

**UNIVERSITY OF CALGARY**

**OPTIONAL CONSENT TO PARTICIPATE IN BIOBANKING**

**TITLE:** *Targeted Therapy with Glycogen Synthase Kinase-3 Inhibition for Arrhythmogenic Cardiomyopathy (TaRGET)*

**SPONSOR:** *Hamilton Health Sciences through its Population Health Research*

*Institute*

**FUNDER**: *Canadian Institute for Health Research (CIHR)*

INVESTIGATORS**:** *Dr. Erkan Ilhan (403-956-3686)*

# INTRODUCTION

You are being asked if you’d like to take part in this biobank because you are participating in the TaRGET study, which includes people with arrhythmogenic cardiomyopathy (ACM).

A biobank is a repository that stores biological samples and information for future research use. A biobank is a type of facility that receives, stores, processes, and distributes biological samples (like blood, tissue, urine, saliva) as well as data related to those samples. Biobanks provide scientists with access to samples and study data to conduct other research.

The researchers doing this study are interested in storing biological specimens (samples) and information so that they can answer different research questions in the future. The researchers are interested in storing information collected as part of the main study so that they can answer different research questions in the future.

We don’t know exactly what these questions will be, but we think they will be related to future research on ACM, though it is possible that the samples will be used to help evaluate other aspects of disease/health. For example, future research may examine your genes to try to better understand your vulnerability to arrhythmogenic cardiomyopathy and, if tideglusib is found to be effective, factors that affect response to the medicine. Your sample may also be used to try to better understand other heart or medical conditions.

This biobank involves genetic testing. Researchers will be looking at your genes (DNA).

Hereditary genetic testing (to look at whether ACMruns in families) may be done on these samples.

Future research may involve whole genome sequencing. Whole genome sequencing is the analysis of the complete set of genetic instructions in a cell.

Every person has their own unique set of genes or ‘genome’. Sometimes there are differences between individuals, but these differences are very small. The reason this is important is because these results might contain information (for example, an inherited genetic disease) that could impact you or your biological (blood) relatives. When you donate your genetic information or materials you are sharing information about yourself, and it can be used to identify these relatives.

If you agree, it is possible that the samples stored in the biobank may be used to create cell lines. Cells are the building blocks that make up all living organisms and the tissues of the body. A cell line is when the researchers use the samples you have provided and change them so that they can grow more cells (identical to the ones you provided) into the future. This allows researchers to create an unlimited number of cells from the sample that you provided.

In addition to storing data in the study database, the study data or samples may also be shared for future use in public databases with protections for your privacy. The goal of this sharing is to make more research possible which may improve people’s health. Some types of future research may include looking at your information/samples and information/samples from other participants to see who had side effects across many studies or comparing new study data with previously collected study data.

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

The researchers will collect leftover samples from your participation in the main study, which will be stored for future use. In addition to the sample, information that was collected as part of the main study could be stored in the biobank and used in future research.

**WHAT WILL HAPPEN WHEN I AM FINISHED WITH THE STUDY?**

You may not be able to receive tideglusib after your participation in the study is completed. Dr. Ilhan will talk to you about your options as the end of the study approaches.

# HOW LONG WILL I BE IN THIS STUDY?

It will take about 2 years to collect the information and collect the samples.

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

Even with protections in place, there is a risk that your information could be released by accident. There is a risk that someone could trace the information back to you. The chance that someone could do this is very small, but the risk may grow in future if people come up with new ways of tracing information back to people.

Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your relatives. There is no way to predict what effects such an information loss would have. For example, if an insurer, a current or future employer, or law enforcement were to learn your genetic code it could result in loss of privacy and to possible future discrimination in employment or insurance against you or your relatives. Even though this risk is unlikely, we think you should be aware.

Another risk is that if you agree to take part, your information or samples could be used in a research project to which you might not agree, if you were asked specifically about it. We think this consent form will give you a good idea of the kinds of research projects that might be done. Please ask us if you have any questions about this.

There are no medical or physical risks to you from participating in this study. We are storing blood that is leftover from the tests done as part of the main study – we are not collecting any new samples.

# ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?

You will not directly benefit from participation in this study, but we hope that the research may help other people in the future.

**ARE THERE COSTS ASSOCIATED WITH PARTICIPATING IN THE STUDY?**

Tideglusib will be supplied at no charge while you take part in this study.

The costs of your medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available.

You may not be able to receive the study medication after your participation in the study is completed. There are several possible reasons for this, some of which are:

* The study drug may not turn out to be effective or safe.
* The study drug may not be approved for use in Canada.
* Your caregivers may not feel it is the best option for you.
* You may decide it is too expensive and insurance coverage may not be available.
* The study drug, even if approved in Canada, may not be available free of charge.

The study doctorwill talk to you about your options as the end of the study approaches.

Taking part in this study may mean that you need to make more visits to the hospital/clinic than if you were getting the standard of care treatment. You may:

* Have more travel costs.
* Need to take more time off work.
* Have other additional personal costs.

If you decide to participate in this study, parking at the Foothills Hospital will be reimbursed. You will need to provide your license plate and vehicle make information to the study team in advance of your appointments for your parking to be reimbursed.

**CAN I CHOOSE TO LEAVE THE STUDY?**

You can change your mind and decide to stop participating (called withdrawal) at any time without having to provide a reason. You need to tell the local research team if you want to withdraw. If you don’t tell the research team, you will still be in the study.

If you withdraw from the biobank, your samples will be destroyed. If tests have already been done on your sample(s) it will not be possible to withdraw those results. If your samples were shared with other researchers before you withdrew, it will not be possible to destroy or recall those samples.

You can also request that the information collected before you withdrew be removed from the biobank – please let the researchers know if you chose this. However, even if the information is removed, record of your participation in this study (for example, this signed consent form) will not be destroyed. It will not be possible to delete/recall information that has been shared with other researchers. Information that has been published cannot be removed from the database.

You can request withdrawal of your samples and information until 15 years after the main study (TaRGET) ends*,* whenthe samples and information will be made anonymous. It won’t be possible to return samples after this because the researchers will not know which sample/information is yours.

**WILL MY RECORDS BE KEPT PRIVATE?**

If you decide to participate in this biobank, the research team will collect information about you. Information will be collected from your participation in the main study, TaRGET.

As part of this study, researchers will collect information that could directly identify you. This includesyour name, address, phone number, email address, date of birth and sex.

Directly identifying information (like your name) will be removed from the samples and the information the research team collects about you and replaced with a code (‘coded data’). The research team at the University of Calgary will have a list that links your name and other directly identifying information to your code so that your coded data can be linked back to you if necessary (for example, if you would like to withdraw). This list and any other documents that could directly identify you, like this signed consent form, will be kept separate from the coded data and samples in a secure place at this institution (just like for the main study).

The coded samples and data will be stored at Clinical Research Laboratory and Biobank-Genetic and Molecular Epidemiology Laboratory (CRLB-GMEL) at the Hamilton General Hospital in Hamilton, Ontario, Canada. Samples will be kept until they run out. Information in the biobank will be kept indefinitely.

The coded samples and data may be shared with other researchers, including for-profit companies like drug or health-related companies, in Canada or around the world to answer future research questions.

The rules around privacy and research in other countries may not be the same and may not be as strong as the rules in Canada, however, only coded samples and information will be shared – they will not contain any information that can directly identify you. In many cases, these researchers will be required to obtain approval from a Research Ethics Board (REB) that is responsible for ensuring the rights, safety, and wellbeing of participants but in some cases, this may not be required. You will not be asked or told about these other studies, and the results of these studies will not be shared with you.

Reports about any research tests done with your samples and information will not be given to you or your health care provider(s). These reports will not be put in your medical records.

We hope to publish the results of the research. When we do, your identity will remain confidential.

**IS THERE A CONFLICT OF INTEREST?**

The University of Calgary will be receiving funds from the Population Health Research Institute (PHRI) to help offset the costs of conducting this research. PHRI is a non-profit academic research institute located in Hamilton, Ontario.

Dr. Jason Roberts, the Principal Investigator, is named as an inventor on a patent application that has been filed for use of tideglusib and related molecules as treatments for arrhythmogenic cardiomyopathy.

**QUESTIONS ABOUT THE STUDY**

If you have further questions concerning matters related to this research, please contact:

Dr. Erkan Ilhan (403-956-3686) OR the research coordinator (403-210-6414)

**If you have any questions concerning your rights as a possible participant in this research, please contact The Chair of the Conjoint Health Research Ethics Board, University of Calgary, at 403-220-7990.**

**SIGNATURES**

I agree that my samples that were already collected may be usedfor the optional research described above.

YES NO Initial: \_\_\_\_\_\_\_\_\_\_\_

I agree that my samples that were already collected may be used to create cell lines.

YES NO Initial: \_\_\_\_\_\_\_\_\_\_\_

* All my questions have been answered,
* I understand the information within this informed consent form,
* I have read, or someone has read to me, each page of this optional informed consent form,
* I allow access to my medical records and specimens as explained in this informed consent form,
* I do not give up any of my legal rights by signing this optional informed consent form,
* I agree to take part in this study.

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**Participant’s Name** Signature and Date

**(Please print)**

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| Witness’ Name (please print) |  | Signature and Date |

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Investigator/Delegate Name Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

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