**INFORMED CONSENT TO PARTICIPATE IN A DATABASE**

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**FULL DATABASE TITLE:**

**DATABASE SHORT FORM NAME:**

**PRINCIPAL INVESTIGATOR:**

**CONTACT NUMBER:**

**DATABASE SPONSOR OR FUNDER:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INFORMED CONSENT**

You are being asked to consider allowing your personal health information to be collected as part of the <<ENTER NAME>>database(the “Database”).The purpose of the Database is to gather information from as many patients as possible, in order to conduct research in the future.

This form explains the purpose of the Database, provides details about the information that will be collected, and the rights of patients participating in the Database. Please read this form carefully and ask any questions you may have. Make sure all your questions are answered to your satisfaction before deciding whether to participate.

Participating in the Database is your choice (voluntary) and you have the right to choose not to participate, or to stop participating at any time. Your decision to participate or not in the Database will not affect your clinical care.

**INTRODUCTION**

You are being asked to consider having your[specify as applicable: past, current and future] personal health information included in the Database because you are a patient in the <<enter division/dept/program>>at Sunnybrook Health Sciences Centre (“Sunnybrook”).

The <<enter division/dept/program>>serves the needs of patients who have: [describe in layman’s terms the applicable disease / condition/ patient characteristics]

**WHAT IS THE PURPOSE OF THE DATABASE?**

The purpose of the Database is to collect information from [describe in layman’s terms the applicable disease / condition/ patient characteristics]that will assist researchers in future research studies on [describe in layman’s terms the types of potential future studies] **in** order to improve care and quality of life for patients. [Modify the following statement to suit the particular database initiative: *One of the most important tools for this type of research is the collection and analysis of clinical information about current patients, including their medical history, diagnostic tests, treatments, and other relevant patient-related information*]. Researchers who wish to access information stored in the Database for future research projects will be required to obtain research ethics board approval of their proposed research project before any data will be provided.

Participants in the Database accept that personal health information collected from them will be used by researchers from Canada or from other countries for future research on <<describe type of studies>> and potentially other health conditions. It is impossible to predict all of the future studies that may use the information collected from you.

**WHAT DOES PARTICIPATION INVOLVE AND HOW MANY PEOPLE WILL TAKE PART?**

As you are a patient in the <<enter division/dept/program>>, we are requesting your permission for Sunnybrook to include your personal health information in the Database. We will gather [specify as applicable: past, current and future] information from all patients who agree to be part of the Database.

Access to and use of your Sunnybrook health records for inclusion in the Database will include: [list the records that will be included]

1. ;
2.

# WHAT ARE THE RISKS AND BENEFITS OF PARTICIPATING?

There are no expected direct risks or benefits related to participation in theDatabase, however, the information you contribute may help other patients in the future.

**WHAT ARE THE COSTS OF PARTICIPATING?**

Participation in the Database will not involve any additional costs to you, nor will you be paid to participate. You will not benefit from or receive any compensation for any future discoveries or inventions that may arise from the use of information in the Database.

**HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?**

You have the right to have any information about you and your health that is collected, used or disclosed to be handled in a confidential manner.

All of your personal health information that is collected or used for theDatabase will be handled in a confidential manner and stored securely. [Describe how information will be stored i.e. de-identified/coded or identifiable <<The information in the database <<**will/will not**>> contain your name or address or any information that directly identifies you]. Your information will be identified by a code [describe any other indirect identifiers that may be used e.g. partial date of birth].

The following people may look at information in the Database to make sure the applicable laws and guidelines are being followed:

* <<Representatives from Sunnybrook Health Sciences Centre, who oversee the creation of databases;
* Other>>

The Database personnel will keep the information they see or receive about you confidential, to the full extent required by applicable laws. Even though the risk of identifying you from the Database is very small, it can never be completely eliminated. However, every effort will be made to maintain your privacy.

Researchers requesting access to the Database for future research projects will not have access to your identifiable personal health information. All data supplied to researchers will be coded and will not contain your identifying information.

**HOW LONG WILL MY INFORMATION BE KEPT?**

[Describe how long information will be kept. If the plan is to keep data in perpetuity state the following <<In order to support future research, your information will be kept in the Database indefinitely unless otherwise indicated>>.

**DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?**

[Describe any conflicts of interest or relationships that exist or may appear to exist. If no conflicts of interest exist state] <<There are no conflicts of interest to declare related to this Database>>. The costs of developing the Database are covered by [describe detail].
 **WHAT ARE THE RIGHTS OF PATIENTS CONSENTING TO THIS DATABASE?**

You have the right to receive all information that could help you make a decision about participating in thisDatabase and you also have the right to ask questions and to receive answers throughout your participation. You can also choose to end your participation at any time without having to provide a reason. If you choose to withdraw, your choice will not have any effect on your current or future health care. If you withdraw your consent to participate, you will have the right to request that your personal health information collected prior to your decision to withdraw be permanently deleted from the Database. No new information about you will be collected without your permission. However, your personal health information that has already been disclosed to researchers for research projects prior to the date of withdrawal of your consent cannot be returned.

If you have any questions about the Database or if you wish to withdraw your consent to participate in the Database at any time in the future, you may contact one of the persons in charge of theDatabase <<enter name / contact number>>.

If you would like to speak to someone for answers about your rights or if you wish to express a concern, you may you may call the **Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.**

**DOCUMENTATION OF INFORMED CONSENT FOR THE <<ENTER NAME>> DATABASE**

You will be given a copy of this informed consent form after it has been signed and dated.

Name of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I understand the statements below:

* Participation in the **<<ENTER NAME>>** Database (“Database”) has been fully explained to me and all of my questions answered to my satisfaction.
* I have been informed of the risks and benefits, if any, of participating.
* I have been informed that deciding to participate is my choice (voluntary), that I can withdraw from participation at any time. If I chose to withdraw, I may request that my personal health information collected prior to my decision to withdraw be permanently deleted from the Database. However, any of my personal health information that that has already been disclosed to researchers prior to my decision to withdraw will not be returned.
* Information collected and stored in the Database and used in future research projects will not be used to manage my clinical care. The only exception to the use of information in the Database for research purposes alone would be if future research makes new findings that are important to your health. If this occurs, we ask your permission for a member of your healthcare team to contact you at that time.
* All future research conducted using the information in the Database will be first reviewed and approved by a Research Ethics Board.
* I have read each page of this form.

By checking the boxes below and signing this form I consent to the following (check all that apply):

[ ]  **Internal use**: Access to and use of my <<list specific records including surveys, questionnaires, tools etc. or specify if ALL>> medical records collected during my time at Sunnybrook by the Database personnel for the purposes of including my personal health information in the Database as described. My information will only be used at Sunnybrook by Sunnybrook researchers.

[ ]  **External use**: Disclosure of my de-identified personal health information to researchers both inside and outside of Sunnybrook, which may include outside of Canada, for future research on <<describe type of studies>>, and potentially other health conditions, that have been approved by a Research Ethics Board.

**[INCLUDE THE FOLLOWING IF APPLICABLE]**

[ ]  If future research makes new findings that are important to my health, I consent to be contacted by a member of my health-care team at that time.

[ ]  I do not want to be contacted under any circumstances.

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Name of participant/Substitute Signature Date

Decision-maker (print)

**ASSISTANCE DECLARATION**

Was the participant assisted during the consent process? [ ]  Yes [ ]  No

[ ]  The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the database was accurately explained to, and apparently understood by, the participant/substitute decision-maker.

[ ]  The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the participant/substitute decision-maker, and believe that that participant/substitute decision-maker has understood the information translated.

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Name of Person Assisting (Print) Signature Date

Person obtaining consent

By signing this form, I confirm that:

* The **<<ENTER NAME>>** Database and its purpose has been explained to the participant named above
* All questions asked by the participant have been answered
* I will give a copy of this signed and dated document to the participant

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Name of Person obtaining Signature Date

Consent (print)