**Participant Information and Consent Form**

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

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

**Investigator:** Dr. Habib Khan

London Health Sciences Centre University Hospital

London, Ontario

519-615-1950

**Sponsor:** Dr. Andrew Krahn

University of British Columbia

## Note: If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say “you” or “your” in this consent form, we mean you and/or your child.

You are being invited to participate in the Hearts in Rhythm National HiRO Registry and Biobank because you or a first degree family member has been diagnosed with an inherited heart rhythm disorder (arrhythmia).

If you wish to participate in this study, you will be asked to sign the consent form at the end of this letter of information before any study procedures can begin. You should only sign the consent form if you are volunteering to participate and after you have fully read and understood how the study will work, what the study doctor and study staff expects you to do, and any possible benefits and risks that may result from your participation. You will receive a copy of the signed letter of information and consent form for your personal records so you can refer to it while you are in this study.

## WHO IS CONDUCTING THE STUDY:

Dr. Habib Khan is the doctor conducting the study at London Health Sciences Centre (LHSC). Dr. Andrew Krahn from Vancouver, British Columbia is leading the project with other Canadian, Inherited Heart Rhythm Disorder clinics that will also be recruiting participants for this study. The other centres involved in this study include Montreal, Laval, Hamilton, Ottawa, Toronto, Kingston, Calgary, Victoria, and Halifax.

## BACKGROUND

## Inherited Heart rhythm disorders include arrhythmogenic right ventricular cardiomyopathy (ARVC), Brugada Syndrome, Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) and Long QT Syndrome (LQTS). They affect one in 200 Canadians and can result in tragic sudden cardiac death (SCD), reduced quality of life and productivity, and high health care expenditure. SCD kills 30,000 Canadians/year. Importantly, clinical screening for at-risk individuals has tremendous potential for timely monitoring and treatment. Treatment typically involves lifestyle modifications, such as avoidance of strenuous exercise, drugs that may worsen the phenotype or medical therapy with beta-blockers or quinidine which can provide substantial protection from SCD. Patients who have cardiac events while on medical therapy, have suffered an unexplained cardiac arrest (UCA), or are deemed sufficiently high risk are offered an implantable cardioverter defibrillator (ICD). ICD therapy provides protection however; it is commonly associated with life-long device related complications.

## PURPOSE:

To create a Canadian research database and bio bank, designed to collect healthcare information and samples on patients being investigated and treated for inherited heart rhythm conditions. This will provide a means to study inherited heart rhythm conditions that will provide an accurate picture of this population in Canada.

## PARTICIPATION:

This study is designed to collect all of your healthcare information that relates to your inherited heart rhythm diagnosis or if you are a family member participating, we will collect all the tests and results that you will have to help determine whether you have the same condition. You will not be required to do anything out of your standard medical care. If you agree to participate and sign this consent form your healthcare information will be collected.

It will include your:

* Healthcare history
* Ethnicity
* 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
  + Genetic testing results
* A family tree or pedigree will be constructed by your study staff (doctor or coordinator)
* Any other testing done that may be related to your medical condition will also be collected

Your healthcare information will be given a unique study code that will identify your research information. This code will not include any personal identifying information. The study-related data will be copied into a research database housed on the University of British Columbia Information Technology Virtual Server UBC University Data Centre, 2405 Westbrook Mall, Vancouver BC V6T1Z3.

*Follow Up*

Most patients with inherited heart rhythm conditions and their family members (who have not had the diagnosis ruled out) are seen at least once a year by their cardiologist. When you see your cardiologist at your yearly visits, the study-related information will be collected and entered into the research database.

Your healthcare information will be collected at least until 2025 and will be kept indefinitely. It is important for you to understand that the data gathered into the database will be owned by the study investigators, and Dr. Krahn will have the ultimate responsibility for the database. In addition to the research carried out by the study doctors, there may be other researchers at other institutions in Canada and internationally that may ask to share the data that is gathered. Sharing data 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 the HiRO research team. You will not be contacted for future use of the coded data in the database with other researchers. Your research data will not be sold for profit.

## BENEFITS:

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 rhythms.

## RISKS:

Taking part in this study will not put you at any physical risk. The only known risk to your participation would be that your research data may be linked to your healthcare records that may identify you. However the research data will be securely stored on a secure database.

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

## Optional Studies

You do not have to participate in any research, including optional studies, to be cared for by the doctors and other healthcare professionals in the Inherited Heart Rhythm Clinic at LHSC.

## Bio Bank

You are also invited to participate in an optional bio bank arm of this study. If you agree to participate in this bio bank, 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 Letter of 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.

## Next of Kin Consent: Post Mortem (after death) Specimens for Research

If you have a first-degree blood related family member who died from cardiac arrest due to an inherited heart rhythm condition, a copy of your family member’s autopsy report (how and why death occurred) or coroner’s report is obtained and added to your clinic record as part of standard of care. The deceased patient’s next of kin (NOK) (estate trustee, spouse, adult children, parents or siblings) provides authorization for the clinic staff to obtain the autopsy from the Coroner’s Office.

The researchers would also like to collect healthcare information and bio specimens (materials taken from the human body, such as tissue, blood, plasma) from patients who have died from a cardiac arrest that is believed to be related to inherited heart rhythm conditions and include the information and bio specimens in the National HiRO Registry. This is being done to learn more about these rare complex cases in order to help prevent unexplained cardiac arrest. To be able to use the deceased’s healthcare information and bio specimens for research, it is necessary for us to obtain separate permission of the next of kin (NOK), we will give you a separate Letter of 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.

**ALTERNATIVE TO STUDY PARTICIPATION:**

You do not have to be in this study to be treated for your medical condition. If you choose not to participate in this study, the study investigators will not collect your study- related data. You will be followed per standard of care in the Inherited Heart Rhythm Clinic at LHSC. Your decision not to participate in this study will not affect any treatment that you receive.

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## VOLUNTARY PARTICIPATION/WITHDRAWAL:

Your participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. If you wish to withdraw please notify the study doctor, Dr. Habib Khan.

## CONFIDENTIALITY:

Protecting your privacy is very important to us. Your study-related health records will remain confidential to the extent allowed by law. A study identification number will identify you. Information about your heart rhythm condition will be securely stored in Dr. Habib Khan’s research office. The information recorded in the research database will be identified by your unique study code number and will link the research record with your health record. This will allow the information in the research database to be updated at each hospital visit. The master list that contains the link to the code number and your name and other identifying information will be kept on the protected hospital network server with access only to Dr. Habib Khan and his research staff. Data will be stored in the database for as long as the study will be useful, the local records will be kept for 15 years following the end of the study and they will all be destroyed following the standard 15 year retention period.

De-Identified study data is stored on the electronic database called PDG. No research data will ever be stored on PDG in an identifiable manner. When the you sign the e-consent form, just your name/signature will be temporary stored until the research coordinator logs on and downloads your returned consent form. Once the consent form is downloaded, all data related to that consent form (including their name/signature) is permanently deleted. The research coordinator will then add you to the master decoder sheet, a file that correlates study participant ID and patient name, and add you to the PDG data system in a de-identified manner. Therefore, name is always permanently deleted from the system before the research ID# is assigned and any data is uploaded. The master list that contains the link to the code number and your name and other identifying information will be kept on the protected hospital network server with access only to Dr. Habib Khan and his research staff

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the study investigators 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. The results of this study may be published as a scientific paper to help other doctors help their patients. However your privacy will be protected and you will never be identified by name or by a description of you.

In the future researchers may want to share the data 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 your de– identified information might be transferred to organizations located outside of Canada*.*

Studies involving genetics now routinely collect information on race and ethnic origin because of the inherited nature of the conditions being studied. Providing information on your race or ethnic origin is voluntary.

Representatives of Western University’s Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. Representatives of Lawson’s Quality Assurance and Education Program may also require access to your study-related information in order to ensure the study is following the proper laws and regulations.

## Future Research

The data that we are collecting during this research will also help to identify those patients who may be eligible to participate in future research projects that involve more than just an analysis of existing data. In the future you may be approached to participate in other research projects at the Inherited Heart Rhythm Clinic at LHSC.

In that instance you will be given detailed information describing the project and you will have the opportunity to decide at that time whether or not you want to participate in the new project.

# COMPENSATION

This study will not cost you anything; you will not be paid for your participation in this research. In the long term, the results of this research study may be valuable for commercial and/or intellectual (for example patent) purposes. It is important that you realize that you will not have any claim on or receive any money from products that may result from this long term investment.

## CONTACT INFORMATION:

Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

If you have any questions or desire further information about this study before or during participation, you can contact:

Dr. Habib Khan, Study Doctor 519-615-1950

Research Coordinator 519-685-8500, Ext. 36808

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Experience Office at LHSC at (519) 685-8500 ext. 52036 or access the online form at: https://apps.lhsc.on.ca/?q=forms/patient-experience-contact-form.

A copy of this Letter of Information and Consent will be placed on your hospital chart and you will receive a copy to take home with you. Participation does not release the investigators from their professional and ethical responsibility to you. You do not waive your legal rights by signing the consent form.



**Consent Form**

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**Investigator:** Dr. Habib Khan

I have read the letter of information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Future Research:

I would like to be informed of future research projects associated with the Inherited Heart Rhythm Clinic at LHSC. □ Yes □ No

*Participant’s Signature Printed Name Date*

*Signature of Person Printed Name Date Obtaining Consent*

*Substitute Decision Maker Printed Name Date Signature*

*Witness Signature Printed Name Date*

*Translator Signature Printed Name Date*