INFORMATION AND CONSENT FORM

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| **RESEARCH PROJECT: MP-33-2021-2872**  Hypertrophic Cardiomyopathy - Registry, Biobank and Imaging Data Repository  **HiRO-HCM**  **Principal Investigator**  **Dr. Habib Khan**  **Granting agencies**  Canadian Institutes of Health Research (CIHR)  Fonds de la Recherche du Québec – Santé (FRQS)  Montreal Heart Institute Foundation |

**PREAMBLE**

In this consent document, “you” always refers to the study participant If you are a substitute decision maker (SDM) (i.e. someone who makes the decision of participation on behalf of a participant), please remember that “you” refers to the study patient. If an SDM is needed for this study, you will be asked to review and sign the consent form on behalf of the participant.

We are inviting you to take part in this research biobank because you have hypertrophic cardiomyopathy or you carry a genetic variant predisposing to this disease. This research database and biobank are created for the purpose of carrying out future research projects in hypertrophic cardiomyopathy. You are entirely free to accept or refuse to participate.

Before you agree to take part in this registry and biobank and sign this consent form, please take the time to carefully read, understand and consider the following information.

This form may contain words that you do not understand. We invite you to ask the investigator in charge of this registry and biobank or other staff members involved, any questions you consider useful and ask them to explain any words or information that is not clear to you.

**NATURE AND OBJECTIVES OF THE RESEARCH PROJECT**

Hypertrophic cardiomyopathy is one of the most prevalent inherited cardiac diseases, affecting one in 500 individuals. It is characterized by an enlargement (thickening) of the heart muscle which can lead to heart function disturbances. This disease can cause heart failure, atrial fibrillation, stroke, or arrhythmias that can lead to cardiac arrest.

In recent years, several studies have identified genes (DNA) linked to inherited cardiac disease. The results of these studies provide information that then guide medical specialists in the care of their patients.

The HiRO-HCM registry and biobank, in which you are invited to participate, will bring added value to the understanding and treatment of hypertrophic cardiomyopathy.

The objective of this study is to establish a database, cardiac imaging databank and a biobank of samples from patients with hypertrophic cardiomyopathy as well carriers of genetic defects predisposing to this disease. HiRO-HCM will allow various research projects to be performed in the future in order to:

1) assess the natural history of HCM and identify genetic and non-genetic factors affecting the occurrence of complications.

2) characterize the contribution of different types of genetic variants in disease manifestation in carriers of gene defects.

**NUMBER OF PARTICIPANTS AND LENGTH OF PARTICIPATION**

Approximately 2000 participants will participate in the HiRO-HCM registry and biobank from approximately 16 participating centers in Canada and the United States. Of those, about 300will be from the London Heath Sciences Centre.

If you agree to participate in the HiRO-HCM registry and biobank, a member of the research team will contact you to collect your medical data. This first visit will take approximately 30 minutes, and will also include the collection of biological samples described further in this document. In addition, one of the research staff may contact you, yearly, to collect data on your medical conditions related to hypertrophic cardiomyopathy. This visit will be by telephone and will last approximately 15 minutes. Alternatively, this data collection can be completed at the time of your clinically organized appointments to LHSC or as a stand-alone study visit.

The HiRO-HCM database, images and biological samples is established for an indefinite period of time, as long as funding to maintain it is available. Funding is currently available until at least 2026. As a result, different research projects using the data, images and biological samples that you agree to provide can be done for several years. The projects may be completed by making data and/or bio samples available to other research parties. This would only occur following approval by the MHI ethics committee, the HiRO-HCM steering committee, and the local ethics committee.

**RESEARCH PROJECT FUNDING**

The researcher in charge of the HiRO-HCM registry and biobank received funding from the following granting agencies to establish and manage this registry and biobank: Canadian Institutes of Health Research (CIHR), the Fonds de la Recherche du Québec - Santé (FRQS) and the Montreal Heart Institute Foundation.

If you would like additional information about the funding for this study, or about the role of the doctor in charge of the study, please speak to the study staff or contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

**RESEARCH PROJECT PROCEDURES**

**Database component**

If you agree to participate in this registry, data will be collected from your medical file or during your regular medical follow-ups with your attending physician.

Once you have signed the information and consent form, the following information will be collected from your medical file:

* Cardiac and other medical history;
* Ethnicity;
* Weight, height and blood pressure;
* Current medication;
* Results of clinical and genetic investigations previously done or that you will undergo for your heart condition;
* Any other tests done that may be related to your illness.

In addition, by participating in HiRO-HCM you agree that the results of the tests and exams carried out in the future during your regular follow-ups will be collected to be included in the registry. If you choose to participate, a sample of your blood or saliva will be collected for genetic analysis. No tests other than this sample collection and those requested by your attending physician will be performed for your participation in the HiRO-HCM.

The following information will be collected at your annual follow-ups for as long as registry funding is available:

• Symptoms related to hypertrophic cardiomyopathy;

* Clinical events related to heart disease such as the occurrence of heart failure, blood clots, and cardiac arrhythmia;
* Cardiac imaging exams;

• Electrocardiograms;

• Interrogation of your cardiac implantable device (monitor, pacemaker, defibrillator), if you have one.

Patients with hypertrophic cardiomyopathy and some carriers of a genetic defect predisposing to this pathology are seen once a year by their cardiologist. If you do not see your cardiologist within a year, a follow-up phone call will be made by a delegated member of the London Heart Rhythm Program research team.

**Biobank component: biological sample collection**

A sample of your blood (approximately 10-20 ml, or 2-4 teaspoons) will be drawn. This sample will be taken at your research center by a healthcare professional and will take 5 minutes. From this blood sample, DNA will be extracted for genetic studies, and plasma for biomarker studies.

In the event that it is not possible for you to provide a blood sample, you will be asked for a sample of your saliva, which you can retrieve yourself at home using a collection kit. A member of the research team will send you the kit which you can then return to the Beaulieu-Saucier Pharmacogenomics Center (PGx) of the Montreal Heart Institute. Instructions regarding saliva collection and shipping will be provided to by the study coordinator.

This saliva sample will allow DNA extraction for genetic studies, but will not allow plasma extraction. The research team may ask for your permission to take a blood sample as well in the future.

In addition, if you require cardiac surgery for your medical care, a sample of heart tissue taken during the procedure will also be deposited in the biobank. This sample will allow additional analyses, such as gene expression in diseased heart muscle. No additional samples will be taken from your heart. The stored sample is from tissue extracted by the surgeon to treat your disease in a procedure that is part of your usual medical care and not for this research study.

The analyses done on these samples may identify gene variations likely to be involved in hypertrophic cardiomyopathy and potentially to learn more about the disease, understand and treat it.

**Cardiac imaging bank section**

If you agree to participate in the study, copies of cardiac imaging exam, that you have had or will undergo as part of your usual medical care, will be transferred confidentially and securely to a secure server and stored by the Canadian Imaging Network (CAIN), located at the Montreal Heart Institute. The cardiac imaging repository is under the responsibility of Dr. Rafik Tadros.

This imaging data repository will contribute to research efforts by allowing centralized analyses of heart imaging, in order to better understand the influence of genetic variants on the severity of HCM.

Images of the following exams will be collected, if available:

* first and last cardiac ultrasound;
* first and last cardiac magnetic resonance.

**RISKS ASSOCIATED WITH THE RESEARCH PROJECT**

Participation in the HiRO-HCM registry and biobank does not imply any specific tests or medical exams. Your participation consists of you accepting that your clinical data and cardiac imaging acquired by your treating physician be collected and deposited in a research database. Your participation also consists in submitting to a blood and/or saliva sample so that the plasma and DNA can be extracted to be deposited in the biobank.

Taking a sample of your blood may cause discomfort when the needle is inserted into a vein in your forearm. Side effects may be fainting, inflammation of the vein, pain, bruising, or bleeding where the sample is taken. There is also a small risk of infection at the needle insertion site.

Participation in HiRO-HCM involves a risk linked to a possible breach of confidentiality concerning your personal information and your medical and genetic data which could result in an invasion of your privacy, and lead to discrimination on the part of employers or insurers to you. When you allow the collection of your genetic data, you are sharing genetic information not only about yourself, but also about biological relatives (related by blood) who share your genes and DNA. However, the risk of breach of confidentiality is minimal. Every effort is made to protect your privacy and ensure your confidentiality, as described in the "Confidentiality" section. Researchers using the registry and biobank for research purposes will not receive any data or samples that have not been previously coded (therefore your personal identifiers such as your name will have been removed and researchers will not know your identity).

Since 2017, a Canadian law has prohibited anyone from forcing a person to undergo a genetic test or to communicate the results of a genetic test to provide them with goods or services, or to enter into or maintain a contract with them. This law applies to an insurance company or an employer. Accordingly, the London Health Sciences Centre will not communicate your results to any insurance companies or employers without consent from you. Furthermore, you yourself have the right to accept or refuse any such request made to you.

COVID-19 pandemic

With the situation of the COVID-19 pandemic, risks related to the spread of the virus may be incurred during travel and by going to the research center. The staff has taken necessary measures to protect you and minimize the risks. Infection prevention and control rules are strictly applied, whether in connection with the wearing of personal protective equipment, hand hygiene and the disinfection of surfaces and equipment.

**BENEFITS**

You may personally benefit from your participation in this registry and biobank, but this cannot be guaranteed. However, the results obtained will contribute to furthering scientific knowledge in this field.

**RETURN OF INDIVIDUAL RESULTS AND OF INCIDENTIAL FINDINGS**

The research projects that will be conducted thanks to the HIRO-HCM bank will not have as objective to provide you with the results of analysis, exams or of medical or genetic tests. Normally, no personal results will be transmitted to you. However, even though it is not what they are looking for, a research team could identify an abnormality while studying your data, images or biologic sample part of the bank.  If this situation should occur and a new medical condition concerning you was discovered, it will be possible to contact you to inform you if ALL of the following conditions are met:

* You have agreed to be contacted to receive individual results;
* It involves a serious and foreseeable risk for your health or that of your biological family;
* The risk of injury can be avoided by prevention or controlled through scientifically approved and available treatment;
* If this is a genetic disease, you agree to first meet with a genetic counsellor who will explain the possible consequences, benefits and risks of the test results to you.

Any return of individual results and incidental findings presupposes your commitment to inform the research team of any change in address so that they can contact you if necessary.

**PROCEDURE IN THE EVENT OF DEATH**

In the event of your death while participating in the HiRO-HCM biobank, it may be useful for the research project investigator and the sponsor to know information about your health condition at the time of your death and the causes of your death. For this purpose, you may authorize the project investigator to obtain a copy of your medical record from another health care or extended care facility. This may include a copy of your record from the emergency department or from any department of another hospital, nursing home or medical clinic. The information collected will only be used for the purposes of this research and will remain confidential. It may be shared with the sponsor or granting agency of this study.

**VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW**

Your participation in this biobank is voluntary and you may refuse to participate. You may also withdraw from HiRO-HCM at any time, without giving any reason, by informing the research team.

Your decision not to participate in this registry and biobank, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the teams providing them.

The investigator in charge of this biobank, the Research Ethics Board, the granting agency, or the sponsor may end your participation without your consent. This may happen if new findings or information indicate that your participation is no longer in your interest, if you are not following the study instructions, or if there are administrative reasons to terminate the project.

If you withdraw from this bank or are removed from it, the data, samples and images will be destroyed. However, information and data that have already been used to carry out a research project will be retained, analyzed or used to ensure the integrity of the project.

Any new knowledge acquired during the duration of this registry and biobank that could have an impact on your decision to continue to participate will be communicated to you quickly.

**CONFIDENTIALITY**

During your participation in HiRO-HCM, the investigator in charge and the research staff members will collect information in a study file about you which is required to meet the scientific goals of the HiRO-HCM registry and biobank.

This may include information from your medical chart concerning your past and present state of health, your lifestyle, as well as the results of all tests, exams, and procedures that will be performed. Additional information that we will be collecting from you includes your full name, initials, home address, sex, age, ethnicity, and your hospital patient identification number (PIN). We will also be collecting your phone number and email address to allow us to contact you about study related items.

Blood, saliva, tissue samples and copies of medical imaging exams will be under the responsibility of the principal investigator and kept for an indefinite period for the exclusive purposes of this registry and biobank. Blood, saliva and tissue samples will be stored in the Beaulieu-Saucier pharmacogenomics laboratories (PGx) located at the Montreal Heart Institute or in the premises of the research center of the Montreal Heart Institute, under the responsibility of Dr. Rafik Tadros. Biological samples and copies of medical imaging exams will be identified by a code number. All information collected will remain confidential within the limits provided by law. You will only be identified by a code number. The physician co-responsible for the bank at the center where you were enrolled to participate will keep in a secure place a list allowing him to link your HiRO-HCM identification code to your identity. Only this co-responsible physician and his research team will have access to the key linking your identification code in HiRO-HCM to your identity.

The researcher responsible for this registry and biobank will send the coded data concerning you to the sponsor or his representatives.

The research data collected from this database, images and biobank may be published or be the subject of scientific discussions, but it will not be possible to identify you.

All research projects to be carried out using the HiRO-HCM bank must first have been approved by a competent research ethics committee.

You have the right to consult your data in HiRO-HCM to verify the information collected and have it corrected if necessary.

**Who will have access to your personal data?**

Your personal data may be stored in limited-access paper files and electronic databases. The study doctor/staff will have access to these paper files and databases. Other people may also need to see this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements, including:

* People authorized by the sponsor such as monitors and auditors;
* The independent ethics committee or institutional review board that reviews the study to ensure that it meets scientific and ethical standards;
* The Quality Assurance and Education Officers from the hospital’s Office of Research Services may audit this research study for quality assurance purposes

Each of these individuals will be obligated to protect the confidentiality of your personal data and to use and disclose it only as described in this document.

**Communication OF GENERAL RESULTS**

You will be able to know the progress and the general results of this study if you make a request to the research team.

**SHOULD YOU SUFFER ANY HARM**

Should you suffer harm to this biobank, you will receive any care and services required for your health condition.

By agreeing to participate in HiRO-HCM, you are not waiving any of your rights nor discharging the doctor in charge of this registry and biobank, the sponsor or the institution, of their civil and professional responsibilities.

## **COMPENSATION**

Your parking costs in connection with your participation in the research will be paid by a coupon which will be given to you during your visit, if a visit is necessary, as compensation for costs incurred due to your participation in this registry and biobank.

**CONTACT PEOPLE**

If you have any questions or if you have a problem related to this registry and biobank, or if you would like to withdraw, you may contact the physician in charge or someone on the research team at any time at the following numbers:

**London Health Sciences Centre**

Dr. Habib Khan, Investigator: Tel.: 519-663-3746

For more information about your rights as a study participant of the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

**CONSENT FORM**

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I have reviewed the information and consent form. Both the HiRO-HCM registry and biobank, and this information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After consideration, I consent to participate in this registry and biobank in accordance with the conditions stated in this form.

I authorize the research team to have access to my medical record.

**PLEASE CHECK THE APPROPRIATE BOX BELOW BEFORE SIGNING**

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| In the event of my death, I consent to any health care or long term care facility, including a hospital, nursing home or medical clinic providing a copy of my medical record to the investigator of this study, should this be requested. This information may be shared with the sponsor or granting agency for this study. | I agree | I refuse |

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| I agree to be contacted for return of individual results to the extent foreseen in this form. | I agree | I refuse |

**CONSENT FORM for HiRO-HCM STUDY**

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

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Print Name of Participant Signature Date *(DD-MMM-YYYY)*

My signature means that I have explained the study to the participant named above. I have answered all questions.

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Print Name of Person Obtaining Consent Signature Date *(DD-MMM-YYYY)*

Your signature on this form indicates that you are acting as a substitute decision maker(s) for the participant and the study has been explained to you and all your questions have been answered to your satisfaction. You agree to allow the person you represent to take part in the study. You know that the person you represent can leave the study any time.

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Print Name of Substitute Decision Maker Signature Date *(DD-MMM-YYYY)*

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Relationship to Participant

Was the participant assisted during the consent process?  **YES  NO**

If **YES**, please check the relevant box and complete the signature space below:

The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

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Print Name of Translator Signature Date *(DD-MMM-YYYY)* Language

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

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Print Name of Witness Signature Date *(DD-MMM-YYYY)* Relationship to Participant