**Document Title**

Letter of Information and Consent

 **Study Title**

Left Ventricular Non-Compaction Prevalence in Cardiac Dysfunction and Arrhythmias

 **Principal Investigator**

## Principal Investigator

Dr. Habib Khan

University Hospital (519) 615-1950 ext. 34526

 **24 Hour Contact Information** (for Clinical Trials)

## 24 Hour Contact

Please visit your local emergency room and ask for the on-call Cardiologist and let them know that you are a study participant under Dr. Habib Khan.

This study is self-funded by the Principal Investigator, Dr. Habib Khan.

 **Funder Information**

There are no conflicts of interest to declare related to this study.

 **Conflict of Interest**

Left ventricular non-compaction (LVNC) is a rare heart condition with an increasing prevalence worldwide. LVNC is characterized by impaired compaction of the heart wall, resulting in hypertrabeculation which can lead to altered heart function. In the long run, LVNC may cause complications such as irregular arrhythmias, strokes, heart failure or sudden cardiac death.

 **Introduction**

You are being invited to participate in this research study about the genetic risk factors of LVNC because you have a confirmed diagnosis of this heart condition.

You will be given a copy of consent document once it has been signed.

 **Why is this study being done?**

Recently, many studies have identified genetic mutations that predispose patients to LVNC. The results of these studies provide information that then guide medical specialists in the care of their patients. This study, in which you are invited to participate, will bring added value to the understanding and treatment of LVNC.

The objective of this study is to establish a large clinical registry linked with the Inherited Arrhythmia Clinic, a subdivision of the London Heart Rhythm Program, detailing the genetic mutations predisposing patients to LVNC.

 **How many people will take part in this study?**

This study aims to recruit more than 100 patients yearly over the course of 10 years to participate in this study, up to a maximum of 2000 patients overall. It is expected that this study, and your participation in it, should take10 years to complete. We aim to access your medical records on a yearly basis for up to ten years, but potentially longer if there is insufficient data collection over a period of 10 years.

 **What will happen during this study?**

The initial study visit will take place following your routine visit to the Inherited Arrhythmia Clinic. A delegated member of the research team will provide you an overview of the study and if you agree to participate, will have you sign the consent form and provide you with a copy of it for your personal reference.

 **What are the study procedures?**

There are no study specific procedures that will be conducted. You will be approached either during your routine clinic visit at the Inherited Arrythmia Clinic or by letter/email if you do not have an upcoming appointment. We will access our medical records at the time of enrollment and annually for a minimum of 10 years. The purpose of this is to get an understanding of your general health and well-being over time.

 **What are the responsibilities of study participants?**

If you are participating in another study, please inform the study doctor or nurse to see if you are eligible to participate in this study.

 **What are the risks and harms of participating in this study?**

Please note that because we are collecting personal identifiers, there is always the risk of a privacy breach.

 **What are the reproductive risks?**

There are no reproductive risks associated with this study.

 **What are the benefits?**

There are no known benefits to you associated with your participation in this research study. As such, you may not receive direct benefit from being in this study. Information learned from this study may help lead to improved treatment of LVNC in the future.

 **Can participation in this study end early?**

Participation in this study can end early. An investigator may terminate your participation in the study in any of the following scenarios outlined below.

* + - You withdraw consent
		- You are lost to follow-up
		- The Regulatory Authority/ies or research ethics board withdraw permission for this study to continue

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care.

 **Voluntary Participation**

We will give you new information that is learned during the study that might affect your decision to stay in the study.

An alternative to the procedures described above is not to participate in the study and continue on just as you do now.

 **What other choices are there?**

 **What are the rights of participants (including in the event of a study related injury)?**

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

You do not waive any legal rights by signing the consent form.

You will not incur expenses for participation in this study.

 **Are participants paid to be in this study?**

You will not be paid to be in this study.

 **Can participants choose to leave the study?**

If the researcher decides to withdraw you from the study

The researcher may decide to withdraw you from the study if any of the following situations occur: you withdraw consent; you are lost to follow-up.

If you request to be withdrawn from the study

If you decide to withdraw from the study, no new information will be collected without your permission and the data already collected will not be used for the purpose of this research study.

 **How will participant’s information be kept confidential?**

The personal identifiers that will be collected for this study, in addition to the justification for collecting this information, can be found below.

1. Name
	* 1. Collecting the name allows researchers to avoid duplicate data entry and ensure that the correct patient records are being accessed by delegated research team members.
2. Full Date of Birth
	* 1. Collecting the full date of birth allows researchers to calculate and examine changes in disease progression with age.
3. Biological Sex
	* 1. Collecting the biological sex will allow researchers to examine if LVNC diagnosis is correlated with sex.
4. Race and Ethnicity
	* 1. Collecting data on race and ethnicity will allow further exploration of the genetic contributions of LVNC.
5. Age
	* 1. Collecting age will be used to examine changes in disease progression with age.
6. Hospital Patient Identifier Number (PIN)
	* 1. Collecting the hospital PIN will avoid duplicate data entry and be used for the purpose of query resolution.
7. Telephone Number, Email Address and Physical Address
	* 1. Collecting this information will allow delegated members of the research team to be able to contact patients if needed.

All identifiable information collected during this study will be kept confidential and will not be shared with anyone outside the study, unless required by law. This information will be accessed by delegated members of the research team only.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held to check that the information collected for the study is correct and follows proper laws and guidelines. They may also be given remote access to these records through the internet via secure video conference or through redacted (personal identifiers blacked out) copies. Examples include:

* + - Representatives of Lawson Quality Assurance Education Program
		- Representatives of Western University and its Health Sciences Research Ethics Board that oversees the ethical conduct of this study.

The study doctor will keep any personal health information about you in a secure and confidential location for 15 years. A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file.

Your name, or other identifiable information, will not be declared in any reports, publications, or presentations that may come from this study. The REDCap platform will be used in order for data collection and storage. REDCap’s privacy policy can be accessed using the following link - <https://projectredcap.org/software/mobile-app/privacypolicy/>. This data will be stored in the hospital’s secure shared drive, in University Hospital, London, ON, Canada. Although all appropriate and necessary measures will be taken, there is a risk of a potential privacy breach.

 **Will information about this study be available online?**

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov,](http://www.ClinicalTrials.gov/) as required by U.S. Law. This Web site will not include information that can identify you. At most, it will include a summary of the results. You can search this site at any time.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics (519) 661-3036, 1-844-720- 9816, email: ethics@uwo.ca. The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential.

 **Whom do participants contact for questions?**

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

 **Consent**

**Left Ventricular Non-Compaction Prevalence in Cardiac Dysfunction and Arrhythmias** (PI: Dr. Habib Khan)

Please initial the appropriate boxes for each statement before signing.

|  |  |  |
| --- | --- | --- |
| 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.  | [ ] I agree | [ ] I refuse |

|  |  |  |
| --- | --- | --- |
| I agree for the research team to access my medical records **retrospectively** (in the past) to obtain the necessary information.  | [ ] I agree | [ ] I refuse |

|  |  |  |
| --- | --- | --- |
| I agree for the research team to access my medical records **prospectively** (following the baseline visit) to obtain the necessary information. | [ ] I agree | [ ] I refuse |

|  |  |  |
| --- | --- | --- |
| I consent to have the data collected in this study be used for future research related to LVNC without being asked for further consent. | [ ] I agree | [ ] I refuse |

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.

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.

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

Consent

**Left Ventricular Non-Compaction Prevalence in Cardiac Dysfunction and Arrhythmias** (PI: Dr. Habib Khan)

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Print Name of Substitute Decision Maker |  | Signature |  | Date *(DD-MMM-YYYY)* |
| Relationship to Participant |  |  |  |  |