**SUNNYBROOK RESEARCH ETHICS BOARD (REB)**

**Instructional Notes for Informed Consent Form (ICF) Template   
– *not to be included in the informed consent form***

**Instructions**

This ICF Template has been designed to meet current regulatory and ethical standards.

* The Sunnybrook REB requests that all ICFs follow the prescribed structure and format as set out in this template to facilitate REB review. Other ICFs that are compliant with the applicable regulations and guidelines as outlined in the [Informed Consent Form Checklist](http://sunnybrook.ca/research/content/?page=sri_csrc_reo_forms) will be accepted for review.
* To assist in drafting the ICF, it is recommended that the Informed Consent Form Checklist be used concurrently.
* Sections and headings in **BLACK TEXT** should be included in an ICF, however, if text in black is incorrect or irrelevant to your study, the REB will consider new wording on a case by case basis.
* Sections and headings in **RED TEXT** may be omitted if they are not relevant to the specific protocol.
  + All red text should be edited appropriately for the specific protocol. After all edits have been completed, convert the text to black
  + [Instructions] must be deleted after the required information has been inserted.\
* The Summary of Informed Consent Form on pages 20-21 of this template is required to be included for studies funded or supported by a US federal funding agency but also can be utilized for other studies if useful. Please ensure the Summary of Informed Consent Form is included at the beginning of the ICF document.

For queries related to the ICF Template, contact the Research Ethics Office.

**INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Full Study Title:** << same as the Protocol and REB application >>

**Principal Investigator:** << name, department and telephone or pager number>>

**Sponsor or Funder:** This study is being funded by << Funding Body(ies) including internally funded sources and in-kind support (i.e. equipment and drug suppliers). >>

**Sponsor’s Study ID:** <<Insert sponsor’s ID if applicable>> [Required for studies that are regulated by Health Canada]

**Emergency Contact Number (24 hours / 7 days per week)**: [Required for studies that include greater than minimal risk research procedures or interventions]. **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**INFORMED CONSENT**

[If applicable] << 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. >>

You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood.

This form explains the purpose of this research study, provides information about the study , the tests and procedures involved, possible risks and benefits, and the rights of participants.

<< You may take as much time as you wish to decide whether or not to participate. >> [If time permits] << Feel free to discuss it with your friends and family, or your family doctor. >> [If time is limited] << The study staff will tell you if there are any study timelines for making your decision. >> Please ask the study staff or one of the investigator(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study. If you wish, someone may be available to verbally translate this form into your preferred language.

Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time.

**INTRODUCTION**

You are being asked to consider participating in this study because you << have condition X / are about to undergo Y procedure OR are a healthy individual / are a nurse >>.

[Explain the background for the study referring to knowledge to date (i.e. what prompted the need for this study?), the study drug/procedure/device or test, and why it might help in language accessible to a lay audience. Emphasize the big picture as to why the study is important, and avoid study details (i.e. to test safety and efficacy) which are described later in the document.]

**[Required for all Division 5 clinical trials]**

<< Health Canada has not approved DRUG (including trade name)/DEVICE for use or sale for (condition), although they have allowed its use in this research study. >>

OR

<< Health Canada has approved DRUG (including trade name) for use or sale for (condition), although they have not approved its use for (condition). Health Canada has allowed the use of DRUG (including trade name) in this research study. >>

**WHAT IS THE USUAL TREATMENT?**

[Describe current standard of care for the condition.] << Usually, (condition) is treated with/by [insert standard of care]. >> [If applicable, include] << You [select one] may/will not receive the usual treatment for (condition) if you decide to participate in this study. >> [For clinical trials involving placebo, describe any therapy that will be withdrawn or withheld for purposes of the research study, and the anticipated consequences.]

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to << enter objectives/rationale >>. [Refer to suggestions below.]

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. >>

Qualitative Research Study example:

<< explain the hypothesis being tested and what the research is supposed to demonstrate. >> << This will be accomplished through focus groups. A focus group is a small group of representative people who are asked by a moderator to speak about their opinions as part of research. >>

**WHAT WILL HAPPEN DURING THIS STUDY?**

[Describe treatment/intervention by study group, and probability of assignment to each study group. See suggestions below. If these suggestions are not applicable, provide a detailed description appropriate to the specific protocol. For studies with more than two study groups, consider inserting a flow chart similar to the Study Plan at the end of this document.]

Double-Blinded, Randomized Studies:

<< Participants in this study will be randomly (by chance) placed in one of (total number of study groups) study groups. Neither you, the study staff nor the investigator(s) can influence or will know which group you are in. However, in case of an emergency the study treatment can be identified. You will have a (%) chance of being placed in [select one] any/either group. >>

Placebo, Double-Blinded, Randomized Studies:

<< This is a placebo-controlled study. A placebo is a pill that looks like the study drug but does not have any active or medicinal ingredients. The placebo in this study will be the same shape, size and colour of DRUG (including trade name), but is not expected to have any effect on your (condition). A placebo is used to eliminate bias in the study, making the results of the study more reliable. Participants in this study will be randomly (by chance) placed in one of the two study groups (DRUG (including trade name) or placebo). Neither you, the study staff nor the investigator(s) can influence or will know which group you are in. However, in case of an emergency the study treatment can be identified. You will have a (%) chance of getting placebo during the entire study. >>

Single-Blinded Studies:

<< Neither you, the study staff nor the investigator(s) can influence which group you are in. You will not know which group you are in, but your study doctor and study staff will. >>

Open Label, Randomized Studies:

<< Participants in this study will be randomly (by chance) placed in one of (total number of study groups) study groups. Neither you, the study staff nor the investigator(s) can influence which group you are in. You will have a (%) chance of being placed in [select one] any /either group. You and the study staff will know which group you are in. >>

Qualitative Research Study example:

<< A moderator will organize the focus groups. Each focus group discussion will be about (# of minutes or hours) in length and will take place (specify location, i.e. in a private meeting room at Sunnybrook Health Sciences Centre). You will be asked to attend one focus group to speak about your experiences with (condition/intervention). The focus group sessions will be audio taped. >>

**Consider inserting a STUDY PLAN here. See end of this document for an example STUDY PLAN.**

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

[If this study will be recruiting both patients and non-patients (e.g. staff, students), provide enrollment numbers for each of these groups of participants.]

It is anticipated that about << # of participants >> people will participate in this study at about << # of centres >> centres throughout <<region >>. About << # of Sunnybrook participants >> people will participate in this study at Sunnybrook. The length of this study for participants is << duration of time for participants in weeks, months or years >>. The entire study is expected to take about << total length of study in months or years >> to complete and the results should be known in << # of years >>.

Qualitative Research Study example:

It is anticipated that about << # of participants >> people will participate in << # or range of focus groups >> focus groups in this study at Sunnybrook. The length of this study for participants is << a single >> focus group that will take about << duration of time for participants in minutes or hours >>. The entire study is expected to take about << total length of study in months or years >> to complete and the results should be known in << # of years >>.

**WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?**

[If this study will be recruiting both patients and non-patients (e.g. staff, students), provide responsibilities for each group of participants.]

If you decide to participate in this study you will be asked to do the following:

[Name and explain each of the procedures/responsibilities as it will be experienced by the research participant in lay terms. Clearly explain if there are parts of the study which a participant can choose not to participate in. It is helpful to separate the phases of the study under specific headings (i.e. screening, baseline, randomization, follow-up, etc.) and to include the purpose of the visit. If similar tests are done on multiple visits, try to minimize redundancy by grouping visits together.]

Details to be considered:

* The tests that will be done to assess eligibility, and the fact that depending on results, << there is a chance that you will not be eligible to participate in the study >>.
* **If the study uses competitive enrolment**, <<This study will use competitive enrolment. This means that once a certain number of participants have entered the treatment phase of the study from all of the research sites combined, no more participants will be enrolled into the study at any site. It is possible that you may finish the screening phase and be ready to enter the treatment phase of the study, but not be enrolled into the study. >>
* The total time commitment for participation.
* The total number or frequency of visits/contacts. << You will be asked to return to Sunnybrook Health Sciences Centre for nine visits over the next 18 months. >>. [Note: If the study will involve a large number of complex visits, the use of a simplified study visit table with broad categories is encouraged in lieu of a description of each of the study visits in paragraph format. An example is provided:]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Visit#/Week# | Questionnaires | Bloodwork | Chest X-Ray | Study Drug |
| 1; Week1 | X | X | X |  |
| 2; Week 3 |  | X |  | X |
| 3; Week 5 | X |  |  |  |

* The location of visits/contacts. << All study visits will take place at Sunnybrook Health Sciences Centre, (wing, floor and room number if known). >>
* The length of time for each visit/contact.
* What will happen at each visit/contact point with the investigator including by telephone/letter (i.e. procedures, tests, questionnaires, interventions, treatments and interviews). The more invasive the procedures, the more detail should be provided. If a questionnaire is to be completed, provide a description of the questionnaire/types of questions that will be asked, how long it will take to complete and that the participants have a choice of not answering any questions. Repeated explanations are not necessary, so only explain at first instance.
* What is being done as part of the study versus what is being done as part of standard care.
  + The focus should be on research-related procedures, specifically those that are experimental. << These procedures are experimental and being tested in this study. >>

OR

* + << These procedures are part of the regular care for (condition). >> [If applicable] << However, some of them may be done more often than if you were not taking part in this study. >>
* The drugs that will be administered and their therapeutic action in lay terms [i.e. hydrochlorothiazide which is a water pill designed to help get rid of excess fluid in your body].
* The need for “washout” of any drugs that the participant is currently taking and the potential risks/discomforts of this.
* Information regarding audio/videotaping and explicit options to consent (or not) to recording.
* Any follow-up contacts by telephone or mail and what is involved and how long each will take.
* Provide details on the patient’s ability to access the new drug upon study completion. If drug will not be made available, then state << The study drug will be provided to you only during this study and not after the study is over. >>
* If there are any products used in this study that may be culturally sensitive (e.g. pork, beef, etc.) please include the following statement:
  + << [Type of product] products were used to produce [product to be used in study]. Please speak with your study doctor if you have any concerns about these product(s). >>

**Collection of Human Biological Material and/or Genetic Data**

Details about the collection of human biological materials (i.e. tissue, organs, blood, plasma, urine, saliva, other bodily fluids, embryos, fetuses, fetal tissue and human reproductive material etc.):

* **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.**
* Specify whether the collection of samples/tissues is optional (i.e. for a sub-study directly related to the main research study) or mandatory for study participation.
  + When collection of the sample/tissue is required, state << The collection of (type of sample) is a necessary part of this study. >>
  + OR when optional, state << You may decide not to have your (type of sample) collected and still participate in this study. >> and use the check boxes on the signatory page.
* What the sample/tissue is to be used for (i.e. current research study, commercial use (for profit) or future unknown research/banking) << The (type of sample) will be used for research purposes only and will not be sold. The research done with your (type of sample) may or may not help develop commercial (for profit) products or tests. There are no plans to provide payment to you if this happens. >>
* **The type and amount of sample/tissue to be taken, the manner in which sample/ tissue will be taken, the safety and invasiveness of acquisition;**
* **The conditions of preservation of the sample/tissue.**
* How long the sample/tissue will be stored, the location of storage (i.e. **Company/Institution Name, City, Country**) and how the sample/tissue will be disposed.
  + << The (type of sample) will be discarded or destroyed once it has been used for the purposes described in this form. >>

OR

* + << The (type of sample) will be kept until it is used up, and then discarded or destroyed. >>
* Whether the participant will receive the results of any testing; << You (will/will not) be informed of the results if the (type of sample) is tested. >>
* [If applicable, **required for genetic research**] << If, as a result of your participation in this study, any new clinically important information about your health is obtained, you will be given the opportunity to decide whether you wish to be made aware of that information. >>
* **When collecting and banking genetic material**, address the associated ethical issues, including future contact of participants, families, communities and groups.
* Whether the sample/tissue will be linked to the participant, **the safeguards to protect the participant's privacy and confidentiality; << Any of your (type of sample)** that is sent outside of the hospital will have a code << and your initials >> and will not contain your name or address, or any information that directly identifies you. >>
* Whether the participant can withdraw their samples and who to contact to do so. The following statement should also be included; <<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.>>

**[If the study includes genetic testing (mandatory or optional), include the following:]**

**Genetic Testing**

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

Hereditary genetic testing (to look at whether << specify condition >>runs in families) will << not/will/may >> be done on these samples.

[Include if applicable (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) using language accessible to a lay audience:]

The study << will/may >> involve whole genome sequencing. Whole genome sequencing is the analysis of the complete set of genetic instructions in a cell.

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

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

You will << be given the choice/not given the choice >> to find out about genetics testing results.

If you are a First Nations, Inuit, Metis, or an indigenous person who has contact with Elders, you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including genetic testing.

# WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

# 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. If you decide to take part in this study, you should contact << study staff name, department, telephone or pager number >> about any side effects or study-related injuries that you experience. [The contact information provided here must not be a telephone number that defaults to an answering machine after regular business hours when the following conditions apply: the study involves more than minimal risk and there is the potential for participants to experience adverse events after regular business hours OR the study requires an emergency contact number.]

# [Describe the reasonably foreseeable risks, harms, discomforts and inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant, and how these will be managed.

# Separate the risks by study drug, procedure or intervention as appropriate.

# Address incidence/frequency, severity, and long term impact/reversibility.

# List frequencies/percentages in order of importance (i.e. rare but serious, very likely, likely, less likely, rare).

# Include percentage frequency with each side effect.

# Any serious side effects or risks such as stroke, heart attack or death should be listed in a separate paragraph and not buried in the text, or listed first if using the table format.

# Include psychological and emotional risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues. ]

[Below is a sample of a table that may be used. The category percentages are a guideline and may be modified as appropriate.]

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Side Effect | Frequency | | | | Severity | | | Long Term Impact | |
| Very Likely  (30-100%) | Likely  (10-30%) | Less Likely  (1-10%) | Rare  (0-1%) | Mild | Moderate | Severe | Temporary | Permanent |
| XXXX |  | X |  |  |  | X |  | X |  |
| YYYY | X |  |  |  |  |  | X | X |  |

[Describe briefly additional discomforts associated with common tests/procedures such as blood draws, x-rays, etc… if these tests are not a part of the participants’ normal clinical care.] <<There is a possibility of pain, bruising, swelling or infection related to giving blood. These discomforts are minimal and brief. >>

[If applicable] << The effects or discomforts of tests/procedures that are part of this study but are part of your normal clinical care will be reviewed by your [select one] family/treating doctor. >>

[Studies that present real and potential risks of fetal or reproductive harm should have a description of this risk. If reproductive risk exists, participants should be advised not to become pregnant (or father a baby) while in this study and after the study as applicable.]

<< The effects of DRUG (including trade name) / INTERVENTION on unborn babies or sperm are unknown. You should not take part in this study if you are pregnant or planning pregnancy. If you and your partner are of childbearing potential (physically able to have children) and you are sexually active, it is important that you practice an acceptable method of birth control during this study and for <<number>> months after you have stopped taking the study drug to prevent pregnancy. Clinically acceptable methods of birth control for this study include intrauterine devices (IUD), birth control pills, hormonal implants, injectable contraceptives, and using barrier methods such as condoms, vaginal diaphragm with spermicide, or sponge. >>

<< The medicine taken while breast-feeding can also pass into a nursing child through the breast milk. In this case, there is a possibility of causing harmful side effects to the child. The safety of DRUG (including trade name) / INTERVENTION during breast-feeding is not known. For this reason, those who are breast-feeding cannot take part in this study. >>

<< If you become pregnant or conceive a child during this study, or within <<number>> months after you have stopped taking the study drug, you are requested to notify your study doctor immediately. The study doctor will ask if you/your partner is willing to provide updates on the progress of the pregnancy and its outcome. If your partner becomes pregnant, they will be asked to sign a consent form to allow access to this information. If your partner does not consent to this, it will not affect your continued participation in the study. It is also recommended that you tell the doctor who will be taking care of you/your partner during the pregnancy that you took part in this study. >>

Qualitative Research Study examples:

<< You may become uncomfortable during the focus group while discussing your experiences with (condition/intervention). The moderator for the focus group will attempt to provide appropriate responses and will offer you the option to leave the focus group. Additionally, you may disclose information that may identify people or facilities. To minimize such risk, the moderator will encourage participants to refrain from using names. All names and identifiers will be deleted during the transcription process. Transcription is taking the words and dialogue on the audio tape and writing or typing it word for word. Additionally, during the focus group, the moderator will remind participants that the information shared is private and should not be repeated outside the focus group. >>

OR

<< There are no medical risks to you from participating in this study, but taking part in this study may make you feel uncomfortable. You may refuse to answer questions or stop the interview at any time if you experience any discomfort. >>

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff. [If applicable] << This may include new information about the risks and benefits of being a participant in this study. >>

**WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

# You may or may not benefit directly from participating in this study. << However, possible benefits include (describe possible benefits) >>. [If placebo-controlled study you cannot promise ANY benefit from test article.] Your participation may or may not help other people with << condition >> in the future. [If there is likely to be no benefit to participation, then state] << There are no benefits to you from taking part in this study. >>

# WHAT OTHER CHOICES ARE THERE?

# 

# If you decide not to participate in this study, << there is no other treatment available >>. OR

# If you decide not to participate in this study, << other treatment choices may be available. These may include: [Enter alternatives, including the option of doing nothing, and their important potential benefits and risks. Separate options into approved medications/interventions and other research studies.] >> [If time permits] << You can further discuss these treatment options with your [select one] family/treating doctor or the investigator(s) before deciding whether to participate in this study. >>

**CAN PARTICIPATION IN THIS STUDY END EARLY?**

<< 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: [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 << and plans will be made for your continued care outside of the study >>.

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 medical treatment or health care>> OR << your employment status >>.

If you withdraw voluntarily from the study << or at the request of your family doctor >>, you are encouraged to contact << name, department and contact information >> [if applicable] << immediately >>. << You may be asked questions about your experience with the study drug, and to cooperate in having whatever laboratory tests and physical examinations considered necessary to safely stop your study involvement. >>

[**For all multi-visit studies**] << If you withdraw your consent, the information about you and (type of sample/tissue) that was/were collected before you left the study will still be used. No new information about you will be collected (and no further testing of your (type of sample/tissue) will be done) without your permission. >>

**WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?**

<< Participating in this study may result in added costs to you for [Enter additional expected costs for parking, transportation, lunch, etc… Note: The Sunnybrook REB recommends that all study participants receive reimbursement for parking for visits that are above standard of care.] [If applicable] Although you will not have to pay for any study medications you take while participating in this study, you may need to pay for medications to treat the side effects that you may experience as a result of participating in this study. Your private health care insurer may not pay for all of these added costs. >>

OR

<< Participation in this study will not involve any additional costs to you >> [if applicable] << or your private health care insurer. >>

**WHAT HAPPENS IF I HAVE A RESEARCH RELATED INJURY?**

[If applicable] << If you become sick or injured as a direct result of your participation in this study, your medical care will be provided. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. >>

By signing this consent form, you do not give up any of your legal rights.

**ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?**

You will not be paid to participate in this study. << If you decide to participate in this study, you will be reimbursed $ [enter actual or maximum dollar amount] for some study related expenses such as [enter expenses such as parking, taxi, lunch]. [If applicable] You will receive payment [enter interval such as monthly, every six months, at each visit, etc…] throughout the study. [If applicable] If you decide to leave the study, you will receive a prorated payment for participating in the study. >>

**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 for this study to be handled in a confidential manner.

If you decide to participate in this study, the investigator(s) and study staff will look at your personal << health >> information and collect only the information they need for this study. << “Personal health information” is health information about you that could identify you because it includes information such as your;

* name, address, telephone number, date of birth, new and existing medical records, or the types, dates and results of various tests and procedures. >>

You have the right to access, review and request changes to your personal health information.

The following people may look at your personal << health >> information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

* <<Sponsor Name>>, the company that makes the {DRUG (including trade name) / INTERVENTION}, and its representatives and partner companies;
  + [If applicable] The role of the sponsor’s representatives include << role of sponsor’s representatives >>.
* Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre or the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook; and
* Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada <<, and other regulatory bodies such as the United States Food and Drug Administration (FDA) >>.

Access to your personal << health >> information will take place under the supervision of the Principal Investigator.

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

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. Study data that is sent outside of the hospital will be used for the research purposes explained in this consent form.

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. Any information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection may not be as strict as in Canada. However, any information will be transferred in compliance with all relevant Canadian privacy laws.

[**If identifiable data will be sent outside of the institution, include the following section:]**

Along with non-identifying study data, this study requires the transfer of identifiable information to <<insert name of institution/organization/individual etc.>> for the purposes of <<specify purpose>>. The following information will be transferred:

* <<Specify identifiable information to be transferred>>

The Principal Investigator will keep any personal << health >> information about you in a secure and confidential location in accordance with applicable regulations and policies and then destroy it according to Sunnybrook policy. [Drug, device or natural health product studies that are regulated by Health Canada require 15-year study-related record retention. There are no defined regulations or standards for other research studies (i.e., non-regulated). The Sunnybrook research ethics board's recommended standard is 10 years for non-regulated studies. However, sponsor, publishing journal or professional affiliation standards for record retention may apply.]

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

You have the right to be informed of the results of this study once the entire study is complete. [If applicable] << If you would like to be informed of the results of this study, please contact (name, department and contact information). >>

OR

<<If you would like to be informed of the results of this study, please provide your name, address and telephone number to (contact name, department and contact information). >>

[**Required for all studies subject to FDA’s jurisdiction. Do NOT modify text.**] << A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](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. >>

**[If this study will be collecting data over the internet or using apps/tools/devices, include the following section:]**

Collecting data using technology over the internet or using apps/tools/devices can increase potential risks to privacy and confidentiality. This study will be using <<insert what technology will be used>> to collect data for this study. 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. Please read the terms and agreement of the service provider for further information regarding data security and confidentiality of the technology being used.

**[For studies using U.S. based internet service providers such as Survey Monkey, include the following section:]**

This study will be using U.S. based internet service providers which means that the electronic data will be stored and accessed in the U.S. and is therefore 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.

**[If study will use methods to locate participants if they become lost to follow-up:]**

<< You will be asked to identify a person that the investigator(s) and/or study staff will contact if you are not reachable for follow-up that can provide information on how you can be reached and your health status. Upon your approval, the investigator(s) and/or study staff will inform this person of this possibility. >>

<< A civil register may be contacted by the investigator(s) and/or study staff to determine your whereabouts in the event that you are not reachable for follow-up. >>

**Other future research**

**[ICJME require access to data in publicly accessible databases in many situations and for future research. Investigators also may plan for secondary use of data. It is important that you plan for required data retention and clarify your intended future use. If de-identified data or samples may be used or shared for future research, include the following:]**

Your coded study data and/or coded samples may be used or shared with other researchers [If applicable] <<(inside and outside of Canada)>> for future studies.  “Coded” means that directly identifying information (such as your name and date of birth) will be replaced by a code, which will be applied to the study data and/or samples.   This may include storing the coded study data and/or samples in controlled-access databases/biobanks, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. Very limited coded study data may also be placed in an open access, publicly accessible database.  The goal of sharing is to make more research possible. However, the code matching your study data and samples with your name and other directly identifying study data will not be shared. [If applicable] <<Data that is shared in a database or with researchers outside of Canada may not be subject to the same ethical oversight as would be observed within Canada.>>

You will not be asked if you agree to take part in future research studies using your study data and/or samples. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data and/or samples. You << will/will not >> receive compensation for use of your coded study data and/or coded samples.

**[OR, for studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) where researchers will NOT be using specimens or information for future research (even if identifiers are removed), include the following paragraph. This paragraph is not required for non-US federally funded studies:]**

Your study data and/or samples will not be used or shared with other researchers for future studies, even if the researchers remove any information that could directly identify you.

**ARE THERE ANY CONFLICTS OF INTEREST/RELATIONSHIPS?**

[Describe any conflicts of interest or relationships that exist or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family as well as those of the institution. A conflict of interest exists if there is a potential benefit or the perception of a benefit to the investigator(s), study staff, member of their immediate family and the institution beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker’s fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person/entity with the conflict of interest, the type of incentive or inducement, and its source. See examples below.]

[If applicable] << Individuals name>> is receiving personal financial payment from << Sponsor/Funding Body(ies)>> for <<providing advice on the design of the study >>.

[If applicable: Any known institutional conflicts of interest/relationships are also to be declared in this section.]

[If no conflicts of interest exist, state] << There are no conflicts of interest to declare related to this study. [If applicable] The Principal Investigator is receiving financial payment from the Sponsor to cover the cost of conducting this study. >>

**COMMUNICATION WITH YOUR FAMILY DOCTOR**

[If applicable] << Your family doctor << may/will >> be informed that you are taking part in this study so that your study doctor and family doctor can help you make informed decisions about your medical care. >>

**WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?**

You have the right to ask questions and to receive answers throughout this study.

If you have any questions about this study you may contact the person in charge of this study (Principal Investigator) << **Name, department and contact information** >>.

<< The Sunnybrook Research Ethics Board has reviewed this study. >> If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the **Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 688144.**

**DOCUMENTATION OF INFORMED CONSENT**

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

Full Study Title: << same as the Protocol and REB application >>

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

Participant/Substitute decision-maker

By signing this form, I confirm that:

* This research study has been fully explained to me and all of my questions answered to my satisfaction
* 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 << health >> information, << medical record >> and research study data as explained in this form
* I have agreed, or agree to allow the person I am responsible for, to participate in this research study
* << I understand that my family doctor may be informed of my participation in this research study >>
* << This informed consent document may be placed in my medical records >>

[The box below is to be used for studies where there is collection of optional samples (i.e. for a sub-study directly related to the main study)]

|  |
| --- |
| I **agree** to allow my << type of sample(s) >> to be collected for the optional study(ies) as described in this consent form.  I **do not agree** to allow my << type of sample(s) >> to be collected for the optional study(ies) as described in this consent form. |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of participant/Substitute Signature Date

decision-maker (print)

**ASSISTANCE DECLARATION**

[The Assistance Declaration provides a mechanism for potential participants who are unable to read the informed consent form (e.g. due to illiteracy, visual impairment, motor function deficits, limited English proficiency, etc.) to participate in research studies.]

Was the participant assisted during the consent process (e.g. for needs related to reading ability, visual impairment, motor function deficits, limited English proficiency, etc.)?  Yes  No

The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study 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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Assisting (Print) Signature Date

Person obtaining consent

By signing this form, I confirm that:

* This study 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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person obtaining Signature Date

consent (print)

[**Required for clinical trials**.]

Statement of Investigator

I acknowledge my responsibility for the care and well-being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Investigator (print) Signature Date

[**As applicable**]

Witness Attestation

I attest that I was present during the full duration of the informed consent process. The research study appears to have been accurately explained to the participant/substitute decision-maker and all of their questions have been answered. I confirm that the participant/substitute decision-maker has provided their voluntary consent to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Witness (print) Signature Date

Example STUDY PLAN [Modify as applicable]

<< Another way to find out what will happen during this study is to read the study plan below. Start reading at the top and read down the list, following the arrows. >>

[Please modify as applicable.]

Start Here

Informed Consent

Screening

Randomization

Study Drug A

1 year

Placebo Group

1 year

Study Drug B

1 year

1 year post treatment follow up

1 year post treatment follow up

1 year post treatment follow up

[For studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) include this summary of information as required by the US federal regulations at the beginning of the ICF. May be used for other studies if found to be useful for participant understanding. This summary should contain only the information that is most likely to assist a prospective participant in understanding the reason for or against participating in the research, as outlined below. Some items included in the summary section may be repeated in the subsequent consent sections if necessary to ensure the subsequent sections make sense or if the information is core to informed consent (e.g., risk of death), otherwise duplication should be avoided.]

Summary of Informed Consent Form

**Study Title**: *<<* insert study title as written on the protocol >>

Below is a summary of information about the study. There is more information in the document (called an “Informed Consent Form” that follows this summary. Please read the Informed Consent Form. The research team will also talk to you about the study and you can ask any questions you may have.

**Participation in research is voluntary**. It is your choice whether you take part in this clinical trial.

Study purpose

The purpose of this trial is << provide a brief description of the primary reason why the research is being conducted, no more than 2-3 sentences. *>>*

Duration

It is expected that study participation will last << provide expected duration. >>Participants will be followed for << define period of time. >>

Study Procedures

[Briefly describe the intervention(s), highlight key study procedures and, if applicable, outline procedures that may be lengthy/burdensome to participants]

This study is looking at << describe interventional group(s). >> Participants will also << briefly describe key procedures e.g., study visits every X weeks during which the researchers will do some tests. >> [If applicable:] You will be asked to do << describe lengthy or burdensome procedures >> which may take << specify time >> extra time.

Risks.

[Describe the most important risks. Consider those most probable and/or associated with the highest magnitude of harm. Key information should not include the full list of risks.]

Participation in this study may involve risks to you. These risks are described in detail in the informed consent form.

[Include the risks participants are most likely to experience. This should not include the entire ‘very likely’ or ‘likely’ category from the main consent. Researchers must review the risks and identify those that are most likely.]

The risks you are most likely to experience are:

* << Specify risk in lay language with expected frequency >>

[If applicable, include any serious risks. For the purposes of this summary, serious risks are considered those that may result in death, hospitalization, or are permanent.]

The most serious risks are:

* << Specify risk in lay language with expected frequency >>

Benefits.

[Insert direct benefit, or state if there is no direct benefit. If direct benefit to participant is unknown but there is a greater benefit to society, include for example:]

We do not know if you will receive medical benefit from participation but researchers hope that this study will fulfil its purpose and benefit others in future.

Alternatives.

You do not have to participate in this study to receive medical care.

[If applicable:] You may have other medical options – you should discuss this with your health care provider.