHMAN™ Device will be covered by Medicare and Medicaid in eligible populations. For participants not eligible for Medicare and Medicaid, coverage will be requested from the participant's private insurer. You should call your insurer to discuss whether or not the use of this study device in this study will be covered. If you do not have insurance, you may be required to pay out of pocket for the use of this study device in this study.

STUDY ORGANIZATION

This study will take place in approximately 150-250 sites in North America and other countries internationally, and about 4000 people are expected to take part.

The study sponsor is Hamilton Health Sciences Corporation through its Population Health Research Institute (PHRI), and the study is being coordinated by the Population Health Research Institute, which is an academic research institute that operates within Hamilton Health Sciences and McMaster University in Hamilton, Ontario Canada.

WHO CAN PARTICIPATE

To take part, you must meet all of the following criteria:

1. Be at least 18 years of age
2. Have long-term atrial fibrillation (often called "persistent or permanent" atrial fibrillation)

   or

   Have one or more periods of short-term atrial fibrillation (often called "paroxysmal" atrial fibrillation) along with a medical history of stroke, or a history of blood clots in arteries in your body (called systemic embolism)
3. Have been identified as being at an increased risk of stroke by your physician
4. You must be taking oral anticoagulant medication for at least 90 days before enrollment into the study, and no documented plan to permanently discontinue treatment for the expected duration of the study.

Please note: if you are in any way capable of becoming pregnant, you may be requested to complete a pregnancy test before you are enrolled, and to commit to appropriate contraceptive measures for the duration of the study. Becoming pregnant while you are in this study may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, currently pregnant individuals will be excluded from the study.

While you are in this study, you cannot take part in another clinical research study.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your or your family member's performance appraisal or employment at this clinical research center. You may refuse to participate, or you may withdraw from the study at any time without penalty or anyone blaming you.

HOW AND WHAT ARE THE TREATMENTS BEING TESTED

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

One group of participants will receive the WATCHMAN™ Device (called the "Anticoagulation and Device" or "Device" group), and the other group will not receive the device (called the "Anticoagulation" group). Both groups will continue to take anticoagulant medications prescribed by their regular doctor.

Participants will be randomly divided (like a flip of a coin) into one of the two groups to be compared in this study. The randomization will be done by a computer located centrally at the Population Health Research Institute. The researchers at your hospital cannot influence to which group a participant is assigned. You will know which group you are assigned to.

LENGTH OF YOUR PARTICIPATION

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.

After enrollment, study visits will occur every 6 months. If you are assigned to receive the WATCHMAN ™ Device, you will have an extra visit for the procedure, and may also have an extra 1 or 2 in-person follow-up visits after the procedure to check on the device. Study visits can be completed by telephone or other virtual/video connection method with you or a family member, or if you are attending the clinic in person for regular follow-up, they may be completed during your regular visits, or using your medical records. The follow-up visits or calls are estimated to last about 10-20 minutes.

Each participant will have a final study visit when the study is declared over. The final end of study visit may occur earlier than 6 months from your previous (second-to-last) visit. The timing of the final end of study visit will depend on the study collecting enough data from all participants to accurately analyze the results.

PROCEDURES TO BE FOLLOWED DURING THE STUDY

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.

<u>Baseline Procedures</u>

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 Anticoagulation and Device Group (a 50% chance) you will be scheduled for a WATCHMANTM Device implantation within a target of 15 calendar days. Your study doctor may adjust your medications or ask you to start taking antibiotics. Your study 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 study as directed by the study doctor.

ANTICOAGULATION AND DEVICE Group – Device Implantation Procedure and Follow-up Care:

On the day of the device implantation procedure your study doctor will review your health status and answer any questions you may have.

The study 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 study 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^{TM} 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^{TM} 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 study doctor will tell you what the timing for this follow-up will be.

You will also have a study visit at forty-five-days after randomization, and after that you will be followed up every six months (from your randomization date) in person, via video or virtual call, or by telephone. At these visits, your medications will be reviewed, you will answer a questionnaire about your health, and you will be asked if you have experienced any significant health events since your last visit. At the 24-month visit, and at the final end of study visit, you will complete the brain health questionnaire called the "Montreal Cognitive Assessment". 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.

ANTICOAGULATION Group – Follow-up Care:

If you are assigned to the Anticoagulation Group, you will continue treatment with oral anticoagulant medications for the duration of the study as directed by the study doctor. At these visits, your medications will be reviewed, you will answer a questionnaire about your health, and you will be asked if you have experienced any significant health events since your last visit. At the 24-month visit, and at the final end of study visit, you will complete the brain health questionnaire called the "Montreal Cognitive Assessment". 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. Your study follow-up visits will be conducted by telephone, at the study doctor's office, or by video/virtual call.

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.

WHAT WILL HAPPEN AT THE END OF THE STUDY

After the study finishes, you will remain under the care of your primary care provider. They will decide what is best for you regarding your anticoagulant medication. If you had a device implanted during the study, it will stay in your heart when the study ends. The frequency of medical visits after you have completed the study will be up to your study doctor or primary care provider as well.

If you are interested in knowing the results of the study, your study doctor can share them with you once the study is complete and the results have been analyzed. The results will also be published in a medical journal and/or presented at a medical conference. 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, this Web site will include a summary of the results. You can search this Web site at any time.

RESTRICTIONS TO BE FOLLOWED DURING THE STUDY

The only restrictions to be followed during this study are avoidance of pregnancy, avoidance of participating in a second clinical study, as well as treatment with direct thrombin inhibitors.

POSSIBLE RISKS OR SIDE EFFECTS OF TAKING PART IN THIS STUDY

Participants who take part in this study are subject to risks that are similar to those shared by other patients who receive a WATCHMAN ™ Device, or who take oral anticoagulants, as part of normal medical care outside of this study. There may also be additional risks or side effects which are unknown at this time. The known possible risks and side effects of taking part in this study are listed below. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

*Potential risks associated with the test to look at your heart, the **TEE.***

This type of imaging is often standard for various types of heart surgery. If you are in the left atrial appendage closure group, your cardiologist will use this imaging to confirm correct placement of the WATCHMAN ™ Device. Risks related with the TEE include problems with breathing or heart rhythm, infection of the heart valves, and bleeding or tear of the esophagus (food pipe).

*Potential risks associated with the test to look at your heart, the **Cardiac CT.***

As with any X-ray, there's some exposure to radiation. The levels of radiation are considered safe for adults. Additional much less frequent risks may include pain at needle insertion, bleeding or bruising at the insertion site, allergic reaction to contrast dye (e.g. rash or swelling), feel hot when injecting the contrast dye, similar risks with blood draw, and/or kidney damage if you have a pre-existing kidney problem.

*Potential Risks associated with **Intracardiac Echocardiography (ICE)***

The risks and discomforts involved in imaging the heart with ICE are similar to risks with other diagnostic procedures in the heart. There is a risk that you may need additional medical treatment including surgery if you experience a complication during ICE. The most common risk (more than 20% of patients) is bruising or collection of blood under the skin (hematoma) where the camera is inserted.

Less likely complications (3%-20% of patients) may include irregular heartbeats, allergic reaction to the contrast dye, chest pain/discomfort, fluid around the heart, damage to your blood vessel, or bleeding or pain at the groin puncture site.

Very rare complications (less than 3% of patients) may include air bubbles in the bloodstream, blockage of an artery or vein by a clot or foreign matter (embolism), blood clotting within blood vessels or in the heart, collection of blood around a vessel puncture site (pseudoaneurysm), damage to the valves in your heart, damage to your blood vessel, fluid around your heart, heart attack, infection in your heart or death.

Potential Risks associated with **WATCHMAN™ Implant and Device**

The implant procedure and the WATCHMAN ™ Device itself has potential risks.

The most common risk (more than 20% of patients) is bruising or collection of blood under the skin (hematoma).

Less likely complications (3%-20% of patients) may include irregular heartbeats, allergic reaction to the contrast dye, anesthesia risks, chest pain/discomfort, low blood pressure, fluid around your heart, 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, swelling, or 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 lead to 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, bleeding, 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, respiratory failure, potential brain damage due to lack of oxygen, transient ischemic attack, damage to the valves in your heart, improper wound healing, altered mental state, blockage of an artery or vein by a clot or foreign matter (embolism), heart failure, bleeding requiring transfusion, altered blood value, 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.

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.

BENEFITS

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 taking medications called “oral anticoagulants” (often known as blood thinners) that help to prevent blood clots. Studies have also found that closing off the left atrial appendage with a WATCHMAN ™ device permanently implanted into the heart is as effective as some types of blood thinner therapy for reducing the risk of stroke or serious blood clots. The question being studied in the LAAOS-4 study is whether adding the WATCHMAN ™ device to anticoagulation therapy reduces the risk of stroke or serious blood clots compared to not adding the WATCHMAN ™ device. While there is no guaranteed benefit to you from participating in this study, the treatments used in both study groups are proven to reduce the 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.

ALTERNATIVE PROCEDURES OR TREATMENTS

You do not have to participate in this study. Alternatives to study participation include implantation of a commercially available left atrial appendage occluding device outside of the study, surgical removal of your left atrial appendage, and/or remaining on long-term anticoagulation medications. The study doctor will review the potential risks and benefits of these alternatives with you.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

PARTICIPATION AND WITHDRAWAL FROM THE STUDY

Your participation in this study is purely voluntary. Your decision not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose to participate, any new information that becomes available during the study that may affect your willingness to continue participation will be provided to you in a timely manner. You may discontinue your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled. Should you wish to withdraw your consent, please notify the study doctor at the telephone number listed on the first page of this consent form. If you should decide to discontinue your participation in the study, you may be asked to undergo additional tests for your safety or your compliance with the requirements of the study.

If you withdraw your consent to participate, the information about you that was collected as part of the research project between the date you signed the current form and the date you withdraw your consent will still be used, to protect the quality of the research study. No new information about you will be collected and used. If you withdraw from the study, we hope that you agree to be contacted at the end of the study to confirm your health status. Agreeing to this is optional and refusal to allow this will not affect future care you receive from your regular doctor.

The study doctor, the research Institutional Review Board (please see the section below titled "Research Institutional Review Board"), regulatory agencies, or the study sponsor may stop the study or stop your participation in the study at any time if they decide that it is in your best interest or in the best interest of all participants. They may also do this if you do not follow instructions. If you have unrelated other medical problems, the study doctor will decide if you may continue in the research study.

IN CASE OF RESEARCH RELATED INJURY

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.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. 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 The sponsor will cover necessary medical costs directly related to a research injury, provided certain eligibility criteria are met. Costs for medical care that you might incur for injuries or illnesses that are not a direct result of research activities will not be covered by the study.

RESEARCH INSTITUTIONAL REVIEW BOARD

This study has been reviewed by the research Institutional Review Board (IRB). This group of people is independent from your study doctor, the study sponsor, and study funder. It reviews the science and ethics of a study before it is allowed to start. The purpose of this committee is to protect you as a participant.

LEGAL RIGHTS

By signing the consent form, you do not waive your legal rights and you do not release the study doctor, the institution, the sponsor or their representatives from legal responsibility of negligence.

PAYMENT AND COST FOR PARTICIPATION

There will not be any monetary payment to you for participating in this clinical study.

In the USA, the cost of the WATCHMAN™ Device will be covered by Medicare and Medicaid in eligible populations. For participants not eligible for Medicare and Medicaid, coverage will be requested from the participant's private insurer. You should call your insurer to discuss whether or not the use of this study device in this study will be covered. If you do not have insurance, you may be required to pay out of pocket for the use of this study device in this study.

CONFIDENTIALITY AND RELEASE OF PERSONAL INFORMATION

As required by Federal, State and Local Law, your Personal Information will be kept as confidential as possible. Personal information is defined as any information that identifies you or information from which you could be identified, and may include information such as your name, identification numbers, medical insurance numbers, your health information, and other information that may individually identify you.

To protect your Personal Information, a unique patient identification code will be assigned when you join the study. Use of the unique code throughout the study will ensure your Personal Information is kept separate from study data, and no study data will have information that could identify you. This is called "de-identifying" the data.

Your coded study data will be processed manually as well as by computer, and analyzed during and after the study. Data from the study are typically used in a way such that even the results do not identify individual study participants.

Your name or identifying information will not be provided for publications in medical journals, however whenever you give your identifiable health information to a person or business, there is a risk of inadvertent disclosure, a risk that your information may be released to others without your permission. If you choose not to participate in this research study, your personal health data will not be collected or processed as part of this study.

Does the study involve Electronic Medical Records?

What is an Electronic Medical Record?

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

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of 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). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare.

To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR/?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION
If you decide to be in this study, the study doctor and study staff will use and share health data about you found in records to conduct the study.

These records may include some or all of your medical records, from any healthcare facility you visit including, but not limited to: hospital records and reports; electrocardiograms and reports; echocardiograms and reports; operative reports; laboratory reports; treatment and test results; immunizations; allergy reports; prescriptions; consultations; clinic notes; notes relating to information obtained and any other records that are needed. In the future, personal health information (such as your name, birthdate, or social security number, as necessary) may be used for inquires to national health care registries in order to obtain vital health status of participants in this study.

Your Personal Information will not be used unless necessary for your safety, the purpose of the study, or for regulatory obligations.

If you decide to participate in the study, the Sponsor and others who work with the study, such as the study staff, organizations contracted by the Sponsor to do study related activities and Institutional Review Board (IRB), will see de-identified health information about you. The U.S. Food and Drug Administration (FDA) or other regulatory agencies, IRB and Sponsor's representatives may inspect your medical records. Additionally, other authorized personnel at Penn Medicine and the University of Pennsylvania , including offices that support research operations may receive your study information.

The Sponsor may use the de-identified information in any of the following ways:

- To analyze and make conclusions about the results of the research study
- For reporting undesirable events to government health agencies governing clinical research
- For processing, monitoring, auditing and control of the research study or the conduct of inspections by the relevant authorities
- To reanalyze the study results in the future or to combine your information with information from other studies
- For regulatory submissions for product approvals to government regulatory agencies (including those in other countries)

Your collected data will be securely sent to the Population Health Research Institute. Your information will be kept in a secure location with access limited to authorized personnel only. In the electronic database, your data will be identified only with a code number.

Sponsors and study doctors must maintain the required records for a period of two years after the date the investigation is completed or terminated or the records are no longer required to support a government health authority application, whichever date is later.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Name of Participant (please print):

_____

Signature: _____ Date: _____

Time: _____

Witness (if applicable)

The informed consent form was accurately explained to, and apparently understood by, the participant, and informed consent was freely given by the participant.

Name of Witness (please print): _____

Signature: _____ Date: _____

ROLE OF STUDY FUNDER

The Sponsor of this study will share your study data, in coded (pseudonymized) form with Boston Scientific Corporation, the manufacturer of the WATCHMAN device 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 WATCHMAN device 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 device 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.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participants;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00071457.

CONSENT SIGNATURE PAGE

Consent for participation in this research study

Your signature indicates that you have read the information in this form and have decided to take part in the study. You will be given a signed copy of this form to keep.

- I have read all of the above information in this consent and authorization form.
- I have had the opportunity to ask questions and have received answers concerning areas I did not understand.
- I have been informed of the risks and benefits, if any, of participating in this research study.
- I willingly give my consent to participate in this study and to comply with the procedures related to it.
- I confirm that my uniquely coded study data will be used in the analysis and de-identified or anonymized data may be included in publications.
- I understand that I am free to refuse to participate in the proposed study, without giving any reason and without my medical care or legal rights being affected.
- I understand that I am free to withdraw from the proposed study at any time, without giving any reason, without my medical care or legal rights being affected.
- I give the study team permission to inform my personal physician of my participation in this study.
- I do not give up any of my legal rights by signing this document.
- I will receive a copy of this signed document.

Name of Participant (please print):

_____

Signature: _____ Date: _____

Time: _____

Name of Person Obtaining Consent (please print):

_____

Signature: _____ Date: _____

Witness (if applicable)
The informed consent form was accurately explained to, and apparently understood by, the participant, and informed consent was freely given by the participant.

Name of Witness (please print): _____

Signature: _____ Date: _____