# Participant Information Sheet and Consent Form

*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.*

*This is a consent form for* ***minimal risk*** *studies. Minimal risk is research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research. Examples of minimal risk studies are those that* ***do not i****nvolve a change to standard of care, an investigational drug or device, or regulated by Health Canada or the FDA, etc.*

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

**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]

**Emergency Contact Number (24 hours / 7 days a week):** Optional: [Required for studies greater than minimal risk]

## Introduction

You are being asked to take part in a research study. In order to decide whether or not you want to be a part of this research study, 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 study doctor 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 study is voluntary, please take your time in making your decision Note: If there is a time constraint to consent, please add (i.e., please make your decision within the next 24 hours).

Optional: [If applicable] It is important to note that the Principal Investigator may also be your treating physician. Your decision to participate in this research study 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 research study 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

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| *Guidance: Provide background information on what prompted the need for this study. Refer to standard of care, knowledge to date etc. Describe the purpose of the study and how many people will take part.* |

* The purpose of this study is to Required: {Add here}. Note: [Be as specific as possible. Do not list inclusion/exclusion criteria].
* Usually this condition is treated with/by Required: {Insert usual standard of care}.
* The problem with/limits of this regular treatment is/are Required: {Explain limitations}.
* This study will look at Required: {Insert name of study intervention} as an Required: {New/Safer/Cheaper} option to Required: {e.g. Treat your diabetes}.
* About Required: {“x” total number} people from Required: {“y” number} places will be in the study. About Required: {z1 – z2} will come from William Osler Health System.

## Study Design

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| *Guidance: Describe what will happen during the study (i.e., procedures)*   * *Describe all tests, measures, questionnaires, participant diaries, etc.* * *Describe the type of information that will be asked in the questionnaires and how the questionnaire will be distributed (i.e., online, in person, over the phone).*   ***NOTE: Optional research or procedures should have a separate informed consent form.*** |

Optional: [Database Collection] The researchers will collect information about you from Required: {Specify source of information e.g., your medical chart and enter this information into an electronic database}. The data will be securely stored, and will be maintained by specify responsible individual/group. Please talk to the research team if there is information that you do not feel comfortable sharing.

Optional: [Imaging] You will be asked to have Required: {Insert name of imaging procedure}. You will be asked to have Required: {Number of Scans} for this study. The scans are being done for research purposes only, and will not be used to guide your medical care.

Optional: [Focus Groups] You will be asked to attend Required: {Specify How Many} focus group(s). A focus group is a small group of representative people who are asked to speak about their opinions as part of the research. A moderator will organize the focus group(s). Each focus group discussion will be about Required: {Specify length in minutes or hours} in length and will take place Required: {Specify Location}. You will be asked to speak about Required: {Explain topics of discussion e.g., your experiences with condition/intervention}.

You will be Required: {Audio/Video} recorded during the Required: {Interview(s)/focus group}.

Optional: [Questionnaires] You will be provided with a questionnaire Required: {Provide information about the timing of questionnaires e.g., before you begin the study and then every two weeks for a year}. The purpose of the questionnaire is Required: {Include description of purpose e.g., to understand how the study intervention and illness affects your quality of life}. Each questionnaire will take Required: {About indicate estimated time to complete in minutes} to complete.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Optional: [Participant Diaries] You will be asked to keep a diary of Required: {Identify information to be recorded}. You will be asked to return the diary to Required: {Enter location/person here}.

[Optional: Specimen Collection] The researchers doing this study will be doing tests on samples (described below) to Required: {Insert study-specific LAY explanation of the research purposes for all samples collected}.

The collection of these samples is a necessary part of this study. Samples will be used only for these purposes. The samples will not be sold.

Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed or destroyed.

Hereditary genetic testing (to look at whether Required: {Specify Condition} runs in families) will not be done on these samples. Optional: [OR] Hereditary genetic testing (to look at whether Required: {Specify Condition} runs in families) Required: {Will/May} be done on these samples.

## Tissue Collection

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| *Guidance:* *Describe the method of tissue sample collection and associated risks. Please see below examples. Note: Please add this section if applicable.* |

A small sample of your tissue that has already been removed by a previous surgery or biopsy will be obtained by the researchers doing this study. No further surgeries or biopsies are required of you for this purpose.

Optional: [If archived] If your biopsy or surgery were completed at another institution, signing this consent form means that you are consenting to the collection of your tissue sample, together with any related personal health information, from that institution.

## Blood/Urine Collection

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| *Guidance:* *Describe the method of blood/urine/other sample collection and associated risks. Please see below examples. Note: Please add this section if applicable.* |

Urine will be collected Required: {Specify number of samples to be collected and timing (e.g., specify if 24 hour collection) if multiple samples are required}. These urine samples will be sent to a laboratory at the Required: {Insert Location} where they will be examined.

Blood samples will be taken by inserting a needle into a vein in your arm. These will be taken at the same time as your standard of care tests whenever possible, Required: {Describe sample timing e.g. at entry to the study and <X> weeks after you stop the study intervention. Specify amount of blood to be collected (in ml and tablespoons) and timing if additional samples are required and the tests to be done on these samples}. These blood samples will be sent to a laboratory at the Required: {Insert Location} where they will be examined.

## How will samples be identified?

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| *Guidance:* *Note: Please add this section if applicable.* |

To protect your identity, the information that will be on your samples will be limited to Required: {Specify which identifiers will be on the sample(s)}. Despite protections being in place, there is a risk of unintentional release of information. Due to technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you.

## Risks Related to Being in the Study

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| *Guidance:*   * *Address risks will all tests i.e., blood tests.* * *Address psychological risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues (e.g. mental health, sexuality).* |

## Benefits to Being in the Study

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| *Guidance: Avoid overstating the benefits. Do not include monetary reimbursement in the benefits section. If applicable, this should be included in a separate section called “Reimbursement”. The following wording should be considered.* |

You Required: {May or May Not/Will Not} receive Required: {Any} direct benefit from being in this study. Information learned from this study may help other people with Required: {Your Condition} in the future.

## Voluntary Participation

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 Required: {Care/Employment Status/Academic Standing}. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

If you choose to withdrawal your participation in this research study, any data collected from you will be Required: {Retained or removed} from the study up until the point of withdrawal.

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

*Optional: [If applicable]* If you no longer want your samples to be used in this research, you should tell Required: {Specify appropriate contact role}, who will ensure the samples are Required: {Describe what will happen to samples if participant withdraws consent, e.g., returned to the hospital from which they were obtained or destroyed}.

If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done. Optional: [OR] You can request withdrawal of your specimens until Required: {Insert expected anonymization point}, when the samples will be made anonymous. It won’t be possible to return samples after this because the researchers will not know which sample is yours.

## Incidental Findings

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| *Guidance: Note: Please add this section if applicable (i.e., NGS testing, hereditary tests, etc.)* |

The tests or procedures that we do during this study might reveal medical information about you that is not part of the objectives of this study but may be relevant to your health. This type of medical information is called an incidental finding. Some incidental findings could be related to treatable conditions or they could be related to factors that may affect your current or future health care. If any incidental findings are discovered and you seek further care for these findings, these will be included in your medical records (which may include information regarding your participation in the study). You Required: {Will/Will Not} be informed of the results if the Required: {Type of Sample} is tested, should you choose.

## Confidentiality

### Personal Health Information

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

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

The information that is collected for the study will be kept in a locked and secure area by the study doctor for Required: {7 years for non-Sponsored/Health Canada registered studies; 25 years for Sponsored/Health Canada studies}. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

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 study 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.

“Study data" is information about you that is collected for the study, but that does not directly identify you.

The study personnel will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislation, including the Personal Health Information Protection Act (PHIPA) of Ontario. Your participation in this research study will be de-identified by replacing your name with a unique participation number. The study key will be kept confidential by the Principal Investigator. Any study data about you that is sent outside of the hospital will have a code and will not contain your name or address, or any information that directly identifies you.

Optional: [If applicable – Canadian] The online survey is hosted by Required: (Company Name), which stores data on servers located in Canada. Collecting data using technology over the internet or using apps/tools/devices can increase potential risks to privacy and confidentiality. The data will reside on an external server and no assurance can be made about its confidentiality or that it will only be used for this research purpose.

Optional: [If applicable – U.S.] The online survey is hosted by Required: (Company Name), which stored data on 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. The Freedom Act allows authorities access to the records of internet service providers. It is therefore possible that this information could be disclosed to U.S. federal officials.

Optional: [If applicable] The Required: {Interview/Focus Group} will be audio recorded for the purpose of data collection. The audio recordings will be transcribed and deleted as soon as possible. Copies of the transcripts will not contain identifiable data (such as your name) and will be securely stored until completion of the study.

Optional: [If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:]

Please note that communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

When the results of this study are published, your identity will not be disclosed.

**Communication with Family Doctor**

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| *Guidance: Note: Please add this section if applicable (i.e., NGS testing, hereditary tests, etc.)* |

Your family doctor/health care provider Required: {Will/May} be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss this with the study team. Note: If communication with the family doctor is optional, please see the attestation page for opt-in language. Please ensure you provide a Dear Doctor letter for REB review if participation will be shared.

Optional: [OR]

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

## Risk of Privacy Breach

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 thatpersonal information or study data will be accidentally released or accessed without authorization is small

## In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

## Expenses Associated with Participating in the Study

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| *Guidance: Include whether participants will incur any expenses as a result of their participation in the study. Include any remuneration, gifts in-kind, vouchers, etc. to subjects and how reimbursement will be pro-rated if subjects withdraw early from study.* |

You will not have to pay for any of the procedures Required: {Or study drug/intervention} involved with this study. Required: You {Will be reimbursed/will not be reimbursed “$X”} for Required: {Transportation, meals, time, inconvenience, etc.}.

Optional: [OR if applicable] Participation in this study will not involve any additional costs to you.

## Conflict of Interest

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| *Guidance: 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 study, will pay the hospital and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

## Questions about the Study

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}. Note: [The 24 hour contact number can be repeated here if determined to be needed for the study (e.g. blinded study)]

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.

Study Title: Required: {Add}

By signing this consent form I agree that:

* This study 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 study at any time.
* I understand the requirements of participating in this research study
* I have been informed of the risks and benefits, if any, of participating in this research study
* I have been informed of any alternatives to participating in this research study
* 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 research study data as explained in this form
* Optional: [If applicable] I understand that my family doctor may be informed of my participation in this research study
* Optional: [If applicable] I understand that participation in this research study will be documented in my medical records.

Optional: [If applicable] Note: Please add any other optional sections if needed.

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| I **agree** to be informed of any incidental findings learned as a result of my Required: {Type of Sample} being tested  I **do not agree** to be informed of any incidental findings learned as a result of my Required: {Type of Sample} being tested |
| I **agree** to notify my family doctor about my participation in this research study  I **do not agree** to notify my family doctor about my participation in this research study |

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

Print Name of Participant Signature Date

[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