# 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.*

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

Investigator: Required: [Enter name, title, and telephone number of the Principal Investigator]

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

**Research Coordinator:** Required: [Enter name(s) with title(s) of Research Coordinator here if applicable]

**Sponsor/Funding Agencies:** Optional: [If applicable, enter Sponsor / Funding Agencies.]

**Protocol number**: Optional: [If applicable, enter protocol number.]

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

## 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.

*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

*Guidance: Provide background information on what prompted the need for this study. Refer to standard of care, knowledge to date etc. Describe the primary reason for the study and draft a paragraph that provides basic information about it. Define any concepts that may not be well understood outside of the research setting (e.g. efficacy). Samples of the type of detail that should be included in the purpose can be found in the bulleted sentences below.*

* You have been asked to take part in this research study because you Required: {e.g. have Type 2 Diabetes}. 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}.
* Optional: [For Health Canada regulated studies] The Required: {study drug/device} used in this study has not been approved for use by Health Canada but is approved for use in this research study. This is why Required: {study drug/device} is considered an experimental Required: {study drug/device}.
* 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 the approach to conducting this research study including if it is randomized, blinded, multi-centre, and other details as appropriate. Note: Include all that apply and add any additional information as necessary.* |

* This study compares the study drug with a placebo. A placebo looks just like {the study drug} but contains no active medication.
* Whether you get the study drug or the placebo will be decided randomly (by chance) like flipping a coin or rolling dice. The number of people getting study drug will be Required: {“x” number} and the number of people getting placebo will be Required: {“y” number}.
* This study will be blinded. This means that you will not be told whether you are on {the study drug/intervention} or on {the placebo/ study drug/intervention} until the study is finished.
* This study will be double-blinded. This means that neither you nor the study team will not know whether you are on Required: {the study drug/ intervention} or on Required: {the placebo/ study drug/intervention} until the study is finished. This information can be found out at any time in case of an emergency.
* As part of this study, you will be asked to stop taking Required: {identify washout agent} for a period of Required: {insert washout period in weeks/months} before you begin the study intervention.
* Your participation in this study is randomized, meaning, participants in this study will be randomly (by chance) placed in one of Required: (total number of study groups) study groups. You will have a Required: (%) chance of being placed in [Required: [select one] any/either group.
* You will be in this study for Required: {duration of participation}.
* There will be Required: {“x” number} of visits during the study. Most visits will last for Required: {“x” minutes/hours}, though some may be as long as Required: {indicate time length as it applies to the study – e.g. for Infusion studies}.

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| It is anticipated that about {# of participants} people will participate in Required: {# or range of focus groups} focus groups in this study at William Osler Health System. Each focus group will take about Required: {length in min/hours} of your time. The focus groups will take place at {Required: {location of focus groups} The entire study is expected to take about Required: {total length of study in months or years}. Phase I studies: *“…test the safety of a new drug {DRUG (including trade name) / INTERVENTION} and see what effects (good and bad) it has on you and your (condition). This is the first time that {DRUG (including trade name) / INTERVENTION} is being tested in people.**OR “find the highest dose of a new drug {DRUG (including trade name) / INTERVENTION} that can be given without causing very severe side effects that are not tolerable. This is the first time that the {DRUG (including trade name) / INTERVENTION} is being tested in people. This is done by starting participants at a dose lower than the one that does not cause side effects in animals. If the side effects are not severe, then more participants are asked to join the study and are given a higher dose of {DRUG (including trade name) / INTERVENTION}. This continues until a dose is found that causes severe but tolerable side effects.”*Phase II studies: *“…see what effects (good and bad) {DRUG (including trade name) / INTERVENTION} has on you and your (condition).”*Phase III studies: *“…compare the effects (good and bad) of a new drug {DRUG(including trade name)/INTERVENTION} compared to the best available existing therapy {STANDARD THERAPY (including trade name)/INTERVENTION/PLACEBO} on you and your (condition) to see which is better.”*Phase IV studies: *“…compare the effects (good and bad) of {DRUG(including trade name)/INTERVENTION} compared to {COMPETITOR’S DRUG (including trade name)/INTERVENTION} on you and your (condition) to see which is better.”* |

## Study Visits and Procedures

*Guidance: Name each procedure that the participant will be involved in and explain each one in lay terms. Verify that the consent form and protocol are consistent. It is helpful to include the purpose of the visit and separate the phases of the study under specific headings (e.g. Screening, Baseline, Randomization, Follow-up, etc.). Include how long each visit and procedure will take. If similar tests are done on multiple visits, try to minimize redundancy by grouping visits together, e.g. “on Visits 1, 2, 4, 6, and 10 the following tests will be done”.*

*The following items should also be considered in this section:*

* *Describe all tests, measures, questionnaires, participant diaries, procedures, interventions, or treatments that are outlined in the research protocol. Repeated explanations/definitions is usually not necessary so only define/explain at first instance.*
* *Make the distinction between research-related procedures and standard-of-care procedures clear. The consent should focus on research-related procedures and discuss standard-of-care where necessary.*
* *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). If responses to the questions are of a sensitive nature, e.g. HIV, illicit drug screen, depression testing, pregnancy, the subject should be forewarned and a sample of the type of question should be provided. If the response necessitates further action, describe what will happen (e.g. Report to public health, refer for counseling, etc.). Subjects should also be told they can refuse to answer any questions.*
* *Specify whether the collection of samples/tissues is optional (add option to consent page), what the sample/tissue is to be used for (i.e., current research study, commercialization, etc.),the type (i.e., blood) and amount of sample/tissue to be taken (i.e., in tablespoons), the manner in which sample/ tissue will be taken (i.e., blood draw),* *the conditions of preservation of the sample/tissue, how**long the sample/tissue will be stored, the location of storage (i.e., Company name, country), how samples will be transferred to storage off-site (if applicable), how samples will be destroyed, if leftover samples will be stored and why (i.e., in case samples are lost).*

***NOTE: Collection of samples/tissues for future unknown research and/or banking (i.e. where the research purpose is not yet known) should have a separate informed consent form.***

***NOTE: Optional research should have a separate informed consent form.***

### Optional: [If applicable] Questionnaires

You will be provided with a questionnaire Note: *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 *Note: include description of purpose e.*g., *to understand how the study intervention and illness affects your quality of life*. Each questionnaire will take about *Note: 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: [If applicable] Participant Diaries

You will be asked to keep a diary of when you *Note: identify e.g., take your study medication*. Please record *Note: identify what is being recorded e.g., the exact time of taking each dose every day*. You will be asked to return the diary to this centre.

## Schedule of Events

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| *Guidance: Using a table with visits and procedures can help illustrate what is involved in the study. In chart form, list what will happen at each visit. Ensure the entire chart fits onto one page and is not separated on to two pages. Note: Consider creating the table in excel and inserting the chart into your document.* |

E.g. **Boxes marked with an X show what will happen at each visit:**

| Visit | Blood test | Questionnaire | Focus Group | ECG | Time |
| --- | --- | --- | --- | --- | --- |
| Screening | X | X | X | X | 2 hours |
| Baseline | X | X |  | X | 1 hour |
| Visit 1 (Week “X”) | X |  |  | X | 20 min |
| Visit 2 (Week “X”) | X |  |  | X | 20 min |

## Reminders

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| *Guidance: List important things to remember during the study. Note: The information below is an example to be amended.* |

It is important to remember the following things during this study:

* You should not eat for 12 hours before visits.
* Do not take medications before visits.
* Do not eat or drink grapefruit during this study.
* Ask your study team about anything that worries you.
* Tell study staff anything about your health that has changed.
* Return study medication/diaries.
* Tell your study team if you change your mind about being in this study.

## Responsibilities to Being in the Study

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| *Guidance: List reminders while participating in the study. Note: The information below is an example to be amended.* |

If you choose to participate in this study, you will be expected to:

* Tell the study doctor about your current medical conditions.
* Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbals, and check with the study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the intervention you receive on this study.
* Tell the study doctor if you are thinking about participating in another research study.
* Return any unused study medication.
* Return any specify e.g., diaries or questionnaires that you take home to complete.
* Tell the study doctor if you become pregnant or father a child while participating on this study.
* Avoid drinking/eating Required: {specify what and for how long}.
* Stop taking Required: {name for specify washout period}.
* Required: {insert name of study intervention} is for you alone and must not be shared with others. Optional: If applicable, include: If someone accidentally takes Required: {insert name of study intervention}, Note: Include instructions e.g., they should immediately go to the nearest emergency department.

## Optional: [If applicable] **Mandatory Sample Collection**

*Guidance: Describe the mandatory sample collection, including the sample type and amount and manner/safety of acquisition, purpose of the research (including any commercial use), measures employed to protect privacy and minimize risk, and length, method, and location of storage. See suggestions below, or revise as applicable to the research*

The researchers doing this study need to do tests on samples (described below) to *Note: insert* s*tudy-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.

Optional: [If applicable] Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed or destroyed [include the following If applicable] unless you wish to give permission for other future research purposes, in which case you will be given a separate optional consent form to sign.

Hereditary genetic testing (to look at whether *Note: specify condition* runs in families) will not be done on these samples. Required: Or Hereditary genetic testing (to look at whether *Note: specify condition* runs in families) Required: will/may be done on these samples.

Optional: [If applicable] If you participate in this study it is possible that there will not be enough of your tissue sample left for other testing that may need to be done in the future. Please speak to the study doctor to discuss this possibility.

Even with protections in place, there is a risk that your information could be released by accident. Advances in technology could also increase the risk that your genetic samples and results could be linked back to you or your blood relatives. These results might contain information (e.g., an inherited genetic disease) that could result in problems for you or your relatives. There is no way to predict what effects such an information loss would have. You will Required: be given the choice/ not given the choice to find out about genetics testing results.

Reports about any research tests done with your samples will not be given to you, the study doctor(s) or study staff, your doctor, or other health care provider(s). These reports will not be put in your medical records. Required: *Or* Reports about research tests done with your samples will be given to the study doctor(s). If you would like to learn the results of this research, please let them know.

## Optional: [If applicable] **Tissue Collection**

*Guidance: Describe the method of tissue sample collection and associated risks. Specify the location and purpose for the review. See example text below, or revise as applicable to the research.*

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 applicable, explain whether they may still participate if a sample is not available or whether a fresh tissue sample will be required – see below]

Optional [If applicable, if archived samples are required from another Institution] 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.

Optional: [If applicable, if a fresh sample is required] As part of this study, you will have a tissue biopsy. A tissue biopsy is a type of surgical procedure, which will remove *Note: state how much tissue is to be taken e.g.* a pea size piece of your *Note: insert tissue type e.g.,* liver. *Explain in lay language whether this will be done using a local or general anesthetic and whether overnight hospital stay may be required.* This procedure has risks such as *Note: specify risks, e.g., blood loss, pain and rarely an infection at the biopsy site*.

These tissue samples will be sent to a laboratory Note: at *insert location* where they will be examined.

## Optional: [If applicable] **Blood/Urine Collection (Required)**

*Describe the method of blood/urine/other sample collection and associated risks. Specify the location and purpose for the review. See example text below, or revise as applicable to the research*

Urine will be collected *Note: 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 *Note: 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 study related tests whenever possible, *Note: 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 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 *Note: insert location* where they will be examined.

### How will samples be identified?

To protect your identity, the information that will be on your samples will be limited to *Note: specify which identifiers will be on the sample(s). If additional personal information is also being provided to the laboratory (e.g., on additional forms provided with the review materials), include a description of the information provided, e.g.,* The laboratory will also receive information containing your…

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.

### Can I withdraw these samples?

*Describe the process for withdrawal of samples, and any limitations to the withdrawal. See the suggested text below, or revise as applicable*

If you no longer want your samples to be used in this research, you should tell *Note: specify appropriate contact role*, who will ensure the samples are *Note: describe what will happen to samples if participant withdraws consent, e.g., returned to the hospital from which they were obtained or destroyed*.

Optional: [If applicable, are there any limits to withdrawal] 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: [If applicable, will samples be anonymized?] You can request withdrawal of your specimens until *Note: insert expected anonymization point,* whenthe 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.

Optional: [If applicable] *Note: State whether or not the participant may continue to participate in this main part of the study, if they withdraw these required samples.*

## Risks Related to Being in the Study

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| *Guidance:** *Include a list of all study related side effects. Separate side effects by study drug or study intervention as appropriate. Use lay language to describe or explain.*
* *Address the frequency and severity of side effects. Sometimes risks need to include side effects that have not been clearly linked to the study drug, e.g. increases and decreases in blood pressure have been Noted in some patients receiving the study drug but it is not clear whether these effects are truly related to the study drug.*
* *Address reversibility of side effects, long term side-effects as applicable and any treatments, interventions or precautions that may be taken to address these risks.*
* *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).*
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You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. You should discuss these with the study doctor. The study doctor will watch you closely to see if you have side effects. When possible, other medicine will be given to you to make side effects less serious and more tolerable. Many side effects go away shortly after the study intervention is stopped, but in some cases side effects can be serious, long-lasting, permanent, or may even cause death.

Optional: [If applicable] If you experience serious side effects that require treatment between regular clinic/hospital visits, it is important that you make every effort to return to the clinic/hospital where Note: insert name of product/agent/device was given. Because Note: insert name of product/agent/device is experimental and is only used in clinics/hospitals involved in research studies, any serious side effects may be best treated by these clinics/hospitals. If you need immediate treatment and are unable to return to the clinic/hospital, the study doctor should be contacted as soon as possible

Required: Describe all reasonably foreseeable risks, harms or discomforts. When detailing information about side effects, categorize risk by frequency.

* Very likely (21% -100%): Click or tap here to describe all reasonably foreseeable risks, harms or discomforts.
* Less likely (5 – 20%): Click or tap here to describe all reasonably foreseeable risks, harms or discomforts.
* Rarely (1 – 4%): Click or tap here to describe all reasonably foreseeable risks, harms or discomforts.

### Reproductive Risks

*Guidance: If the agent(s) used in the study present a real or potential risk of fetal or reproductive harm, this must be described. Generic wording for unknown risk is included below. If the study includes participants of a single gender, ensure this is reflected in the consent form*

It is not known if the drugs used in this study affect an unborn baby (fetus) or sperm. You should not become pregnant or father a child while in this study. Men and women who agree to take part in the study must use two forms of effective method of birth control including one barrier method, e.g. condom. The study doctor will tell you which birth control methods are acceptable.

Participants should discuss these risks with sexual partners of the opposite sex.

If you do get pregnant or father a child Note: specify period e.g., while taking study drug, you should immediately tell the study doctor. Optional: [If applicable] The study doctor will ask if you/your partner are willing to provide information about the pregnancy as part of this study. If your partner becomes pregnant, she will be given a separate consent document to sign to give permission for the collection of this information. You or your partner may choose not to give consent for the collection of this information or may withdraw consent at any time without giving a reason. This will not impact your participation on the study and will not result in any penalty or affect your or your partner’s current or future health care.

Optional: [If applicable] If you nurse (breastfeed) a child Note: specify period e.g., while taking [insert name of product/ agent/ device] and for [identify post-intervention period] after the last dose, you should immediately notify the study doctor. The study doctor will ask if you are willing to provide information about this as part of the study. You will be given a separate document to sign to give permission for the collection of this information, if this should happen.

## Benefits to Being in the Study

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| *Guidance: Avoid overstating the benefits. When there is no intended medical benefit or personal benefit to the subject, the subject should be made aware of this. 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.

Optional: [If applicable] You will not benefit from the placebo used in this study.

## 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

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| *Guidance: Optional: If you will continue to collect data after the point of withdrawal, please make this clear and provide a reason. Optional: For anonymous studies, please add “If you choose to withdraw from the research study, any data collected from you cannot be withdrawn”.* *Optional: For studies collecting tissues or samples, please also include withdrawal of samples, who to contact to do so, and disposal of leftover samples. For example: “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.”* |

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

## Can Participation in the Study End Early?

*Optional: [If applicable]* The sponsor may decide to end the study at any time and for any reason.

The investigator(s) may decide to remove you from this study without your consent for any of the following reasons: *Note: [List reasons in point form. See below for some examples.]*

* The investigator(s) decide(s) that continuing in this study would be harmful to you.
* You plan to become pregnant, plan to discontinue acceptable birth control, or become pregnant.
* You are unable or unwilling to follow the study procedures.
* [Include stopping rules i.e. when there is evidence that the study should be stopped due to safety reasons or lack of treatment effect (when the treatment is not working well).

If you are removed from this study, the investigator(s) will discuss the reasons with you Required: {and plans will be made for your continued care outside of the study}.

## Alternatives to Being in the Study

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| *Guidance: For non-clinical studies this section may not be necessary. Include a disclosure of appropriate procedures or courses of treatment that may be an alternative or standard of care alternative. If the subject can receive the same medications or study intervention without participating in research this must be stated. Address palliative care or non-treatment as alternatives, where applicable.* |

You do not have to join this study to receive treatment for your condition.

* + The following are approved medications/interventions for your condition:
	+ Required: medication 2.
	+ Required: medication 3.
	+ There are also other research studies looking at other treatments for your condition.
	+ You may choose not to have any treatment for your condition.

Your doctor will discuss any of these options with you.

## Incidental Findings

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| *Guidance: See attestation page for optional opt-in to have incidental findings communicated.* |

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.

Optional: [if applicable, collecting ‘race/ethnicity’] Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is Note: voluntary/required.

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 – samples sent outside of Canada] Any information Note: and/or samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data Note: and/or samples, that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

Optional: [if applicable – if FDA regulated] Because this study also falls under U.S. regulations, in the event of an investigation of the study, the US Food and Drug Administration (US FDA) may need to copy and take away records that contain your personal information. If possible, the study doctor will inform you and confirm your consent at that time. By signing this consent form you are agreeing to this release of information. You should be aware that privacy protections may differ in other countries.

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

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.

Required: 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 withoutauthorization 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

*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: [if applicable] You will need to provide your receipts for insert expense types e.g., parking to the research staff in order to be reimbursed.

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

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

* The intervention may not turn out to be effective or safe.
* The intervention 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 intervention, even if approved in Canada, may not be available free of charge.

The study doctor will talk to you about your options.

Optional: [If applicable] After the study is completed, if the study doctor feels that you are benefiting from the experimental intervention, you will continue to be provided with Note: insert name(s) of product/agent/device.

Taking part in this study may result in added costs to you. For example:

* Note: insert name(s) of product/agent/device/intervention used in this study may not be covered by provincial insurance. You can speak with the study team about added costs. Everything possible will be done to help you access reimbursement from your insurance company or other third party payer.
* There may be extra costs that are not covered by your medical plan. Examples of these extra costs could be medications or treatments (such as physiotherapy) to treat side effects that you may experience. If you have private health care insurance, the insurer may not pay for these added costs.
* There may be costs associated with hospital visits. For example, parking or transportation, or snacks/meals during your stay.
* You may miss work as a result of participation in this study.

Optional: [if applicable] It is possible that the research conducted using your Note: samples and/or study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products. There are no plans to provide payment to you if this happens.

## Optional Research

The Researchers doing this study are interested in doing additional optional research. You will be given an additional optional study consent form to read and sign if you wish to give permission for this. You may decide not to participate in the optional research and still participate in this main study.

## Conflict of Interest

|  |
| --- |
| *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.

## Online Information about the Study

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

Required: OR

A description of this clinical trial will be available on Note: insert web address. This website will not include information that can identify you. You can search this website at any time.

## 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 study.

You have the right to be informed of the results of this study once the entire study is complete. Note: Explain how the participant can obtain the results, for example: If you would like to be informed of the results of this study, please contact the study doctor.

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 study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, 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.

## 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 Study Title}

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.

|  |
| --- |
| [ ]  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 Full Name of participant/substitute decision-maker here.]

Name of participant/substitute decision-maker (print)

Signature

[Enter Date here.]

Date

[Enter Full Name of Person Obtaining Consent here.]

Print Name of Person Obtaining Consent

Signature

[Enter Date here.]

Date

|  |
| --- |
| *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 Full Name of Translator here.]

Print Name of Translator

Signature

[Enter Date here.]

Date

[Enter Relationship to Participant here.]

Relationship to Participant

[Enter Language here.]

Language

## Optional: [if applicable] Consent to be contacted for future studies

We would also like to ask that you consider providing consent to be contacted about future research studies. The information that you should consider before agreeing to this is outlined below.

I have been told about the possibility of being contacted for future studies. I understand that my participation in these future studies is voluntary and my refusal to participate will not affect my participation in the main study.

I understand that if I consent to be contacted for future studies, my contact information including my name, phone number, address and hospital number will be stored securely by the study staff for this purpose. No information will be collected about me without my consent. Note: Only [Principal Investigator] research team will be contacting you. You may be contacted for studies that relate to this study’s subject area. You will only be contacted over the Note: next 10 years by telephone, mail, or email (provided you have provided us email consent).

You are not obligated to participate in any research studies that you are contacted about. If you no longer want to be contacted about future research studies, please contact the study coordinator Note: at [add contact information of current research study here].

By signing this section­ of the form I am not consenting to have additional measurements taken, but are consenting to be contacted later on. If you are called for a future research study, you will still have the opportunity to decline at that time, and if you decide you are interested, you will be asked to sign a separate consent form for each individual study.

## Statement of Consent – Future Contact for Research Purposes

I have read the above information, and I agree to be contacted for future research as described above.

[Enter Full Name of participant/substitute decision-maker here.]

Name of participant/substitute decision-maker (print)

Signature

[Enter Date here.]

Date