# Consent to Participate in a Research Registry

*How to use this document: the “Guidance” boxes will help provide further information to add to each section. Front in* ***red*** *requires you to fill in the section, font in* ***blue*** *are for optional section to either add or remove based on the research study, highlighted sections are for reminders. Please delete all boxes in your final version.*

**Registry Title:** Required: [Enter the full study title, exactly as it appears on the Protocol]

**Principal Investigator:** Required: [Name, title and telephone number of the Principal Investigator]

**Co-Investigators:** Required: [Name(s) with title(s) of Co-Investigators if applicable]

**Research Coordinator:** Required: [Name and contact information]

**Sponsor/Funding Agencies:** Optional: [If applicable]

**Protocol number**: Optional: [If applicable]

## Introduction

You are being asked to take part in a research registry. A registry collections information about individuals regarding a specific diagnosis or condition to help care professionals improve treatment, and provide researchers information for future studies including the development and testing of new treatments.

In order to decide whether or not you want to be a part of this registry, you should understand what is involved and the potential risks and benefits. You should take as much time as you need to make your decision. You should ask the Principal Investigator or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this registry is voluntary.

Optional: [If applicable] It is important to note that the Principal Investigator may also be your treating physician. Your decision to participate in this registry will not impact the care you receive.

Optional: [If applicable] It is important to note that the Principal Investigator may be your colleague or supervisor. Your decision to participate in this registry will not impact your employment at WOHS.

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| *Guidance: amend the introduction to address the substitution decision maker, if applicable. For example, “As the patient’s Substitute Decision Maker, you are being asked to provide informed consent as he/she are unable to provide consent for him/herself. If the patient regains the capacity to consent for him/herself, your consent for them will end. Throughout this form, “you” means the patient you are representing.”* |

## Background and Purpose

* You have been asked to take part in this registry because you Required: {e.g. have Type 2 Diabetes}. Note: [Be as specific as possible. Do not list inclusion/exclusion criteria].
* The purpose of this registry is to Required: {Insert purpose here in lay terms – what will the registry be used for and what will it not be used for?}.
* About Required: {“x” total number} people will be included into this registry. About Required: {z1 – z2} will come from William Osler Health System. Note: [Add last sentence if multicentre]

## What information will be added to the Registry?

The researchers will collect information about you from Required: (Specify source of information e.g., your medical chart) and enter this information into an Required: {Electronic/Paper-based} registry. The following information about your Required: {Disease/Condition} will be collected about you:

* Required: {List variables you will collect that is related to their disease or condition}

### Personal Health Information

If you agree to join this registry, the Principal Investigator and Required: {his/her} study team will look at your personal health information and collect only the information they need for the registry. Personal health information is any information that could be used to identify you and includes your:

* Required: {Name,},
* Required: {Address,},
* Required: {Date of Birth,},
* Required: {New or Existing Medical Records, that includes types, dates and results of medical tests or procedures.}.

Optional: [If applicable – collecting information on race/ethnicity] Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. You should be aware that providing this information is not mandatory.

## Where will the data be stored?

“Data” is information about you that is collected for the registry, but that does not directly identify you.

The data will be stored Required: {On a secure server/in a secure location} located Required: {On the William Osler Health System internal server behind protective firewall/ in a secure location on the William Osler Health System premises}.

The data will be maintained by the Principal Investigator. The registry can only be accessed by people who are involved in the research. Please talk to the research team if there is information that you do not feel comfortable sharing.

To protect your identity, your participation in this registry will be de-identified by replacing your name with a unique participation number. The study key will be kept confidential by the Principal Investigator.

Optional: [If applicable – Canadian] The data will be entered onto an online registry that is hosted by (company name), which stores data on servers located in Canada. The data will reside on an external server and no guarantee can be made about its confidentiality.

Optional: [If applicable – U.S.] The data will be entered onto an online registry that is hosted by (company name), which stored data on external servers located in the United States. Data that is stored and accessed in the U.S. is subject to U.S. laws including the U.S Freedom Act. Therefore, no guarantee can be made about its confidentiality.

It is important to understand that despite the protections described in this section being in place, there continues to be the risk of an unintentional release of information. The chance that personal information or study data will be accidentally released or accessed without authorization is small.

## How long will the data be stored for?

The information that is collected for the registry will be stored for Required: {7 years for non-Sponsored/Health Canada registered studies; 15 years for Sponsored/Health Canada studies} then securely destroyed. Note: If data is kept in perpetuity, please clarify and provide clarification for what will happen after the registry is closed.

Only the study team or the people or groups listed below will be allowed to look at your records. Optional: [Your participation in this registry also may be recorded in your medical record at this hospital].

## Who will have access to my data?

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the registry is correct and to make sure the study followed proper laws and guidelines:

* Optional: [If applicable] The study sponsor or its representatives/partner companies.
* Representatives of the William Osler Health System Research Ethics Board.
* Optional: [If applicable] Representatives of Health Canada, or other regulatory bodies (groups of people who oversee research studies) outside of Canada, such as the United States Food and Drug Administration.

## What is the governance/ownership of my information?

1. Note: State the entity or person who have custodianship of the data and the location of the registry
2. Note: Who will have access to the registry (including access to personal information maintained there)
3. Note: Whether the registry will be used for commercial purposes
4. Note: Who the registry data/samples (de-identified) will be shared with
5. Note: The length of time data/samples will be kept
6. Note: For Biobanks only: The researcher’s plan for handling results and findings, including clinically relevant information and incidental findings.

## What are the benefits to participating in the registry?

There are no medical benefits to you for participating in this registry. However, by participating, you may assist us in finding out more about Required: (Insert what is appropriate e.g. disease x). Choosing not to participatein this database will in no way affect your care or treatment at William Osler Health System.

## What are the risks to participating in the registry?

There are no known medical risks to you from participating in this registry.

## Is my participation in the registry voluntary?

Your participation in this registry is voluntary. You may decide not to be in this registry, or to be in the registry now and then change your mind later. You may leave the registry at any time without affecting your Required: {Care/Employment Status/Academic Standing}.

## Can I withdraw my data from the registry?

If you no longer want your data to be used in this registry, you should tell Required: (Specify appropriate contact role), who will ensure the data is removed from the registry.

If you choose to withdrawal your data from this registry, any data collected from you Required: {At what point} will be Required: {Retained or Removed} from the registry.

## How will my data in the registry be kept confidential?

If you decide to participate in this registry, the research team will only collect the information they need for the registry.

Records identifying you at William Osler Health System will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical 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.

If the results of this study are published, your identity will remain confidential.

## Can the data be used for future research?

The Principal Investigator and WOHS REB shall evaluate each research study that is requesting access to data from the registry.

Data from the registry may only be used for future research studies, provided the following criteria is met:

* The study for which the data is requested has received approval from the Principal Investigator,
* The study for which the data is requested has received WOHS REB approval,
* If data is transferred to a third party, an agreement (data sharing agreement – DTA) detailing the terms and conditions for the release of the data has been signed by all individuals.

Any data that is sent off site will not contain identifying information, such as your name. Data used for future research will be used for the purpose of the registry outlined in the Background and Purpose section.

## What are the alternatives to participating in the registry?

You do not have to join this registry to receive treatment for your condition. The alternative to participating in this registry is to not participate.

## Are there expenses associated with participation?

Participation in this registry will not involve any additional costs to you.

## Conflict of Interest Optional: [If applicable]

Note: Include information about any conflicts of interest. Note that the most common form of conflict of interest is the professional benefit gained by the Investigators. Include all of the following information that applies.

Required: {Name of Company}, the sponsor of this registry, will pay the hospital and researcher for the costs of doing this registry. All of these people have an interest in completing this registry. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this registry.

## Commercialization Optional: [if applicable]

The participants will not receive any financial benefit from their participation and/or from the creation of any commercial product made partly or totally from their data.

Should the use of the data for future research or the creation of any commercial product made partly or totally from the data yield earnings, said earnings will be distributed as follow:

* To a research fund supporting the Required: (Add Name) registry administration and development;
* To a research fund supporting research performed with the registry’s data.

## What are my rights as a research participant?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this registry.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the researcher/Principal Investigator, sponsor or involved institutions for compensation, nor does this form relieve the Researcher/Principal Investigator, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

## Optional: [If applicable] What if the researchers discover something about me?

During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may Required: (Insert anticipated incidental findings e.g. find out that you have another medical condition).

Note: Describe anticipated management plan. For example: If any new clinically important information about your health is obtained as a result of your participation in this study, you will begiven the opportunity to decide whether you wish to be made aware of that information.

## Questions about the Registry

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Required: {Principal Investigator} at Required: {Phone} or Required: {Study Coordinator} at Required: {Phone}.

If you have any questions about your rights as a research participant or have concerns about this study, call Dr. Herbert Brill, Chair of the William Osler Health System Research Ethics Board (REB) at 905-494-2120 ext. 50448. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

## Documentation of Informed Consent

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

Registry Title: Required: {Add}

By signing this consent form I agree that:

* This registry has been explained to me and any questions I had have been answered.
* I know that my participation is voluntary and that I may leave the registry at any time.
* I have been informed of the risks and benefits, if any, of participating in this registry.
* I have been informed of any alternatives to participating in this registry.
* I have been informed of the rights of research participants.
* I have read each page of this form.
* I authorize access to my personal Required: {Health} information, Required: {Medical Record} and registry data as explained in this form.
* Optional: [If applicable] I understand that my data may be used for future research purposes.
* Optional: [If applicable] I understand that my data may be sent off-site.

Optional: [If applicable please add]

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| [ ]  I **agree** to allow my data to be used for future research purposes[ ]  I **do not agree** to allow my data to be used for future research purposes |

Optional: [If applicable please add]

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| [ ]  I **agree** to be contacted future research purposes[ ]  I **do not agree** to be contacted for future research purposes |

[Enter Name of Participant/Substitute Decision-Maker here] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [Enter Date here]

Name of Participant/Substitute Signature Date

Decision-maker (Print)

[Enter Name of Person Obtaining Consent here] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [Enter Date here]

Print Name of Person Signature Date

Obtaining Consent

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| *Guidance: include the following if The Assistance Declaration provides a mechanism for potential participants who are unable to read the informed consent form (i.e. illiterate, blind or for who English is their second language) to participate in research studies* |

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.

[Enter Name of Translator here] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [Enter Date here]

Print Name of Translator Signature Date

[Enter Relationship to Participant here] [Enter Language here]

Relationship to Participant Language