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

Instruction to PI/Coordinator: Please delete any parts of the consent template that are not relevant to your particular study. All of the yellow highlighting should be deleted in the final version of the consent form.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Title of Study: **[Study]**

HREB Protocol Number: **[Number]**

Principal Investigator (PI): **[Name]**

[CoInvestigator/Coordinator(s)/Research Assistant]: [Name]

[Sponsor/Funding Agency (if applicable):] **[Sponsor or Funding Agency Name]**

Introduction

You are being asked to participate in this research study because [reason why you're asking person to participate].

Participation in this study is voluntary. Please read this Participant Information Sheet and Consent Form (PIS&CF) carefully and ask the study doctor and study team as many questions as you like before deciding whether to participate in this research study. You may also discuss your options with family, friends or your healthcare team.

Background, Purpose and Design of the Study

The purpose of this study is [study purpose/background].

For interventional studies you should include the following:
This [study drug/device] is considered experimental. This means that the [study drug/device] used in this study has not been approved for general use by Health Canada but has been approved for use in this research study.

This study is taking place in sites across [Canada/North America/the world] at [number] sites. We estimate that [number needed to obtain a valid result] participants will enroll in the study, including [number estimated for enrollment] participants from the University of Ottawa Heart Institute (UOHI).

Study Duration

Your participation in the study will last approximately [days/weeks/months] from screening to termination. Over this time, you will be required to visit the Heart Institute for [number] number of visits.

Study Procedures

Required language if relevant to your study (delete if not applicable). Please include additional language to provide a comprehensive description of the study procedures, see the guidance document for more information.

If the study uses a placebo:
This study compares the effects of the study drug with a placebo. A placebo is an inactive substance that looks exactly like the study drug.

If the study is randomized:
Whether you get the study drug or the placebo will be decided randomly. Randomization means that you are put into a group by chance. [If the study has two arms, define randomization as "similar to flipping a coin". If the study has three or more arms, define randomization as "like pulling a number out of a hat".] The number of people receiving the study drug will be [number] and the number of people receiving the placebo will be [number].

If the study is blinded:
This study will be blinded, which means that you will not be told whether you will be taking the study drug or the placebo until the study is finished.

If the study is double-blinded:
This study will be double-blinded, which means neither you nor the study team will know whether you are taking the study drug or the placebo until the study is finished. [Explain why the participant and the investigator will not know which agent the participant is taking.] However, in an emergency this information can be obtained quickly.

Sample wording of some common situations and tests for the HI:
If the study includes a screening visit:
The first study visit will be a screening visit. The results of the tests and/or questions at the screening visit will help the study team decide whether you can continue in this study. Some of these tests may be part of standard of care while others might be done just for the study.

If the study includes a baseline visit:
The study team needs to find out about your [condition/health] before you begin taking [study drug/intervention] so they can see how well [study drug/intervention] works. This is called the baseline visit. The results of the tests/questions at the baseline visit will help the study team to decide whether you can continue in this study.

Blood Samples:

[Specify volume of each sample in both tsp/Tbsp and ml, and the frequency of testing.]

Cardiac Positron Emission Tomography (PET Scans):

This test takes pictures of your heart to analyze its function. The scans will show the blood flow within your heart and how the heart is pumping. The scans may also identify blocked arteries, problems with the heart valves, areas of your heart that are alive, or viable, as well as areas of scar tissue that are non-viable, due to previous damage to the heart. During the test you will lie still on a padded table, with your arms raised above your head. An intravenous, or small catheter inserted into a vein, will be used to give you a small amount of a tracer, called [name]. A tracer, or radiopharmaceutical, is the agent that allows the camera to see the heart. This test will take approximately [xx] hours to complete. [Add details re: rest and exercise prn]

Coronary Angiogram:

A coronary angiogram, often called 'an angio', is done to view the arteries of the heart. This invasive procedure begins by numbing an area on the arm or groin with medication, and then inserting a needle into the blood vessel. A thin hollow tube, called a catheter, is then moved through the vessel until it reaches the heart. A dye is then injected through the catheter so the doctors can see your arteries on x-ray.

Computerized Tomography Coronary Angiograms (CTA):

In this non-invasive test a series of x-rays are taken to show cross-sectional views, or slices, of the body. A CT coronary angiogram, or 'CTA', is done to exam the blood vessels and blood flow of the heart. An intravenous, or small tube in the vein, is used to inject a dye so that the images of the heart may be seen on xray. You will be required to lie still on a special padded table for the duration of the test, which takes approximately [xx] minutes to complete.

Echocardiography (Echo):

This test involves placing a probe on your chest over your heart to assess the heart's function. This is a type of ultrasound, similar to what is used to see a baby in the mother's womb.

Electrocardiogram (ECG):

In this test, sticky patches connected to wires are put on your skin to record the electrical activity of the heart. In some cases we may need to trim or shave your body hair.

Holter Monitoring:

This test involves placing [x] electrodes (small sticky patches) on your chest which are connected to wires and a small recording device about the size of a cell phone. It records the electrical activity of the heart for [xx] hours and later doctors will be able to review the recorded data.

Intravenous (IV):

A small tube inserted into a vein.

Non-Invasive testing:
Non-invasive testing means that nothing will be inserted or enter inside the body.

Questionnaires:
You will be asked to complete [number] questionnaires, at [define when: each, every other, actual number, etc.] visit(s). The questionnaires are to assess [define: quality of life, your ability to carry out your day to day activities, your level of anxiety, etc.] and will take approximately [minutes] to complete. (Define each questionnaire separately if appropriate.) You may skip any questions that make you uncomfortable or that you do not wish to answer.

Transesophageal Echocardiography (TEE):
In this test, a special ultrasound probe called a transesophageal echocardiography (TEE) probe will be inserted into your esophagus and measurements of your heart function will be done. Your esophagus is the part of the gastrointestinal system leading from your mouth to your stomach.

Example of a table outlining study procedures/tests:
Boxes marked with an X show what will happen at each visit.

Visit	Screening Randomization	Visit 1 (Month 1)	Visit 2 (Month 6)	Visit 3 (Month 12)
Length of time needed	3 hours	1 hour	1 hour	1 hour
Medical History	X			
Physical Examination	X			
Vital Signs	X	X	X	X
Electrocardiogram	X	X	X	X
Blood Test	X	X	X	X
Questionnaire	X	X	X	X

Responsibilities of the Participant

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

- Ask your [insert applicable study personnel] if you have any questions or concerns.
- Tell your [insert applicable study personnel] if anything about your health has changed.
- [List out any restrictions or reminders, as applicable to the study, for example:
- You should not eat for 12 hours before visits.
- Do not take medications before visits.
- Do not eat grapefruit or drink grapefruit juice during this study.
- Return study medication and diaries.
- Prior to any blood test, you must fast for at a period of 12 hours and not consume any coffee.
- Etc.]

Potential Risks and Discomforts

This study has risks, as with any study. Some of the risks we know about. There is also a possibility of risks that we do not know about and have not been seen in participants to date. The following are risks and discomforts you may experience during your participation in this study.

Required language for risks if relevant to your study (delete if not applicable). Please include additional language to provide a comprehensive description of the risks associated with your study, see the guidance document for more information.

Drug side effects:
Some drug side effects can be managed. Most side effects go away when you stop taking the drugs, but others might be long-lasting or permanent. Please call the study doctor if you experience any side effects, even if you are unsure whether it has anything to do with this study. The risks we know about are:
Very likely (21% or more of patients): [describe risks]
Less likely (5% to 20%): [describe risks]
Rare (1% to 4%): [describe risks]
Very rare but serious (less than 1%): [describe risks]

Blood Sample risks:
You may experience some temporary discomfort when the blood sample is taken. There is a small risk of bruising, infection or swelling at the site where the needle is inserted, and some people may feel faint or dizzy.
[If the blood samples will be used for genetic research, genetic risks must also be explained.]

Genetic risks:
Risks of Insurability and Employability
We will take all reasonable steps to keep your research information confidential. Should someone not involved in the research find out that you took part in this research study, or if you choose to share your results (if they are provided to you), there is a possibility that this could affect your insurance or employment.

Echo risks:
There are no risks associated with an echo, however you may find the pressure from the probe causes some discomfort.

ECG/Holter risks:
The test is painless, however the patches may feel cold when first applied to the skin. In rare circumstances you may develop a mild rash or irritation where the patches were placed.

Intravenous risks:
An intravenous can, in rare cases, cause minor bleeding, bruising, redness, swelling or infection.

Questionnaire risks:
You might find the interviews and questionnaires [upsetting or distressing or tiring if they are quite lengthy, etc. - specify based on type of questionnaires.] You might not like all of the questions that you are asked. You do not have to answer any question that makes you uncomfortable.

Radiation risks:
[See Radiology application handouts for specific wording based on amount of exposure]

TEE risks:
A rare complication from TEE, occurring in less than 3% of patients, is erosion of the lining of the stomach and esophagus from the TEE probe insertion and movement during examination. Very rarely (less than 0.1%) the TEE probe may cause perforation of the esophagus. You may have a mild sore throat for a brief time after the test.

Pregnancy Risk

Although there is no adequate clinical experience in pregnant or breastfeeding women, results of studies with this drug in animals have shown that this drug might have unknown risks on the unborn child or infant. For this reason, we require that women do not become pregnant or breastfeed an infant during this study, more specifically for a period of [days/months]. In the event of pregnancy, or suspected pregnancy, you must tell your study doctor immediately. The study medication may be stopped to avoid unknown risks.

If you are a woman of childbearing age, you will be given a pregnancy test to ensure you are not pregnant before the study begins. You may also be given another pregnancy test [during/after/at xx weeks, etc. -specify] the study.

Potential Benefits

Required language:
You may not receive any direct benefit from your participation in this study. Your participation may allow the researchers to [explain], which may be of benefit to future patients.

If applicable, you may also add:

1. This study includes procedures that may change the treatment you would otherwise receive, which may be of benefit to you.

2. This study is designed to select by chance which treatment you will receive. If you are receiving the study product, [drug or device name], there is potential you may benefit from its use, but this has not been proven.

Alternative Treatments Available

Required language, if relevant, to describe any appropriate alternative procedures/treatments that might be advantageous to the subject.

You do not have to participate in this study to receive treatment for your condition. The following are approved [medications/interventions] that are currently available for your condition:

- [medication/intervention]
- [medication/intervention]
- [medication/intervention]

You may also choose not to have any treatment for your condition. Upon request, the study doctor will discuss these alternative treatments with you.

Withdrawal from the Study

You may withdraw from the study at any time without any impact on your current or future care at the University of Ottawa Heart Institute. If you decide to withdraw you should contact the study doctor or the study team, before you withdraw, so that they may discuss any issues involved in discontinuing the study. If you withdraw from the study, the final assessment visit(s) may need to be completed to ensure your safety and well-being.

If you choose to also withdraw your consent, the study team will no longer use and disclose your personal health information for research purposes, unless it is necessary to preserve the scientific integrity. [If applicable: Information given to the sponsor before you cancel this consent may still be used.]

The study doctor may also decide to withdraw you from the study for any of the following reasons:

- The study doctor feels it is in your best interest.
- The sponsor or a government agency cancels the study.
- You need [additional medication/treatment] that would interfere with the study.
- You do not follow the study staff's instructions.
- [If applicable: You become pregnant.]

You have the right to check your study records and request changes if the information is not correct. However, to ensure the scientific integrity of the study, some of your records may not be available until after the study has been completed.

Compensation

Required language, please choose one of the two statements:

If you are injured or become ill as a result of your participation in this study, Dr. [principal investigator] and the University of Ottawa Heart Institute will ensure that adequate medical care and treatment is provided to you. The cost of this care and treatment will be paid by [sponsor/funding agency]. Financial compensation for lost wages, disability or discomfort due to an injury is not generally available. You will not give up any legal rights by signing this form.

OR

In the event of a study-related injury or illness, you will be provided with appropriate medical treatment and care. You are not waiving any of your legal rights by agreeing to

participate in this study. The study doctor and the University of Ottawa Heart Institute still have their legal and professional responsibilities.

Study Costs/Coverage

Required language for study costs if relevant to your study (delete if not applicable).

No compensation:
You will not be paid to take part in this research study.

Reimbursements:
[The [drug/intervention] will be provided to you free of charge as long as you participate in the study.] You will be reimbursed for parking and [any other items] costs directly related to this study.

Compensation for time:
You will be paid $[amount] for time taken for you to participate in the study.

[Insert description of payment schedule if applicable.]

If the study is paying for participation, over and above actual reimbursement of expenses, you must include the following required text:
Income earned as a result of your participation in this study that is not for reimbursement of study expenses will be considered taxable income by Revenue Canada. To receive payment for your participation in this study, you must provide the study team with your Social Insurance Number. By the end of February of the following year, the University of Ottawa Heart Institute will issue a T4A for any amount over $500 earned in the current calendar year.

Conflict of Interest

This study is sponsored by [insert]. Although the sponsor will be paying the Principal Investigator (PI) and the University of Ottawa Heart Institute to conduct the study, the PI and UOHI do not otherwise benefit from the study.

Possibility of Commercialization

If the [software development/drug/device] is proven effective, it may be approved for use and available for sale in [Canada/US/Internationally, etc]. If this occurs, the Principal Investigator, UOHI, and/or the Sponsor may benefit from this development.

Confidentiality

Personal health information that identifies you may be used or shared for the purposes of the study. This section of the consent form describes how your information will be used and shared in this study, as well as the ways the UOHI will safeguard your privacy and confidentiality.

All personal health information will be kept confidential, unless release is required by law. For audit purposes only, representatives of the [sponsoring company, [sponsor], or funding agency, [name]] government agencies (such as Health Canada or the U.S. Food and Drug Administration), the University of Ottawa Heart Institute Human Research Ethics Board (HREB) and the University of Ottawa Heart Institute, [as well as any other relevant parties in the auditing process], may review your original medical records under the supervision of Dr. [principal investigator]'s staff.

Results of research studies should be shared, to ensure patients are always provided with the best possible care. Therefore, results from this study may be presented at scientific conferences and/or published in journals but you will not be identifiable in any publications or presentations. For clinical trials with U.S. ties (FDA oversight, NIH funding, etc.) you must include the following language unchanged:
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.
If a Canadian trial is being sponsored or coordinated elsewhere and they registered on another site, replace the website address (see guidance document for more information). Otherwise for all clinical trials without US ties insert:
A description of this clinical trial will be available on [http://www.ClinicalTrials.gov]. 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.

No identifying information will leave the University of Ottawa Heart Institute. All information that leaves the UOHI will be coded with an independent study number. The Master List which links your name and the independent study number will only be accessible by Dr. [principal investigator] and/or his/her staff. The link and study files will be stored separately and securely.

All paper records will be stored in a locked filing cabinet and/or office. All electronic records, including the Master List, will be stored on a secure internal hospital server [any other relevant details] and password protected, again only accessible by Dr. [principal investigator] and his/her staff. No identifiable information will be stored on any mobile devices (laptops, USB keys, CDs, DVDs, etc.). Research files will be kept for a period of [number] years after the study has been completed, as required by law. At the end of the retention period, all paper records will be disposed of in confidential waste for shredding and all electronic records will be securely deleted.

Voluntary Participation

Your participation in this study is completely voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. Your decision will not affect the care you receive at this Institution now or in the future, and will not result in any loss of benefits that you are otherwise entitled.

You will be told of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

Study Contacts

If you have any questions about this study, or if you feel that you have experienced a study-related injury, please contact Dr. [principal investigator] at [phone number] or the study staff at [phone number].

The University of Ottawa Heart Institute Human Research Ethics Board (HREB) has reviewed this protocol. The Board considers the ethical aspects of all research studies involving human participants at the University of Ottawa Heart Institute. If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, extension 19865.

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[Title of Study and HREB Protocol Number]

Consent to Participate in Research

I understand that I am being asked to participate in a research study about [description]. This study has been explained to me by _____.

I have read, or have had it read to me, this [total number of pages] Participant Information Sheet and Consent Form. All of my questions have been answered to my satisfaction. If I later decide that I would like to withdraw my participation and/or consent from the study, I know that I can do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Participant Information Sheet and Consent Form will be provided to me.

Signatures

_____
Participant's Name (Please Print)

_____ _____
Participant's Signature Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained the study to the study participant. To the best of my knowledge, the study participant signing this consent form understands the nature, demands, risks and benefits involved in taking part in this study. I acknowledge my responsibility for the care and well being of the above study participant, to respect the rights and wishes of the study participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

_____
Name of Investigator/Delegate (Please Print)

_____ _____
Signature of Investigator/Delegate Date