

**UNIVERSITY OF CALGARY**

**CONSENT TO PARTICIPATE IN RESEARCH**

**TITLE**: Hearts in Rhythm Organization (HiRO) National Registry and Bio bank:

Improving Detection and Treatment of Inherited Heart Rhythm Disorders to Prevent Sudden Death

**SPONSOR:** University of Calgary

**FUNDER:** Canadian Institutes of Health Research (CIHR)

**PRINCIPLE INVESTIGATOR**: Dr. Erkan Ilhan (403-215-2440)

# INTRODUCTION

Dr. Erkan Ilhan andassociates from the department of Cardiac Sciences at the University of Calgary are conducting a research study.

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.

You were identified as a possible participant in this study because you or a first-degree (blood-related mother, father, sister or brother) family member are being investigated for or have been diagnosed with an inherited heart rhythm condition. Your participation in this research study is voluntary.

# ****WHY IS THIS STUDY BEING DONE?****

Inherited heart rhythm conditions are rare and complex. Cardiologists have many questions about how best to diagnose and treat these patients and the families who may also be affected. Gathering the healthcare information from individuals and their first degree family members with inherited heart rhythm conditions and sudden unexplained cardiac arrest will lead cardiologists and other healthcare providers to a better understanding of these conditions and hopefully lead to improved care.

# HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The National HiRO research team hope to gather data on 10,000 participants across Canada by June 2025. We expect up to 400 people will take part in this study through the University of Calgary.

# WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

This study is designed to collect all of your healthcare information that relates to your inherited heart rhythm diagnosis, or unexplained cardiac arrest. If you are a family member participating, we will collect all the tests and results that you will have to help determine whether you too are at risk. You will not be required to do anything out of your standard medical care for someone examined or treated for an inherited heart rhythm condition or an unexplained cardiac arrest. If you are not seen in the heart rhythm clinic routinely we may telephone you just to stay updated with your heart health. Once you have signed this consent form your healthcare information will be collected. It will include your:

* Healthcare history
* Race
* Sex
* Height, weight, age, blood pressure
* Medications
* Family cardiac history
* Results from all of your cardiac tests such as Magnetic Resonance Imaging (MRI), Echocardiogram, Electrocardiograph (ECG), stress test, Electrophysiology study with voltage mapping and genetic testing results
* A family tree/pedigree will be constructed by your research staff (doctor or coordinator)
* Any other testing done that may be related to your heart health will also be collected

*Follow Up*

Most patients with inherited heart rhythm conditions or sudden unexplained cardiac arrest are seen at least once a year by their heart rhythm specialist. When you see your heart rhythm specialist your healthcare information will be collected and entered into the registry.

**Optional Studies**

You do not have to participate in research to be cared for by the doctors and other healthcare professionals working at the University of Calgary.

1. Bio Bank

You are also eligible to participate in an optional bio bank arm of this registry, which means that we will ask you to donate a blood sample to store for research testing in the future. If you would like to participate in this optional study, we will give you a separate Participant Information and Consent Form that describes the research and any associated risks and benefits so that you can decide if you would like to participate.

By signing this consent form, you authorize the research team to enter your de-identified health information in the HiRO Registry and use your HiRO Registry data for approved research studies, currently and in future. Any subsequent research studies looking to access the data system for research purposes related to the core goals for which the data was originally collected will require review and approval by the Research Ethics Board that the primary researcher is affiliated with.

# HOW LONG WILL MY INFORMATION BE KEPT FOR THIS STUDY?

Your healthcare information will be collected indefinitely or at least until 2025. It is important for you to understand that the information gathered into the registry will be governed by the study investigators, and Dr. Ilhan will have the ultimate responsibility for the data. In the future there may be other researchers at other institutions in Canada and internationally that may ask to share the data that is gathered. Sharing information amongst researchers is important for improving understanding and medical treatment of rare conditions. No information that could identify you will be shared with anyone outside of Dr. Ilhan’s research team. You will not be contacted for future use of the coded information in the registry with other researchers. Your research information will not be sold for profit.

# ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

Taking part in this registry will not put you at any physical risk. The only known risk to your participation would be that your research information may be linked to your healthcare records that may identify you. However, the research information is secured in the same manner as your clinical records and access is limited to research personnel only.

Any risks associated with the optional studies mentioned above will be described in the separate Participant Information and Consent Forms provided for each of those optional studies.

Discrimination by employers and insurance companies may result if you are diagnosed with an inherited heart rhythm condition, but this risk should not be increased by your participation in this project.

# ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?

There may be no direct benefits to you as a result of your participation in this study. However, information obtained during this study may benefit other patients who have a clinical condition similar to yours. Similarly, data from other participants in the study may shed light on cases such as yours. You will be helping to advance the knowledge and understanding of inherited heart rhythm conditions.

# WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?

If you choose not to participate in this registry, your information will not be collected. Your decision not to participate will not affect any treatment that you receive. There will be no disadvantages should you decide not to participate in this study.

# CAN I STOP BEING IN THE STUDY?

You may withdraw your participation at any time without giving reasons.

At any time during your participation, the research doctor (investigator) may wish to take you out of the registry or may discontinue the registry. If this happens, the reasons will be explained to you and you will have the opportunity to ask questions about this decision.

# WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

During the study, the researchers could learn something about you that they didn’t expect. In rare cases there may be future findings about your **heart** health, that are important to report to you. In this case Dr. Ilhan or your own doctor will meet with you to explain the findings and how it might affect your care and lifestyle. You will have the choice whether to have this information included in your healthcare file.

# WITHDRAWAL OF STUDY DATA

If you choose to participate and later decide to withdraw, you have the right to request the withdrawal of your information collected during your participation. This request will be respected to the extent possible. However please note, that there may be exceptions where the information will not be able to be withdrawn. For example, where the research information has been shared with another researcher, where it has been merged with other research information or if the information has already been included in published research findings. In all three of these cases, the information used cannot be used to directly identify you. If you would like to request the withdrawal of your information, please let your research team know.

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

You will not be paid for your participation in this research study. If you are required to come into the clinic for a visit specifically related to this study, you will be reimbursed for parking costs.

# WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

Your confidentiality will be respected.  However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or designate by representatives of the University of Calgary or the Conjoint Health Research Ethics Boardfor the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

Your healthcare information will be given a unique study code that will identify your research information. All of your personal information will be removed such as your name, healthcare number and date of birth. This data will be copied into a research data base housed on the Amazon Virtual Private Network (IP Address: 35.182.13.149/5/hiro), and will be backed up on University of British Columbia Research Server (2405 Wesbrook Mall, Vancouver, BC V6T1Z3).

Information that contains your identity will remain only with the Dr. Ilhan and/or designate and kept in a secure location in the research office of Dr. Ilhan and his research staff. The list that matches your name to the unique study code number will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you that has been entered in this research registry and if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

In the future the researchers may want to share the information collected about you with other doctors and scientists outside of Canadian borders. This may increase the risk of disclosure of information because the laws in those countries (for example the Patriot Act in the United States) dealing with protection of information may not be as strict as in Canada. However, all study related data [and samples], that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the future possibility that your coded information might be transferred to research organizations located outside of Canada*.*

**WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?**

**Use of My Specimens:**

Any specimens (e.g., tissue, blood) obtained for the purposes of this study will be provided to Dr. Krahn and his team. These specimens will not include information that identifies you directly. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such products.

My research data and/or specimens may be kept for use in future research to learn about, prevent or treat other health-related problems.

❑ YES

❑ NO

**Genetic Research:**

When you donate your blood or tissue for genetic testing or research, you are not only sharing genetic information about yourself, but also about biological (blood) relatives who share your genes or DNA.

There are laws in Canada that protect your genetic information, and privacy and confidentiality (i.e., Genetic Non-Discrimination Act, Bill S-201). However, laws in other countries regarding genetic information, privacy, and confidentiality may differ. You may not be afforded the same rights when your information and biological samples are sent to places outside of Canada.

**RESEARCHER CONFLICTS OF INTERESTS**

There are no researcher conflicts of interests to report for this study.

# CONTACT FOR FUTURE RESEARCH

University of Calgary researchers may contact me in the future to ask me to take part in other research studies.

❑ YES

❑ NO

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

It is important that you tell the researchers if you believe that you have been injured because of taking part in this study.

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the CIHR, Dr. Ilhan, the University of Calgary, Alberta Health Services or the Researchers. However, you still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

# WHOM MAY I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

# The Research Team:

You may contact Dr. Ilhan at (403) 215-2440 or Adam David at (403) 210-6414 with any questions or concerns about the research or your participation in this study.

# 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.

# HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?

You can find out about the study results and any publications that come from this study on the HiRO website: <https://hiro.heartsinrhythm.ca>.

# 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

# HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

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 take part in the study. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

# SIGNATURE OF STUDY PARTICIPANT

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

Name of Participant

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

Signature of Participant Date

# SIGNATURE OF PERSON OBTAINING CONSENT

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

Name of Person Obtaining Consent Contact Number

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

Signature of Person Obtaining Consent Date

**SIGNATURE OF THE WITNESS**

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

Name of Witness

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

Signature of Witness Date

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