

CONSENT FORM

TITLE: Referral to Weight Management Centers in Obese Patients with Atrial Fibrillation: A Prospective Review on Weight Loss Efficacy, Atrial Fibrillation Burden, and Therapeutic Practices (REWEIGH-AF)

SPONSOR: Libin Cardiovascular Institute

Servier Canada Inc.

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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. Participation in this research is completely voluntary and will in no way affect the standard of your care.

# BACKGROUND

Atrial fibrillation (AF) is an abnormal heart rhythm characterized by irregular and rapid heartbeats of the upper part in of your heart (the atrial chambers).

# Like other heart conditions, AF may be aggravated by a number of common risk factors. These include being overweight. In this project we want to find out if losing weight will reduce the amount of AF symptoms patients have. Recent information from other research is suggesting that weight loss reduces the amount of AF patients have. One study has shown people who lose 10% or more of their body weight are six times more likely to have less recurrent AF episodes. Losing weight also appears to be beneficial to other common health problems that can make AF worse such as high blood pressure and sleep apnea.

## **WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to find out if patients with AF will benefit from a treatment strategy which includes weight loss management through a physician lead clinic.

**WHAT WOULD I HAVE TO DO?**

If you decide to participate you will be expected to attend visits to the Calgary Weight Management Centre (Bridgeland Professional Centre, 1010 1 Ave NE) as per their regular schedule. You will also be contacted ( by telephone or face to face) for further information regarding your AF and general health either by AF clinic nurses or study staff at 6 and 12 months from enrollment.

These visits will include

* Medical history and review of medications
* Review of lab work
* AF symptom questionnaire

## **WHAT ARE THE RISKS?**

The risks of participating in this study are small. The therapies monitored in this study are standard practices for patients with AF and obesity.

Unexpected side effects of counselling, education, physical activity, medications and procedures may potentially occur.

You may discuss alternative forms of therapy with your doctor. Your participation in this study is completely voluntary, and you may refuse simply by telling your doctor. If you decide not to participate, your decision will not in any way affect your present or future medical care and treatment. At any time, your doctor can decide to stop your participation in this study. If new information about treating atrial fibrillation is available during the course of this study, your doctor will discuss this with you.

## **WILL I BENEFIT IF I TAKE PART?**

If you agree to participate in this study there may or may not be a direct benefit to you. If you are in the study because you have been identified as having Atrial fibrillation. Your condition may be improved during the study but there is no guarantee that this research will help you. The information we get from this study may help us to provide better treatments in the future for patients with AF.

## **DO I HAVE TO PARTICIPATE?**

No, your participation in this study is completely voluntary. You may also withdraw from the study at any time without providing a reason. You may also withdraw any information that has been collected about you until the data is “locked” prior to publication. Withdrawal can be done by contacting the study staff.

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

No, you will not be paid to be in this study, nor is there any cost to you to attend the Weight Management Clinic. Parking costs for followup visits to the Foothills or SHC sites will be paid.

**WILL MY RECORDS BE KEPT PRIVATE?**

If you decide to participate in the study the staff will only collect the information they need for the study, which includes information stored in the Provincial NETCARE database. A study ID number will be used to identify you. Your data will be stored on an electronic database housed at the University of Calgary.

Records identifying you will be kept confidential and secure to the extent permitted by applicable law and will not be disclosed or made publicly available.

Original (identifiable) data may be viewed by the Conjoint Health Research Ethics Board which oversees the ethical conduct of this study, as well as Dr Kuriachan as he monitors the data for safety and completeness.

It is expected that the results of the study will be published, however your identity will remain confidential.

**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*.* If you have further questions concerning matters related to this research, please contact: Dr. Vikas Kuriachan (403) 944-3282

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.

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| Participant’s Name |  | Signature and Date |
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| Investigator/Delegate’s Name |  | Signature and Date |
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| Witness’ Name |  | Signature and Date |
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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