UNIVERSITY OF CALGARY

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CONSENT TO PARTICIPATE IN RESEARCH

TITLE: A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel Group, Active Controlled Study to Evaluate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, Versus Apixaban in Participants with Atrial Fibrillation: **LIBREXIA-AF**

SPONSOR: Janssen Research & Development, LLC Study Number: 70033093AFL3002
Represented by IQVIA RDS Inc.4820 Emperor Boulevard, Durham, North Carolina 27703 USA

INVESTIGATORS: George Veenhuyzen (principal) 403-944-3385
Stephen Wilton
F. Russell Quinn

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

INTRODUCTION

Dr. George Veenhuyzen and associates from the Cumming School of Medicine at the University of Calgary are conducting a research study. You are being asked to take part in this study because you have an arrhythmia (or heart rhythm disorder) called Atrial fibrillation and require anticoagulation, or "blood thinning" to decrease your chances of having a stroke.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare the effects of an experimental drug: *MILVEXIAN* to a similar drug, *APIXIBAN* to determine if it is safe and useful in reducing the risk of stroke and blood clots outside the brain in participants with atrial fibrillation. An experimental drug is one that is not approved by Health Canada.

All reference to the words "study drug" in this document can mean milvexian or apixaban.

Milvexian is not approved for use in any country by any Regulatory Authority, such as Health Canada, that protects public health by overseeing safety and effectiveness of medications. Therefore, it can only be used in a research study such as this one.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 20,000 participants will take part in this study worldwide. About 265 participants from Canada are expected to take part in this study. We hope to enroll 20 participants in Calgary.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Not everyone in the study will get milvexian. There are 2 treatment groups in this study: milvexian and apixaban. You will randomly (like flipping a coin), be put into either the milvexian or apixaban group. You will have a 50% chance of being put into either group. You will either receive milvexian and placebo or apixaban and placebo. Placebo is a tablet without medicine in it. You will take both placebo and study drug to ensure neither you nor the study staff will know which group you are in. However, if needed for a medical emergency, the study doctor/staff can quickly find out which treatment group you are in.

There are 3 parts to this study:

Screening time: Usually one visit

- Review and sign consent form
- Review of your medical history and medications
- Brief physical exam
- Body weight and height
- ECG (electrical tracing from your heart)
- Blood draw, including pregnancy test for applicable women
- Urine sample
- Questionnaires
- Stroke disability scale if needed

Treatment time: Up to 4 years depending on when you enter the study

- Take study medication everyday
- Visits every 3-6 months which include:
    - Medication review
    - Vital signs
    - Review of any side-effects
    - Stroke disability scale if needed
    - Questionnaires if needed
    - Blood draw

The study drug is supplied as a tablet and a capsule. You will take them orally (by mouth), two times daily. You should never take more or less each day than instructed by your study doctor. Please take the study medication as directed on the label. Please finish all the tablets/capsules in the bottles before opening new ones. At all times, you should have only one bottle of each open, 75cc and 160cc.

If you miss a dose of the study drug or if you vomit all or part of the study drug, let the study doctor/staff know.

Follow-up Time: 30 days after you stop taking study drug

- Take NO study medication (Other blood thinning medication may be provided if indicated by your doctor)
- Two visits (at beginning and end of period) which include:
    - Medication review
    - Vital signs
    - Review of any side-effects
    - Stroke disability scale if needed
    - Blood draw
    - Questionnaires

To participate in the study, you must follow the below list of things to do and not do:

Overall study rules

Do:

- Give correct information about your health history and health condition
- Tell the study doctor/staff about any health problems you have during the study
- Participate in all study visit appointments
- Carry your study participation card
- Take specified measures to help prevent pregnancy

Do not:

- Do not take part in any other medical research studies
- Do not get pregnant or cause your partner to become pregnant

Medicines

Do:

- Tell the study doctor/staff about any new medicine/drug or supplements/herbal medicines you take during the study or any changes to your medicines or drugs
- Take the study drug as instructed
- Return unused study drug and all empty packages at visits as instructed by study doctor/staff
- Keep study drug out of reach of children

Do not:

- Do not take any other drugs or remedies unless the study doctor/staff has approved them beforehand, including prescription and over-the-counter drugs such as vitamins and herbs
- Do not give your study drug to anyone else

TELEMEDICINE

You have the option to do some study visits virtually (for example, by telephone or video call). The study staff will provide more information to you on how these virtual visits will be conducted and about the tools that they use.

HOW LONG WILL I BE IN THE STUDY?

The time of your participation is dependent upon the time you enroll. If you join the study, you'll be participating for approximately 4 years. The average participation time will be about 2 years.

WHAT OTHER TREATMENTS ARE THERE OUTSIDE OF THIS STUDY?

Instead of taking part in this study, you may choose to take other treatments that are approved in your country for the prevention of stroke in people with atrial fibrillation. The study doctor will explain to you the benefits and risks of these other treatments. He/She will answer any question(s) you may have regarding the alternative which is standard of care.

WHAT ABOUT MY CURRENT MEDICINES?

You must tell the study doctor/staff about all prescription and over-the-counter drugs you take. This includes vitamins and herbs.

Do not stop taking any of your current medicines unless the study doctor/staff tells you to.

WHAT ARE THE RISKS?

All drugs can cause side effects in some people. You must tell the study staff about any side effect you have. If you do not tell the study staff about the side effects, you may harm yourself by continuing to take part in this study.

Milvexian is a blood thinner (anticoagulant) which is in a class of drugs associated with a risk of bleeding.

Milvexian Risks:

- Minor bleeding (nosebleed, bleeding gums, bruising)
- Serious bleeding in the brain, stomach or bowel which could lead to hospitalization
- Rash, swelling (mainly in the feet, legs and/or ankles)
- Liver and kidney blood test changes

Of note, there have been reported cases of rash requiring hospitalization in patients taking multiple medications in addition to milvexian. Although the milvexian may not have caused these reactions, we can't be sure at this time. Therefore, stop taking study drug and call your study doctor right away if you develop a rash that involves any of the following conditions:

- covers a large area of your body
- painful or blistered

- sores (lesions) in other areas (eyes, inside the mouth or nose, vagina, urethral opening, glans penis, anus)

- sudden malaise (not feeling well), unusual tiredness, fever, loss of appetite, stinging, redness, or burning of eyes, sore mouth, or difficulty swallowing experienced shortly before the rash.

Increased bleeding may also happen during surgery or invasive procedures. A serious bleeding event can be dangerous, permanently disabling, or fatal.

Twenty clinical trials have been completed as of December 2022. In those completed trials, a total of 3,369 participants had received milvexian. Based on what we have learned up to this point about milvexian, adverse drug reactions (potentially related to milvexian) include rash (0.7%), swelling (1.2%) (mainly in the feet, legs and/or ankles), and different types of bleeding events.
Reported bleeding events ranged from mild bleeding (for example nosebleed, bleeding gums, bruising and bleeding at an injection [area where a shot or needle had been given] or surgical [operation] site) to serious bleeding leading to hospitalization (for example bleeding from the stomach, bowels, bleeding hemorrhoids, blood in the urine or bowel movement, bleeding in the head or within the area of a previous stroke and bleeding during surgical operation). The most common bleeding events (>1%) that occurred in milvexian studies are contusion (1.8%), gastrointestinal bleeding (1.5%), and skin bleeding (1.2%).

These bleeding events happened while patients were either taking milvexian alone or with other blood thinner medications. Therefore, the role of milvexian in these events cannot be excluded or confirmed.

Liver (hepatic) laboratory value elevations have been observed in milvexian clinical studies. Although milvexian may not have caused these increases, its contribution cannot be excluded at this time. Your study doctor will be monitoring your liver function during your participation in the study. Please tell your study doctor if you have any yellowing of your skin or your eyes, light colored stool, itching or unusual and extreme tiredness, loss of appetite, continued nausea and/or vomiting, abdominal pain, dark urine or if you have been told you have increased liver laboratory values.

Kidney (renal) disorder cases mainly revealed by abnormal kidney laboratory values have been observed in milvexian clinical studies. Medically significant changes were seen more frequently in patients receiving milvexian 200 mg twice daily than in those receiving lower doses of milvexian or placebo (inactive tablet). This high dose will not be used in studies enrolling patients. Your study doctor will be monitoring your kidney function during your participation in the study. Please tell your study doctor if you have been told you have abnormal kidney laboratory values.

All drugs have a potential risk of an allergic reaction, which could become life threatening. You should stop the study drug and seek medical help immediately if you think you have any of the following symptoms of a serious

allergic reaction: trouble breathing; swelling of the face, mouth, lips, gums, tongue, or neck; or seizures. Loss of consciousness, shock and death may result from heart and lung failure in rare cases.

You must review all current medications with your study doctor at the beginning of the study and inform the study doctor during the study if there are any changes to your existing medications or new medications added.

Certain medications, such as the ones listed below, can have a possible increased risk of bleeding while taking milvexian. If you are taking any of the medications listed now or are asked to start them during the study, you must discuss this with your study doctor immediately:

- Salicylates (aspirin and aspirin-containing products)
- NSAID (non-steroidal anti-inflammatory drug) such as Motrin®, Aleve®, Advil®
- Isoniazid, a medication used for tuberculosis
- Any blood thinners such as:
    - Vitamin K antagonists (for example, warfarin, Coumadin®)
    - Direct oral anticoagulants (for example, Xarelto® [rivaroxaban], Eliquis® [apixaban], Pradaxa® [dabigatran])
    - Clopidogrel (for example, Plavix®)
    - Ticagrelor (for example, Brilinta®, Brilique®)
    - Prasugrel (for example, Effient®)

There may be risks with the use of milvexian alone or with other drugs that are not yet known. During the study, the sponsor will learn new information about the study drug and the risks. It is possible that this new information might make you change your mind about being in the study. If new relevant information is discovered, your study doctor will tell you about it in a timely manner.

<u>Apixiban Risks:</u>

- Minor or serious bleeding events as with Milvexian
- Nausea
- Anemia
- Bruising
- Skin rash
- Abnormal liver tests
- Allergic reaction, potentially severe

Stopping apixaban suddenly increases the risk of blood clot related events.

Patients having spinal/epidural anesthesia or lumbar puncture are at increased risk of bleeding into the spinal area and forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis).

Apixaban should not be used if you currently have certain types of abnormal bleeding or have had a serious allergic reaction to apixaban.

<u>ECG Risks:</u> Adhesive patches/sensors will be applied to your skin. You may have temporary discomfort (pulling on the skin or hair) when the patches are taken off. You may also develop some minor skin irritation from the ECG patch glue.

<u>Blood Draw Risks:</u>

Blood samples will be collected. Using a needle to remove blood from a vein is called “a blood draw”. It may be necessary to try more than once to draw blood. A new needle will be used for each blood draw. You might feel pain or be light-headed from this.
You may have the following where the needle stick is inserted:

- Bleeding at the place where the blood is drawn
- Temporary discomfort
- Bruising
- Infection (rarely)

COVID 19 Related Risks: As the majority of visits for this study must be done in person to allow for exchange of the study medication, blood draws and physical examinations, there is an added risk of you being exposed to COVID 19 from other people within the facility or by use of public transit to attend your appointment. We have several measures in place to reduce this risk as much as possible including screening each patient who attends our facility, use of PPE for all staff and patients, restrictions on the number of people allowed within the space, enhanced general cleaning procedures and sanitization of any space a patient occupies immediately following their visit.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

During the study, the researchers could learn something about you that they didn’t expect. For example, the researchers may find out that you have another medical condition. The researchers will consult with medical experts as needed to evaluate the findings and will then share these results with you. You will be helped with arranging appropriate follow up and care.

I consent for the researchers to share findings with me:

- ❑ YES
- ❑ NO

ARE THERE ANY REPRODUCTIVE RISKS?

We do not yet know if Milvexian is harmful to an unborn baby.

If you are a woman who can get pregnant, a urine pregnancy test will be performed during screening. In some instances, a blood test may be taken to be sure you are not pregnant.

If you are sexually active and able to get pregnant you must use birth control during the study and for 4 days after your last dose of study drug. Birth control methods that can be used while in this study include:

- combined (estrogen- and progestogen) oral, intravaginal, transdermal, injectable hormonal birth-control
- oral or injectable progesterone-only hormonal birth control
- implantable progestogen-only hormonal contraception
- intrauterine device (IUD) or intrauterine hormone-releasing system (IUS)
- bilateral tubal occlusion (also known as having had your tubes tied)
- vasectomized partner (*the partner is your only sexual partner*)
- sexual abstinence for the entire duration of the study and for 4 days after your last dose

The type of birth control you use must be discussed with the study doctor before you begin the study. The study doctor must approve the method you use before you can enter the study. Women using a hormonal method of birth control (such as birth control pills, patch, or injectables) should use an additional non-hormonal method of birth control (such as male or female condom; or cap, diaphragm or sponge with

spermicide) during the study and for 4 days after the last dose of study drug. There is no evidence to suggest that milvexian affects male fertility.

If you get pregnant during the study, you must tell the study doctor immediately. You will have to stop taking the study drug. The study doctor will advise you about your medical care and will continue to follow up and collect information about your pregnancy and the health of your baby. Pregnancies occurring up to 4 days after the last dose of study drug must also be reported to the study doctor. Monitoring of your pregnancy will continue until the outcome is known. The study Sponsor will not pay for routine medical care relating to your pregnancy.

If you are a male participant: If your partner becomes pregnant in the time you are taking study drug, please inform the study doctor. The Sponsor will ask you and your partner to allow them to collect information about her pregnancy and the heath of the baby

WILL I BENEFIT IF I TAKE PART?

Taking part in this study may help prevent a stroke due to your atrial fibrillation while potentially lowering bleeding risk. These benefits are not guaranteed and there may not be any benefit to you by being in this study. During the study, your condition may stay the same or get worse. However, your participation may help future patients.

DO I HAVE TO PARTICIPATE? CAN I STOP BEING IN THE STUDY?

You do not have to participate in this research study. You can agree to be in the study now and change your mind at any time and for any reason. You can withdraw from the study and your decision will not change your regular care from your doctors. You can talk to the study doctor/staff before making this decision as some options may be possible to allow you to remain in the study with less visits to the hospital.

Knowing about your health status during the study and at its end is very important for complete safety follow-up and study information. If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to that point will remain part of the study because withdrawal of data in clinical trials could bias results. The Sponsor will not collect any new information from you for any parts of the study from which you have withdrawn your consent.

If you stop the study drug early, the study doctor/staff will continue to monitor your health until the study is officially completed. This is to make sure that you do not have any unexpected side effects that may have continued after you stopped the study drug. This information will be added to your study record.

If you have side effects after you stop study drug early, the study doctor/staff may contact your other doctors who you see regularly. By signing and dating this informed consent form, you agree that this information can be obtained and added to your study record unless you indicate otherwise.

If you do not want to continue participating in the study, you may discuss a reduced number of visits or test with your study doctor. Options may include:

- Less frequent clinic visits
- Telephone, email, letter or other contact with you
- Telephone, email, letter or other contact with a close friend, relative, or other doctor
- Review of available medical records (within country regulations)

The study doctor will continue to monitor your health status. If the study doctor/staff is unable to contact you by conventional means (e.g., clinic/practice visit, telephone, e-mail, fax, certified mail, or via your provided additional back-up contacts), he/she may also contact you by using public records to find out about your health status.

Knowing about your health status during the study and at its end is very important for complete safety follow-up and study information. By signing this consent form, you agree to grant permission for the study doctor to consult provided family member and close friend contacts, your other doctors, medical records or public records to determine your general health status in the event you are not reachable by conventional means (e.g., clinic/practice visit, telephone, e-mail, fax, or certified mail).

By signing this informed consent form, you agree that this information can be obtained and added to your study record unless you indicate otherwise.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

Yes, the study doctor/staff and the study sponsor have the right to discontinue study medication or remove you from the study at any time, with or without your agreement. These decisions will be made if:

- It is in your best medical interest to stop
- You do not follow the study staff's instructions
- The study is canceled
- You no longer meet the eligibility criteria

The study doctor/staff will discuss with you the reasons for removing you from the study, other treatment, or research options, and plans to follow up with you for side effects, if needed.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will not be paid for taking part in this study.

Parking or taxi fare to attend visits at the Foothills hospital site will be covered or reimbursed.

You, and if applicable, the Caregiver accompanying you, will be reimbursed for those expenses directly related to the study visits such as local travel and parking. Please confirm with study doctor the maximum approved amount.

In order to be reimbursed for expenses you paid, you must provide receipts that document your study-related travel expenses or parking costs. You must also share your banking information with the University of Calgary as they administer these payments electronically.

The Sponsor will pay the study doctor for the study drug and tests that are part of the study. Further/other visits and testing will be provided as needed as per Canadian and local provisions.

WILL MY RECORDS BE KEPT PRIVATE?

If you join this study, the study team will collect and use your personal data to do the research. This personal data may include, among other items, your name, address, date of birth, and health data. Health data includes past medical records and data collected during this study, including data collected when analyzing your blood samples and information in the ConnectCare system, a province-wide electronic health record. This data will be completely anonymized (will have all your personal information removed) before it is shared/recorded for analysis.

Once the consent is signed, you will be assigned a study code. No direct personal identifiers such as your name, initials, date of birth, healthcare number or social insurance number are included in Your Coded Data. This code can only be tracked back to you via a code key which is kept by the study staff.

This study will also collect information about your race and ethnicity which are considered sensitive personal information under data protection law. This sensitive data is necessary to decide if race and/or ethnicity affect how the study drug works and how safe it is in different populations.

Your year of birth needs to be collected because it is required to understand the impact of study drug on different age populations.

If you agree to give this information, your race and ethnicity, and your year of birth will be collected and entered into the same database where the other data about you will be entered, stored, and protected during this study. This will be coded data linked to your participant ID number.

If you have a skin reaction to study drug, your study doctor will document information about it, which may include a written description and photographs in order to manage safety.

Your medical records and study data will be reviewed by the sponsor of this study, or their representatives at IQVIA Inc. Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical records and/or your research records held at the University of Calgary for quality assurance purposes and for verification of clinical study procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. Other relevant organizations may include the Study Sponsor, Health Canada and/or other foreign regulatory agencies. By signing this form, you are authorizing such access.

Records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your identity will remain confidential.

Your Coded Data is needed for the Sponsor to learn about the study drug, get permission to introduce it on the market, monitor its safety and get it covered by health insurances and health service providers. Therefore, Your Coded Data will be used as planned in this study as well as within related research activities in order to:

- Understand how the study drug and similar medicines work in the body;
- Better understand Atrial Fibrillation and associated health problems;
- Develop diagnostic tests;
- Learn from past studies to plan new studies or improve scientific analysis methods;
- Publish research results in scientific journals or use them for educational purposes.

The Sponsor may share Your Coded Data with its affiliates, regulatory authorities, and service providers and, with select investigators and scientists conducting research, which is related to this study. Your Coded Data may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results. Your Coded Data may be transferred to countries outside of Canada, including to the United States, which may have different data protection rules. Your identity will not be revealed in any of these cases. The Sponsor will take appropriate safeguards and security measures to maintain the confidentiality of Your Coded Data when shared with other parties.

You have the right to access and correct the information collected about you during this study as long as the study staff keeps your medical information. You should ask the study staff if you have question about the results of your lab tests. Your right to view, access and correct information may be limited, such as if your request would adversely impact the privacy rights of others or if the study has not been completed.

You may decide to stop taking part or withdraw your consent regarding medical information at any time by notifying the study doctor. No new data will be added to the database; however, the study sponsor may still use information about you that was collected before you withdraw.

Your records and biospecimens (blood and urine) collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

HOW LONG WILL MY INFORMATION FROM THE STUDY BE KEPT?

Records containing your personal data will be retained at the study site for a period of 15 years following the end of the clinical trial. In addition, the sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified use.

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

If you suffer any research related injury or illness, you should contact your study doctor for medical care and advice. You will receive all medical treatment for injury or illness that is a direct result of (1) taking the study medication, or (2) procedures required by the study. Such medical treatment will be at no cost to you, but depending on your injury or illness, may be paid for by your public health insurance, the Sponsor , Janssen Pharmaceuticals, but not the University of Calgary, Alberta Health Services, or the Researchers.

Although no funds have been set aside to compensate you for such things as lost wages or discomfort in the event of research related injury or illness, you do not give up any of your legal rights by signing this consent form.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact Dr. George Veenhuyzen at (403) 944-3385 or 403-210-6047 with any questions or concerns about the research or your participation in this study, or if you feel that you have experienced a research-related injury or reaction to the study drug.

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

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. 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.# NCT05757869

This study has been submitted to *Health Canada* and has been allowed to proceed.

HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?

After all study participants have completed the study. the Sponsor will analyze the data and offer you a summary of the study results that are understandable to the general public. The summary will not include individual results or information that can identify you. The summary may be made available to you through a web portal, local and/or national websites, or directly from the study team.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you.

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

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care.

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the study drug, and possible risks and side effects have been answered to my satisfaction.
- I give permission for my doctors, other health professionals, hospitals, or laboratories to release information to the study site and study doctor about my disease and treatment for the purposes of this study. I understand this information will remain confidential.
- I have been informed that the study team will inform my other doctors about my participation in this study, and I agree to this.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I consent to the processing and transfer of my personal data as described in this consent form.
- I understand that I will be given a signed and dated copy of this document to keep.

Participants PRINTED name	Participant's Signature	Date

Witness PRINTED name	Witness Signature	Date

To the best of my knowledge, the subject signing this Consent Form has had the Study fully and carefully explained by me and the subject has been given the opportunity to ask questions about the Study, the information contained in this Consent Form, and his/her participating in the Study.

Investigator PRINTED name	Investigator Signature	Date

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

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