Instructions Participant Information and Consent Form Template

Standard Research Studies

Researchers must address three components in informed choice: competence, information disclosure and voluntariness (Refer to the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans).

* The investigator should prepare the consent information using ordinary language and avoid using jargon. Supply explanations (in lay terms) for crucial terms. Consent should be written at a grade 8 reading level.
* The consent must be written in 2nd person and should be phrased in a tone that is respectful to the participant (e.g., participant should be *asked* to return for a final visit; participants who become pregnant during the study should be *asked permission* to following the pregnancy.)
* **Use “participant” not “subject” or “patient” when referring to individuals participating in the study.**
* Define all acronyms when they first appear and limit their use.
* Font type/size (normally 11 or 12pt) and formatting should be consistent throughout the document. Please review for spelling and grammatical errors prior to submitting. Eliminate repetitive information.
* The footer of the consent form must include the version date, page number(s), and a place for participant initials.
* The header of the consent form must include clinic/company logo and address.
* Study Title on the Consent should be identical to the title on the protocol and on the application.
* If you need to request personal health information for the participant from another custodian (i.e., primary care physician, medical specialist), consent for the release of this information [referred to in the Health Information Act (HIA), Section 34(1)] must be provided and include the requirements outlined in the HIA, Section 34(2). Please refer to our website <https://hreba.ca/hreba-clinical-trials-committee/templates-and-forms/> - Consent to Disclose Health Registration Information Template.
* All sections of this template are to be included in the final draft unless deletion is well justified, or section is stated as optional.

**NOTE:**

* **The study will not be reviewed unless all mandatory and verbatim requirements are met.**
* **Please ensure the headings are in the same order as in the template, do not add any additional headings or subheadings**
* **If the template is not followed, the study will be returned to the study team prior to the meeting to be corrected**

**In the template below:**

* **MANDATORY AND VERBATIM WORDING** is in black (do not add any other information in these sections unless otherwise indicated in red)
* **INSTRUCTIONS** are in *red italics* (do not include in the ICF)

**Participant Information and Consent Form**

**Research Study Title: ­­­­­­­­­­­­­­­­­­­­­** *[Study Title as written on the protocol]*

*[(Non-technical lay title)]*

*This title should be short & convey the purposes of the study.*

**Protocol ID:**

**Study Doctor** *[If “Study Doctor” is not applicable substitute “Researcher”]***:**

*[Dr. Name]*

*[Department]*

*[Institution/Site]*

*[Contact Number]*

**Sponsor** *[add Funder if different]***: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Emergency Contact Number** (24 hours / 7 days a week): *[Number]*

*A 24-hour, 7-day a week phone number is required for all studies that include greater than minimal risk research procedures or interventions. Please ensure that the number used is available 24 hours/7 days a week.*

Non-Emergency contact numbers are noted at the end of this document under the section heading “WHO DO I CONTACT FOR QUESTIONS?”.

You are being invited to participate in a research study because you have *[explain the main features of the population to which the research applies].* This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information. All questions should be answered to your satisfaction before you decide whether to participate.

The study staff will tell you about timelines for making your decision. You may review this document with family or friends if it will help you understand it and decide about participating.

Taking part in this study is voluntary. You may choose not to take part or, if you choose to participate, you may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study will not result in any penalty or any loss of medical or health-related benefits to which you are entitled.

If you are a religious or spiritual person you may feel that it is important to talk to your elders, religious, cultural, or spiritual leaders or advisors when you are deciding whether to join this research study.

The study doctor, who is one of the researchers, will discuss this study with you and will answer any questions you may have. If you do consent to participate in this study, you will need to sign and date this consent form. You will receive a copy of the signed form.

*Only include this section if the PI/Co-I have a Conflict of Interest.*

**IS THERE CONFLICT OF INTEREST RELATED TO THIS STUDY?**

*Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators or study staff. A conflict of interest exists if there is a potential benefit to the investigator(s), or study staff beyond the professional benefit from academic achievement or presentation of 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 with the conflict of interest, the type of incentive or inducement, and its source. See examples below.*

The *[identify the individual, e.g., study doctor, name]* is receiving personal financial payment from *[identify the source of funds e.g., the study Sponsor]* for *[include reason for payment e.g., providing advice on the design of the study]*.

and/or

The *[identify the individual, e.g., study doctor, name]* *[examples follow as guidelines, choose the wording which applies or create similar wording to accurately disclose the conflict in the current study]* occasionally acts as a consultant for the Sponsor and has received payments from the Sponsor for these services. For example, the *[identify the individual, e.g., study doctor, name]* has *[Note services provided to Sponsor, e.g. presentations re: at scientific conferences, sits on advisory panels/board, and/or provides consultation as an expert in meetings with the sponsor]*.

and/or

The *[identify the individual, e.g., study doctor, name]* *[use wording that discloses things such as whether the Investigator has shares in/owns patent in/etc. the drug company/device/etc.]* Because Dr. *[name of PI/Co-I]* has been paid for these services, it is considered to be a potential conflict of interest by the ethics committee (Health Research Ethics Board of Alberta – Clinical Trials Committee) and the committee requires the study doctor to let you know about this in case you have any questions or concerns. In addition to letting you and the ethics committee know about this conflict of interest (or possible conflict of interest), the *[identify the individual, e.g., study doctor, name]* has provided a management plan to address any concerns that might arise during the research.

The *[identify the individual, e.g., study doctor, name]* will not encourage you to take part in this study over other studies or over standard treatment for your condition, because of this conflict of interest and will not prevent you from withdrawing from the study at any time should you so choose. If you ever have concerns about this, you should talk to the *[identify the individual, e.g., study doctor, name]* or contact HREBA.CTC Toll-Free: 1-877-423-5727.

**WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?**

*This section should include a description of the disease/condition being investigated, current standard therapy, possible deficiencies in the standard therapy and the rationale for the investigational treatment (why the study drug/procedure has potential for participants). This is a very important section for participants as it explains why the study is being done.*

*For instances where there is no established standard treatment use:*

At this time, there is no standard approach or known intervention to treat your condition.

*For studies under Health Canada oversight, include the following or a version there of depending on the scenario:*

Health Canada, the regulatory body that oversees the use of natural health products, drugs and devicesin Canada, has not approved the sale or use of this [product *or* agent *or* device] to treat this kind of condition, although they have allowed its use in this study.

The Health Research Ethics Board of Alberta – Clinical Trials Committee (HREBA-CTC), which oversees the ethical acceptability of research involving humans, has reviewed and granted ethics approval for this study.

**WHY IS THIS STUDY BEING DONE?**

*This section should, in lay terms, reflect the primary objective(s) of the study, as contained in the protocol. This section should be relatively short and not include information on the how the study is designed or conducted. Delete paragraphs that are not applicable.*

*Pilot or feasibility study:*

The purpose of this [pilot *or* feasibility] study is to help understand if it is possible to do the study with a small number of participants before a larger study is started. Because there will only be a small number of participants, it is not expected to give complete answers to the research questions and will not prove safety or effectiveness. The results may be used as a guide for larger studies, although there is no guarantee that those will be conducted. Participation in a [pilot *or* feasibility] study does not mean that you will be eligible to participate in a future larger study.

*Phase I Studies:*

The purpose of this study is to test the safety of a new [product *or* agent *or* device], *[insert name of product/agent/device],* to see what affects it has on you and your *[specify disease]*. This is the first time it has been tested in people.

*or*

The purpose of this study is to find the highest dose of a [product *or* agent *or* device], *[insert name of product/agent/device],* that can be tolerated without causing severe side effects. This is done by starting at a dose lower than the one that does not cause side effects in animals. Participants are given [product *or* agent *or* device] and are watched very closely to see what side effects they have and to make sure the side effects are not severe. If the side effects are not severe, then new participants will be given a higher dose of [product *or* agent *or* device]. Participants joining this study later will get higher doses of [product *or* agent *or* device] than participants who join earlier. This will continue until a dose is found that causes severe but temporary side effects. Doses higher than that will not be given.

*Phase II Studies:*

The purpose of this study is to find out what effects a new [product *or* agent *or* device], *[insert name of product/agent/device],* has on you and your *[specify disease]*.

*Phase III Studies:*

The purpose of this study is to compare the effects on you and your *[specify disease]* of a new [product *or* agent *or* device]*,* *[insert name of product/agent/device],* compared to other[products *or* agents *or* devices]which are commonly used to treat this disease.

*Phase III Placebo Controlled Studies:*

The purpose of this study is to find out *[specify purpose: e.g., whether it is better to receive a product/agent/device, insert name of product/agent/device, or better to receive no further treatment for insert disease type]*. To do this, some of the participants in this study will get [product *or* agent *or* device] and some will receive a placebo (a substance that looks like the study drug but does not have any active or medicinal ingredients). The placebo in this study is not intended to have any effect on your *[specify disease]* or be of benefit to you*.* A placebo is used to make the results of the study more reliable.

***The following sections are mandatory if a placebo is being used.*** *(If placebo is used for blinding purposes only, use only the first two paragraphs):*

**USE OF PLACEBO**

What is a placebo?

A placebo is an inactive substance; it has no medication (drug) in it. It looks the same as the real medication.

Why is a placebo used in this study?

In a research study it is important to obtain accurate information. Many people who have (add name of disorder) disorder (*explain the issues about the disorder that are relevant to the justification for the use of placebo)*. A placebo is used to make the results of the study more reliable (*or list any other reasons)*.

What will I give up if I receive placebo?

As previously mentioned, there are a number of treatments available for the treatment of (add name of disorder) disorder. If you choose to participate in this study, there is a (add the probability i.e., 1 in 5) chance you will receive placebo. This will lengthen the time before you receive a treatment that may be effective. During this time, you may experience worsening of your condition, including increased symptoms such as (*list symptoms)*. If your symptoms worsen and make you uncomfortable or concerned, you can withdraw from the study. You can do this at any time during the study.

*Phase IV Studies:*

The purpose of this study is to look at an approved product to obtain additional information about *[specify purpose, e.g., benefits, side effects, etc.].*

**WHAT ARE OTHER OPTIONS IF I DECIDE NOT TO PARTICIPATE IN THIS STUDY?**

*Explain the alternative options available to the study population, and their important potential benefits and risks.*

You do not have to take part in this study, to receive continued medical care. Other alternatives in addition to standard care may include:

* *[current standard of care]*
* *[other experimental studies may be available if you decide not take part in this study.]*
* *[continuing regular observation and routine follow-up care e.g., symptom management]*
* *[no therapy at this time. With this option, your disease is expected to progress and could spread.]*

Please talk to the study doctor or your care doctor about the known benefits and risks of these other options before you decide to take part in this study. Your study or care doctor can also discuss with you what will happen if you decide not to undertake any treatment at this time.

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

*Phase I/II example:*

Up to *[<X>]* people will take part in this study at this site.

*Phase III example:*

About *[<X>]* people globallywill take part in this study. We plan to enroll about *[<X>]* people at the *[insert local site name]*; but local enrollments may be larger if there is still room in the study and more people want to join.

**WHAT WILL HAPPEN DURING THIS STUDY?**

**ASSIGNMENT TO A GROUP**

*If there is more than one study group, describe how participants are placed into study group(s). See suggestions below. If these suggestions are not applicable, provide a lay description appropriate to the specific protocol.*

*For randomized studies:*

If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have *[explain probability of randomization e.g., an equal or a one in three, etc.]* chance of being placed in [either or any] group. Neither you, the study staff, nor the study doctor can choose what group you will be in.

*Explain whether participants or others will know which group the participant will be in. See suggestions below.*

*For open label, randomized studies:*

You will be told which group you are in.

*For single-blinded studies:*

This is a single-blinded study, which means that you will not know which group you are in, but the study doctor and study staff will.

*For double-blinded studies:*

This is a double-blinded study, which means that neither you nor the study doctor or study staff will know which group you are in. This is done so that you and the study doctor will not be influenced by expectations of the effects of the study [product *or* agent *or* device] or *[list any other reason].* Your treatment will be identified if medically necessary by a process referred to as unblinding. Requests to reveal your assignment for your information or participation in other research studies will not be considered until the study has been completed and the results are known.

*For trials with treatment assigned based on protocol-specific criteria:*

If you decide to participate in this study, then you will be assigned into one of the groups described below. The group you are assigned to will be determined by *[specify assignment criteria]*. You will be told which group you are in.

*If applicable, include the following:*

Once a certain number of participants have entered the intervention phase of the study from all the research sites combined, no more participants will be enrolled into the study at any site. If it is possible that you may finish the screening phase and be ready to enter the intervention phase of the study, but not enrolled into the study.

*If your study includes Competitive Enrollment – the expectation is that the Sponsor will carefully monitor screening and enrolment and will halt further screening if they are close to completion of enrollment. If a consented patient is in screening and meets I/E criteria, they should be permitted to be enrolled. Add the following sentence:*

Everything will be done to ensure that you will be able to participate in the study if you enter the screening period and meet the criteria to enter the study. The Sponsor will inform the study sites when enrollment is coming close to being filled or if there is any hold placed on screening activities

**STUDY INTERVENTION**

*Describe intervention by study group, including a clear identification of experimental components of the study. See suggestions below. If these suggestions are not applicable, provide a detailed description appropriate to the specific protocol.*

*Single arm studies:*

If you agree to take part in this study, you will *[describe intervention and method: e.g., you will be given product or agent by needle into one of your veins; Or you will take product or agent by mouth; Or you will complete X procedure. Include the length of procedure for all non-oral interventions: e.g., the procedure will take about<X> minutes. Include the frequency of intervention for multiple visits: e.g., This will happen every <X> weeks for <X> months. Or Your treatment will be given in cycles, indicate the duration, frequency, and number of cycles.].*

*Multi-group studies (ensure that the Group/Arm names and descriptions are consistent with the protocol):*

Group 1 (Experimental intervention): standard intervention *[specify agent name or regimen or*

*intervention]* plus experimental intervention *[specify the experimental agent name or regimen or intervention].*

If you are randomized into this group, you will *[describe intervention and method: e.g., you will be given product or agent by needle into one of your veins; Or you will take product or agent by mouth; Or you will complete X procedure. Include the length of procedure for all non-oral interventions: e.g., The procedure will take about <X> minutes. Include the frequency of intervention for multiple visits e.g., This will happen every <X> weeks for <X> months. Or Your treatment will be given in cycles, indicate the duration, frequency, and number of cycles.].*

Group 2 (Non-experimental intervention): standard intervention *[specify agent name or regimen or intervention].*

If you are randomized into this group you will *[describe intervention and method: e.g., you will be given product or agent by needle into one of your veins; Or you will take product or agent by mouth; Or you will complete X procedure.* *Include the length of procedure for all non-oral interventions: e.g., The procedure will take about <X> minutes. Include the frequency of intervention for multiple visits e.g., This will happen every <X> weeks for <X> months. Or Your treatment will be given in cycles, indicate the duration, frequency, and number of cycles.].*

Other important information on study intervention:

If you have side effects while you are on this study, the study doctor may make changes to the intervention.

*If participation in this study restricts future treatment options, inform participants of details. See suggested text or revise as applicable:*

If you are in *[identify restriction e.g., this study, Group 1]*, you may not be able to receive *[identify any future options]*.

*If standard treatment is being withheld or withdrawn, inform participants of details. See suggested text or revise as applicable:*

Normally, you would receive *[identify standard treatment]* for *[specify condition]*. If you decide to take part in this study, you [will or may] not receive the treatment.

*For studies with washout period, provide details on washout requirements. See suggested text or revise as applicable:*

As part of this study, you will be asked to stop taking *[identify washout agent]* for a period of *[insert washout period in weeks/months]* before you begin the study intervention.

**Study Procedures**

*Describe the procedures that are used in the study, including clear identification of those procedures that are experimental. Include frequency of the procedures. It is not necessary to describe the risks associated with tests or procedures with which the participant population would already be familiar (e.g. normal care or standard of care). Please include a schedule of visits and procedures in table format if possible.*

Established Procedures

The following established procedures will be done as part of this study. Some of these procedures may be done as part of your standard care, in which case the results may be used. Some may be done more frequently than if you were not taking part in this study. Some of these procedures may be done solely for the purpose of the study. If the results show that you are not able to continue participating in the study, the study doctor will let you know.

*Examples, delete ones that are not applicable:*

* physical examination *- standard tests performed as part of a physical examination do not need to be specified. If other tests are done for study purposes only, they should be specified*
* blood/urine tests *- standard liver function, biochemistry, and other routine blood tests done as part of standard of care do not need to be specified or individually listed. If other tests (such as HIV, Hepatitis) are being done for study purposes only, they should be specified as indicated below*
* central venous catheter - a small tube attached to a needle which is inserted into a large vein (in the neck, chest or groin) that leads to the heart. It allows easy access to veins for taking blood and giving medications and transfusions through the small tube so that you do not need a needle poke each time.
* computed tomography (CT) scan - a series of x-rays of the body from many angles that are turned into 3-dimensional pictures on a screen. CT scans often involve injecting a dye into your vein. Although the dye is relatively safe, occasionally side effects or allergic reactions can occur. These may be mild such as skin rash or hives to severe including difficulty breathing, shock and very rarely may result in death.
* magnetic resonance imaging (MRI) scan - uses a strong magnet to produce pictures of areas inside the body such as organs and other tissue, and inside of bones*. If dye is used for the procedure, include:* MRI scans often involve injecting a dye into your vein. Although the dye is relatively safe, occasionally side effects or allergic reactions can occur. These may be mild such as skin rash or hives to severe including difficulty breathing, shock and very rarely may result in death.
* multi gated acquisition (MUGA) scan - an x-ray to study the heart
* positron emission tomography (PET) scan - to help show how organs and tissues are working by tracing where a small amount of glucose (a sugar) that includes a tiny, harmless amount of radioactivity, goes in your body after it has been injected into one of your veins.
* pregnancy test
* x-rays (e.g. chest, bones)
* *If applicable, specify other tests (i.e. mammograms, etc.) and specify any risks associated with the test or tests.*

*If applicable:*

HIV Testing

The study involves testing to determine your HIV status. This test is required for this research study to find out if *[provide reason for the test if not described elsewhere in the consent, e.g., you meet the eligibility requirements, etc.]*. If you test positive for HIV, you [will *or* will not] be able to participate in this study.

If you consent to be tested for the study, the results of your HIV tests, like all other laboratory test results, will be provided to the sponsor *[describe as Partially De-Identified Information, Coded Information or Anonymized Information, as appropriate.]* and the study doctor.

If you test positive, your study doctor will be required to share your identity and your HIV status with the appropriate public health authority.

If you have concerns about being tested for HIV and the consequences of testing positive, you should speak to the study doctor or your care doctor before providing your consent to be tested.

*If applicable:*

Hepatitis Testing

The study involves testing to determine your hepatitis status. This test is required for this research study to find out if *[provide reason for the test if not described elsewhere in the consent, e.g., you meet the eligibility requirements, etc.]*. If you test positive for hepatitis, you [will *or* will not] be able to participate in this study.

If you consent to be tested for the study, the results of your hepatitis tests, like all other laboratory test results, will be provided to the sponsor *[describe as Partially De-Identified Information, Coded Information or Anonymized Information, as appropriate.]* and the study doctor.

If you test positive, your study doctor will be required to share your identity and your hepatitis status with the appropriate public health authority.

If you have concerns about being tested for hepatitis and the consequences of testing positive, you should speak to the study doctor or your care doctor before providing your consent to be tested.

Experimental Procedures

*Only include if there are experimental tests that are being tested as part of this study. Any standard procedures (e.g., MRI, blood draw, etc.) that are outside of standard of care should be included in the ‘Established Procedures’ section – this section is for procedures that are experimental (e.g., being tested as part of the research). Explain any risks of experimental procedures and medical tests in the risk section.*

The following test(s) [is *or* are]considered experimental and will only be done for participants on this study:

*List the procedures and tests. Include an explanation of what each test involves and the purpose/reason/rationale for including it in the research:*

*If focus groups are a mandatory component of the research, include the following:*

Focus Groups

You will be asked to attend *[specify how many]* focus group(s) *[if more than one focus group, provide information about timing e.g., before you begin the study and then every <X> weeks/ months].* A focus group is a small group of representative people who are asked to speak about their opinions as part of the research. A moderator will organize the focus group(s). Each focus group discussion will be about *[specify length in minutes or hours]* in length and will take place at *[specify location]*. You will be asked to speak about *[explain topics of discussion e.g., your experiences with condition or intervention]. [Specify if there is any recording device(s) used e.g., The focus group sessions will be auto taped].*

While the study team will take precautions to protect your confidentiality we cannot guarantee that other members of the focus group will respect your privacy or keep the discussions of the group confidential.

*If questionnaires are a mandatory component of the research, include the following:*

Questionnaires

You will be provided with a questionnaire *[provide information about the timing of questionnaires e.g., before starting this study and then every <X> weeks for a year. Or every <X> months while you are receiving treatment and once a year after treatment up to <X> years]*. The purpose of the questionnaire *[include a description of purpose e.g., is to understand how your treatment and illness affects your quality of life]*. Each questionnaire will take about *[<X> minutes]* to complete.

The information you provide is for research purposes only and will only be used for the purposes of this study. Your information will not be sold or used for purposes outside this study unless you sign a specific optional consent form that gives your permission for other uses of your information.

Some of the questions are personal; you may choose not to answer them.

*If the questions are of a sensitive nature, explain that they might experience emotional distress as well as what should they do and what type of help will be provided if this happens.*

*If questionnaires include medically relevant information, but won’t be shared, include the following:*

Even though you may have provided information on a questionnaire, these responses will not be reviewed by individuals not involved in this study, e.g., your health care practitioner/team. If you would like them to know this information, please bring to their attention. *If the questions include those related to self-harm, address how the study team will address the risk.*

If your questionnaire is collected and kept in an electronic format, the risk of information being disclosed may be increased.

*If participant diaries are a mandatory component of the research, include the following:*

Participant Diaries

*Inform the participant of the expectations associated with the participant diary. See suggested text or revise as applicable to the research.*

You will be asked to keep a diary of *[identify activity e.g., take your study medication].* Please record *[identify what is being recorded e.g., the exact time of taking each dose daily]*. You will be asked to return the diary to *[centre/clinic/hospital]*. If your diary is collected and kept in an electronic format, the risk of information being disclosed may be increased.

*If sample collection is a mandatory component of the research, include the following:*

MANDATORY SAMPLE COLLECTION

*Mandatory samples are those collected for the purpose of either determining eligibility or for a pre-defined study objective, otherwise they are considered optional. Mandatory samples may only be kept for the period of time required to conduct these tests and any leftover samples must be either returned to the facility from which they were obtained if needed or destroyed. Samples including any samples left over from eligibility testing may only be banked for other future research if the participant signs an optional consent form for banking. Sample collection that is optional (including banking for other future research), must not be part of the main consent and should instead be covered by a separate "optional" consent form. The availability of this option may be mentioned in the consent, see below.*

*Describe the mandatory sample collection, if pertinent to the study protocol, 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 as described below. *[insert study specific lay explanation of the research purpose for all samples collected].*

*[If Applicable]* The mandatory samples that need to be collected for the study’s objectives are: *[In the bullets below, describe the mandatory samples, when they will be taken, and (if applicable) whether archived samples may be used.]*

* .
* .

These samples will only be used for the purposes of this study. They will not be kept or sold for other purposes unless you sign a specific optional consent form that gives your permission for other uses of your samples.

*Specify what will happen to samples once the mandatory research has been completed. For example:*

Once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed or destroyed (unless they are required to be kept for regulatory requirements), *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.

*Include one of the following options:*

Hereditary genetic testing (to look at whether this disease runs in your family) will not be done on these samples.

*Or*

Hereditary genetic testing (to look at whether this disease runs in your family) [may *or* will] be done on these samples.

*Describe who will be informed of the results of the mandatory research. For example:*

Reports about research tests done with your samples will not be given to you, the study doctor(s), study staff, your care doctor or other health care provider(s). These reports will not be put in your medical records.

*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.

*If applicable:*

Whole genome sequencing (determining the entire DNA sequence of the sample) [may *or* will] be done on these samples.

*If there is a mandatory genetic portion to the study, include the following paragraph*

There may be risks to your eligibility for employment, life insurance, mortgage insurance or private health insurance if the results of genetic testing were to be inadvertently disclosed to certain parties. Safeguards have been established to ensure that such disclosure will not occur. For example, we have taken steps to ensure that a coded number, rather than your name, will be used to identify your sample and that your name will not be disclosed in association with the sample at any time. In addition, the results of genetic testing will not be placed upon your medical record. Despite these efforts, we cannot guarantee you with 100% certainty that your genetic information could never be linked to you. You may feel that it is important to discuss this with family members who could be affected.

*If applicable:*

Tissue Collection (Mandatory)

*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.

*[If applicable, explain whether participants may still participate if a sample is not available or whether a fresh tissue sample will then be required, see below.]*

*If a fresh tissue sample is required:*

As part of this study, you will need to have a tissue biopsy. A tissue biopsy is a type of surgical procedure, which will remove *[state how much tissue is to be taken e.g. a pea size piece]* of your *[insert type of tissue]*. *[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 *[specify risks, e.g., blood loss, pain and rarely an infection at the biopsy site]*. The procedure and risks will be fully discussed with you at the time of the biopsy, and your consent will be obtained.

*Identify location where the specimens will be retained. For example:*

These tissue samples will be sent to a laboratory at the *[Institution, City, Country. Note: minimum required location is Country]* where they will be examined to *[explain the purpose]*.

*If applicable:*

[Blood and/or Urine] Collection (Mandatory)

*Describe the method of blood/urine/or 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 *[specify number of samples to be collected and timing, e.g., 24 hour collection and if additional samples are required].* These urine samples will be sent to a laboratory at the *[Institution, City, Country. Note: minimum required location is Country]* where they will be examined to *[explain the purpose].*

*And/or*

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 *[describe sample timing e.g., at entry to the study and <X> weeks after you go off the study].* *[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 *[Institution, City, Country. Note: minimum required location is Country]* where they will be examined *[explain the purpose]*.

Identification of Samples

*Identifiers such as "patient/hospital identification numbers, patient name or birth date" may not be used. If tissue samples leaving the centre are identified with pathology identification number, it must be specified amongst the identifiers below.*

To protect your identity, the information that will be on your samples will be limited to *[specify which information will be on the sample(s)].*

Despite protections being in place, there is a risk of unintentional release of information that could lead to loss of privacy. Due to technological advances in genetics, there is also a risk of unintentional release of genetic information from the samples. This information can be linked back to you and can lead to possible future discrimination in employment or insurance, against you or your biological relatives.

Withdrawal of Samples

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

If you no longer want your samples to be used in this research, you should tell the study doctor. The study doctor will ensure the samples are returned to where they were obtained from or destroyed.

*Describe any limits of the withdrawal, if applicable. 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.

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

***Optional****: use a table format to present the established and experimental procedure schema being used in this study.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Initial* | *Day 14* | *Day 28* |
| *[Physical Examinations]* | *[x]* | *[x]* | *[x]* |
| *[Blood Tests]* | *[x]* | *[x]* | *[x]* |
| *[X-Rays & Scans]* | *[x]* | *[x]* | *[x]* |
| *[Lung Function Test]* | *[x]* |  | *[x]* |
| *[Quality of Life Questionnaires]* | *[x]* |  | *[x]* |

*If applicable:*

OPTIONAL RESEARCH

The researchers doing this study are interested in doing additional optional research. You will be given a separate optional study consent form(s) to read and sign if you wish to give permission to this. You may decide not to participate in the "optional" study and still participate in this main study.

**WHAT ARE THE POTENTIAL SIDE EFFECTS FROM PARTICIPATING IN THIS STUDY?**

*This section should include a description of the likelihood of any discomforts and inconveniences associated with participation and of known or suspected short- and long-term risks.* ***This information should be labelled as “very common”, “common”, “uncommon”, and “rare” with a percentage for each label (i.e., greater than 10%).***  *On occasion, this information may be more easily read by the participant if presented in a tabular format. Do not include the side effects associated with standard of care, only those directly associated with participating in the study.*

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be 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 drugs will be given to you to make side effects less serious and more tolerable. Many side effects go away shortly after treatmentis stopped but in some cases side effects can be serious, long-lasting, permanent, or may even cause death.

*For studies using non-marketed drugs or other investigational interventions 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 *[insert name of product/agent/device]* was given. Because *[insert name of product/agent/device]* is experimental and is only used in clinics/hospitals involved in research studies, any serious side effects of the product may be best treated by these clinics/hospitals. If you need immediate treatment and are unable to return to the clinic/hospital where *[insert name of product/agent/ device]* was given, you should go to the nearest medical clinic/hospital and tell them that the study doctor should be contacted as soon as possible.

Risks and side effects related to the experimental intervention *[insert name of product/*

*agent/device]* being studied includes: *May use NCI US template for risk categorization or a recognized alternative - e.g., CIOMS*

***Nature of risks to include:*** *describe all reasonably foreseeable risks, harms, or discomforts. Include both physical and psychological/emotional risks as applicable to the research;*

***Language:*** *Include lay language explanation of any side effects;*

***Categorization:*** *When detailed information about the side effect profile for the intervention is known, categorize risks by frequency. Examples of these categories are provided below – other categorizations may be used depending on the presentation of risks in the Investigator Brochure/Product Monograph;*

***Information to provide:*** *address frequency, severity, and long term impact or reversibility. When applicable, specific symptoms for serious side effects of which the participant should be aware (e.g. in order to seek immediate medical assistance should be included.*

*Very likely (greater than 21% or more than 20 people in 100):*

*Less likely (5 – 20% or between 5 and 20 people in 100):*

*Rarely (1 – 4% or less than 5 in 100 people):*

*When limited numbers of individuals have been exposed to the drug (less than 100), and the risks cannot accurately be quantified, the following language should be included (if applicable):*

As of *[date]*, only *[<X>]* people have been given this intervention and the side effects that have been reported are: *specify - examples*

* *[<X>]* experienced *[specify side effect]*
* *[<X>]* experienced *[specify side effect]*

It is not yet known if these side effects are caused by the study intervention or how likely these side effects will be.

*Or if applicable:*

*[Insert name of product/agent/device]* is in an early phase of development and so the side-effects in humans are unknown at this time. Animal studies to date show *[insert findings* *– list using lay language].*

*If the study agent will be used in combination with non-experimental treatment/therapy, the consent should include the following, if applicable:*

You will receive the standard treatment for the disease you have. An experimental drug is being added to this. This combination could change the side effects or the effectiveness of the standard treatment. This could mean that you experience more side effects than you would with only the standard treatment. If could also mean that the standard treatment does not work as expected.

*It is not necessary to include a list of risks or side effects of standard treatment if given alone, however the following statement should be included:*

The risks and side-effects of the standard or usual treatment will be explained to you as part of your standard care. These risks are not included in this consent form.

*If applicable:*

It is possible that other drugs (prescription and non-prescription drugs), vitamins, or herbals can interact with the drugs used in this study. This can result in either the intervention not working as expected or result in severe side effects. *List if known.*

*If a Data and Safety Monitoring Board is being used include:*

A Data and Safety Monitoring Board (DSMB), an independent group of experts, will be reviewing the data throughout the conduct of the study to ensure continuing participant safety as well as scientific validity and quality of the research.

**WHAT ARE THE REPRODUCTIVE RISKS?**

*If the agent used in the study presents 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 that this is reflected in the consent form.*

Theeffects that *[name of product/agent/device]* may have on an unborn baby (fetus) are unknown. You must not become pregnant or father a baby while taking *[name of product/agent/device]* and for *[identify post-intervention period]* after the last dose. The study doctor will discuss effective birth control methods with you to ensure that you do not become pregnant or father a baby during the study.

Women of childbearing potential and men must use proven birth control methods.

*Or*

Theeffects that *[name of product/agent/device]* may have on an unborn baby (fetus) are unknown. If capable of producing sperm, and if your partner is pregnant, breastfeeding, or able to have a baby, you must agree to follow effective birth control methods during the intervention period or within *[time period]* after the last dose of *[name of product/agent/device]*. Your study doctor will discuss these methods and the period of time they will be needed after the last dose of the therapy.

If you receive another therapy for your disease while on this study, other than the study drug there may be additional methods to prevent pregnancy you are required to use. Your study doctor will discuss these methods and the period of time they will be needed after your last dose of therapy.

If you think that you have become pregnant or may have fathered a child while taking part in the study, tell your study doctor immediately. You should also notify your family doctor that the mother/father received an experimental drug: *[name of product]*

If you are a woman and you become pregnant during your participation in this study, your treatment with study drug will be stopped and you may be withdrawn from some of the study procedures but not from follow-up by your study doctor. The study doctor will ask for your permission to stay in contact with you throughout the length of the pregnancy or longer and collect information on the outcome of your pregnancy

If you are a woman, you must not donate eggs (ova, oocytes) or freeze eggs for future use for the purposes of assisted reproduction during the study and for at least X weeks after the last dose of injectable study drug and X weeks after your last dose of the oral study drug.

If you are a man who is sexually active with a woman of childbearing potential and you have not had a vasectomy, you must agree to use a barrier method of birth control (e.g., a condom [with spermicidal foam/gel/film/cream/suppository if available in your locale] or a partner with an occlusive cap [diaphragm or cervical/vault caps] plus spermicidal foam/gel/film/cream/suppository if available in your locale) during the study and for X weeks after the last dose of the study drug.

If you are a man, you must not donate sperm during the study and for X weeks after the last dose of study drug.

**Highly Effective Birth Control Methods for Participants include:**

* Hormonal methods of birth control
* Pills
* Implants (placed under the skin by a health care provider)
* Shots/injections
* Patches (placed on the skin)
* Vaginal rings
* Intrauterine device (IUD)
* Intrauterine hormonal-releasing system (IUS)
* Surgery to tie both fallopian tubes (bilateral tubal ligation/occlusion)
* Your male partner has had a vasectomy (male sterilization) and testing shows there is no sperm in the semen
* Sexual abstinence (not having sex)

No one method of birth control is 100% effective.

Please inform your study staff if you change your birth control methods during the study.

If you become pregnant or your partner becomes pregnant during the study, the study doctor will ask you to contact them for information about the pregnancy and you will be *[explain whether the participant will be removed from the study / more closely monitored / removed from active treatment but remain in other part of the study / etc.]*

*For trials with pregnancy reporting, include the following:*

If you become pregnant while taking *[name of product/agent/device]* or within *[identify post-intervention period]* of your last dose *[of name of product/agent/device]* you should immediately notify the study doctor. Your study doctor will: 1) discuss how your pregnancy will affect your participation in the study 2) ask if you are willing to provide information about the pregnancy 3) discuss why they are wanting to collect this information and 4) discuss what will occur should you choose not to provide this information. You may choose not to give consent for the collection of this information or you may withdraw consent at any time without giving reason. This will not result in any penalty or affect your current or future health care.

*Or*

If you father a child while taking *[name of product/agent/device]* or within *[identify post-intervention period]* of the last dose *[of name of product/agent/device]* you should immediately notify the study doctor. The study doctor may ask if your partner is willing to provide information about the pregnancy as part of this study. She will be given a separate consent document to sign for permission to collect this information. 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 in this study and will not result in any penalty or affect you or your partner’s current or future health care.

*The optional pregnant partner consent form should be submitted to the REB for review and approval only when/if required (i.e., as a modification/amendment)*

*For studies that include women who may nurse or breastfeed include the following:*

Women should not nurse/breastfeed a baby while taking the study intervention(s) or within *[identify post-intervention period]* months after the last dose because the intervention(s) used in this study might be present in breast milk and could be harmful to a baby.

*For studies with reporting of exposure through lactation, include the following:*

If you nurse/breastfeed a babywhile taking the study intervention(s) or within *[identify post-intervention period]* months after the last dose, you should immediately notify your 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 consent document to sign for permission to collect this information, if this should happen. You may choose not to give consent for the collection of this information or may withdraw consent at any time without giving reason. This will not result in any penalty or affect your current or future health care.

*If applicable to the study:*

The intervention(s) used in this study may make you unable to have children in the future. The study doctor will discuss this with you.

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

*Inform participants of the potential benefits that may arise because of their participation in this study. If there is no known clinical benefit, ensure this is stated. There should be no statements that could result in coercion or inducement.*

*If the benefit to participation is unknown, include the following:*

Participation in this study may or may not be of personal benefit to you.

*If the benefit is known, include:*

The expected benefit from taking part in this study is *[specify benefit]* but there is no guarantee that the intervention may be of direct benefit to you.

Although participation in this study may be of no benefit to you personally, it is hoped that what is learned here will be of future benefit to others suffering from *[add disease name]*.

**Alternatives to Participation**

*This section should identify alternatives to enrollment in the research (e.g., standard of care). If the study drug is available without participating in the study, please clearly state this. List the trade name(s) of commonly used medications. A discussion of the risks and benefits of the alternatives or a statement indicating that the study doctor will discuss the risks and benefits of the alternatives with the participant must be included.*

You do not have to take part in this study, to receive continued medical care. Other alternatives in addition to standard care may include:

Please talk to the study doctor or your care doctor about the known benefits and risks of these other options before you decide to take part in this study. Your study or care doctor can also discuss with you what will happen if you decide not to undertake any treatment at this time.

**WHAT ARE MY RESPONSIBILITIES AS A STUDY PARTICIPANT?**

*Identify participant responsibilities. Include, add to, or modify bullets below as applicable.*

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, that you may be taking 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 on another research study;
* Attend all scheduled study visits and undergo all of the procedures described above;
* Return any unused study medication;
* Return any *[*specify e.g., *diaries or questionnaires]* taken home to complete;
* If you have any concerns about the questions in a questionnaire, discuss your concerns with the study doctor.
* Tell the study doctor if you become pregnant or father a child while participating on this study;
* Avoid drinking/eating *[specify what and for how long];*
* Stop taking *[insert name of product/agent/device]* for *[specify length of washout period]*;
* *[Insert name of product/agent/device]* is for you alone and must not be shared with others. If someone accidently takes *[insert name of product/agent/device], [include instructions e.g., they should immediately go to the nearest emergency department].*

**HOW LONG WILL I BE PARTICIPATING IN THIS STUDY?**

*Specify the duration of intervention, follow-up schedule, and total length of research involvement. See suggestions below or revise as applicable to the research.*

The study intervention will last for about *[insert duration in weeks/months]*. *If the intervention varies by group assignment, ensure this is specified*.

*Briefly describe follow-up visit schedule, as applicable. Suggested text as follows:*

You will be asked to come back to the centre *[specify location e.g., clinic/hospital]* for follow-up, *[specify time period e.g., <X> days after the last dose of study treatment]*. You will then be asked to come back *[describe follow-up schedule e.g., every <X> months for <X> years]*.

You may be seen more often if the study doctor determines that this is necessary.

**WILL THERE BE ANY LONG-TERM FOLLOW-UP INVOLVED WITH THIS STUDY?**

*If there is long-term follow-up as part of the study, include the following as applicable:*

No matter which group you are randomized to, and even if you stop receiving the study intervention early, we would like to keep track of your health for *[define a period of time] to [describe the purpose of the long-term follow-up e.g., look at the long-term effects of your participation on the study]*. We would do this *[specify follow-up method and frequency e.g., having you come back to the hospital/clinic or having someone from this centre call you to see how you are doing].*

*If the study doctor wants additional information about a participant’s health status to further evaluate the safety or efficacy of the product/agent/device, include the following.*

In the event it is necessary to further evaluate the safety or efficacy of the *[product/agent/ device]*, it may be necessary to have access to additional information about your health status. The study team may attempt to obtain study-related information about your health from you or from other private sources, including your care physician *[or include other private sources]*. This may include contacting you again by phone or letter, but only if you have not withdrawn your consent for future contact. However, contacting you, your care physician or using other private sources of information, is optional, please indicate your decision using the check boxes below.

You give permission to the study doctor or member of the study team to attempt to obtain study-related information about your health status to further evaluate the safety or efficacy of the *[product/agent/device]*. This may include contacting your care physician,

🞎 Yes 🞎 No Participant’s Initials:

Name/phone number of care physician:

or by contacting you by phone or letter (i.e., future contact).

🞎 Yes 🞎 No Participant’s Initials:

In addition, the study team may also attempt to obtain study-relevant information about your health information from public sources such as national patient registries.

*If the study doctor wants to contact secondary contacts because they cannot locate a study participant, include the following. Please note that this activity is optional and requires consent from the participant.*

If the study doctor needs to follow up with you but cannot locate you, either because you have moved and not updated your contact information or if, for some reason, your contact information is no longer accurate, the study doctor would like to obtain your new contact information (e.g., address, telephone number) by calling or writing to the persons you have named as your secondary contacts**. This is optional**. If you agree, please indicate your decision using the check boxes below.

You give permission to the study doctor or member of the study team to contact your secondary contacts if the study doctor or study team no longer have accurate contact information for you.

🞎 Yes 🞎 No Participant’s Initials:

Name/phone number of secondary contacts:

*If the study doctor is not able to obtain information through the participant’s secondary contacts and wants to use a third party locator, include the following. Please note that this activity is optional and requires consent from the participant.*

If the study doctor cannot obtain information through your secondary contacts, he/she would like to ask for assistance of a third party that specializes in locating persons. The study doctor may only share limited information about you (name and last known address) with a third party locator. None of your personal health or study-related information will be shared with the third party locator. The third party locator will consult public sources and databases to obtain your current contact information but will not contact you. The third party locator will only share this information with the study doctor or study team to help complete the follow-up stage of the study. Only the study doctor or a member of the study team will attempt to contact you directly. **This is optional**. If you agree, please indicate your decision using the check boxes below.

If the study doctor is not able to obtain your contact information from your secondary contacts, you give permission for the study doctor to provide your name and last location to a third party that specializes in locating persons.

🞎 Yes 🞎 No Participant’s Initials:

**CAN I CHOOSE TO LEAVE THIS STUDY EARLY?**

You can choose to end your participation in this research (called early withdrawal) at any time without having to provide a reason. If you choose to withdraw early from the study without finishing the intervention, procedure or follow-up, you are encouraged to contact the study doctor or study staff.

If you choose to leave the study early you can withdraw from some or all parts of the study. For example:

* You can stop treatment but continue will follow up procedures.
* You can stop treatment and follow up procedures but allow the Study Doctor to continue to gather information from your medical records.
* You can stop all treatment, follow up, and further information collection.
* You can allow the Study Doctor to continue to use information and samples collected before you withdrew from the study; or, if information and samples have not yet been used, you may ask for the information and samples to be destroyed. Some information and samples have to be kept by the study to show the study was run properly. Some tests and information may have already been completed and the results combined information from other participants and it is no longer possible to withdraw them from the study.
* You are asked to discuss these things with your Study Doctor before you withdraw.

*If applicable:*

You may be asked questions about your experience with the study intervention, and to have laboratory tests and physical examinations considered necessary to safely stop your study involvement.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the study doctor know. However, this would also mean that you withdraw from the study.

*For clinical trials with regulatory oversite, include the following:*

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no further testing will be done on samples already collected and no additional information will be collected or sent to the Sponsor after you withdraw your permission.

I agree that the Study Doctor or a member of the study team may contact me after I have withdrawn from the study to obtain follow-up information only.

❑ YES ❑ NO

Participant’s Initials: \_\_\_\_\_\_\_\_

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

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

*Identify reasons why participants may be taken off the study. Examples are outlined below. Include or modify bullets below as applicable.*

* The intervention does not work for you;
* You are unable to tolerate the study intervention;
* You are unable to complete all required study procedures;
* New information shows that the study intervention is no longer in your best interest;
* The study doctor no longer feels this is the best treatment for you;
* The Sponsor decides to stop the study;
* A regulatory authority (for example, Health Canada) or the research ethics board withdraws permission for the study to continue;
* Your treatment assignment becomes known to you or others (the study doctor or study staff);
* If you become or plan to become pregnant.

*If applicable:*

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form.

If you are removed from the study, the study doctor will discuss the reasons with you *[if applicable]* and plans will be made for your continued care outside of the study.

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

*If there will be a disclosure of personal identifiers i.e., disclosed on research-related information/documents, including samples and scans or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of all institutional and REB policies with respect to the disclosure of personal identifiers.*

Your confidentiality will be respected and no information that discloses your identity will be collected, used, or disclosed without your consent, unless required by law. You have the right to control the collection, use and disclosure of your personal data and your personal health information. You also have the right to check health records and ask for corrections to be made. By signing this informed consent form, you consent to the collection, use and disclosure of your personal data and personal health information for the study in the manner described in this consent form.

***5 Different Ways that Samples, Data, and Health Information can be Stored and Used***

When thinking about your personal and health care information, who can look at it, and why they want to look at it, it is important to know the different ways your information may be stored.

|  |  |  |
| --- | --- | --- |
| Identifying Information | The information is still linked to you. | For example, it may include your name, health care number, or other personal information. |
| Partially De-Identified Information | Some of the links have been removed. | For example, it may include your initials, partial birthdate, and the city you live in. No single piece of information identifies you but putting pieces together may allow you to be identified. |
| Coded Information | All personal identification is removed and replaced with a code. | Depending on who has access to the code, it may be possible to re-link the information back to you. |
| Anonymized Information | All personal identification is removed without any code or link back to you. | Risk of being linked back to you and you being identified is very low. |
| Anonymous Information | Information collected never had any personal information attached to it. | Risk of you being identified is very low or impossible. |

If you decide to participate in this study, the study doctor and study staff will only collect the information they need for this study.

Identifying Information, including information collected from your medical files/records, such as your Electronic Medical Records (EMR), Netcare, Connect Care, charts, etc., will be kept confidential to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your Identifying Information at the site where these records are held for quality assurance purposes and/or to verify that the information collected for the study is correct and follows proper laws and guidelines:

*Only include those organizations requiring permission for direct access to participant medical records containing identifying information (e.g., permission to conduct on-site monitoring/auditing). Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:*

* *For industry sponsored studies - [sponsor name],* the sponsor of this study or designates of the sponsor; *Or*
* *For cooperative groups - [organization name],* the research group coordinating this study;
* Members of the Regulatory/Audit team at *[the current site],* for quality assurance purposes;
* The Health Research Ethics Board of Alberta – Clinical Trials Committee, which oversees the ethical conduct of this study;
* *Include for studies under Health Canada oversight only -* Health Canada, which oversees the use of natural health products/drugs/devices in Canada and the conduct of clinical trials;
* *Include for studies subject to US FDA oversight -* U.S. Food and Drug Administration, which oversees the use of drugs in the U.S. and the conduct of clinical trials;
* *If applicable,* Other regulatory agencies that have oversight of this study;

*\*Please note: The disclosure of identifiable information to another individual or organization not listed here will require approval by the Health Research Ethics Board of Alberta – Clinical Trials Committee.*

*If applicable:*

Authorized representatives of the above organizations *[and the organizations listed below]* may **receive** Coded Information (only Coded Information may leave the study site) related to the study from your medical/clinical study records that will be kept confidential in a secure location and may be used in current or future relevant health research. Your name or other information that may identify you will not be provided. The records received by these organizations will be Coded Information (i.e. coded with a number). The key that indicates what number you have been assigned will be kept secure by the researchers directly involved with your study and will not be released.

The following organizations may receive Coded Information:

*Include organizations with permission to receive study data only (organizations with direct access must be included in the list above). Include a brief description of these organizations’ role in the research.*

* *[include organizations to receive Coded Information]*

*If the research involves mandatory centralized off-site review, include this section. Provide a description of the material(s) being reviewed centrally, including the type, reason, location, retention and identifiers. See suggested text below or revise as applicable to the research.*

Copies of your *[specify material being submitted e.g., scan type e.g. CT or MRI]* will be collected as part of this study. This is required for *[include a description of rationale, e.g., quality assurance and data management]*. The copies will be sent to *[specify location conducting the review e.g., City. Country]* and kept until the end of the study monitoring period *[or specify other retention period]* when then they will be destroyed.

To protect your identity, the information that will be on your *[specify material e.g., scans/ specimens]* will be Partially De-Identified Information (i.e. limited to *[specify which identifiers will be on the sample(s). If the sponsor requires the participant's initials to be part of the participant's study code, add which may include your initials.] Identifiers such as "patient name, hospital identification number, birth date" may not be used. If additional personal information is being provided to the central review location (e.g., on additional forms provided with the review materials), include a description of the information provided.*)

Any disclosure of your Identifying Information will be done in accordance with federal and provincial laws including the Alberta Health Information Act (HIA). The organizations listed above are required to have organizational policies and procedures to protect the information they see or receive about you, except where disclosure may be required by law. The study doctor will ensure that any personal health information collected for this study is kept in a secure and confidential location *[organization, location]* as also required by law.

If the results of this study are published, your identity will remain confidential. It is expected that the Coded or Anonymized Information collected during the study will be *[include description of proposed uses of data, e.g., used in analyses and will be published/presented to the scientific community at meetings and in journals]*. *If applicable,* This Coded Information may also be used as part of a submission to regulatory authorities around the world to support the approval of this intervention.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated. Every effort will be made to keep your Identifying Information confidential, and to follow the ethical and legal rules about collecting, using and disclosing this Identifying Information.

Your study data and medical records will be stored in the study databases and/or paper files (at the study site *[If applicable, add “or the location in Alberta approved by the Study Doctor]*) for at least 15 years as per Health Canada requirements. Such retention period may be extended as required by the Sponsor for a longer period if justification is provided and longer time period is specified.

*Add the following section(s) to the confidentiality section if they are applicable to your study and are not being dealt with in an optional consent form*.

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**Service Providers** *[Include only those paragraphs that are applicable]*

If you agree for visits to be conducted at your home, then your name or contact details will be shared with a third party to enable delivery of the study drug or for a nurse to visit your home (*[add names and roles of third parties i.e., Home Visits, Telemedicine etc.]*). After provision of these services and completion of the study, the record of your name and address will be deleted from the service providers system.

When couriers are used during this study, the study staff will provide the courier with your name and your address. After delivery/ collection and completion of the study, the record of your name and address will be deleted from the courier`s system. Only your study doctor and the study staff will be able to link the shipment information to your identity. You will be provided with the name and contact information for the courier.

*If a third party is being used to provide payments (see below under, Will I Receive Any Payments For Participating In This Study?) include:*

*[name of third party]*will be used to provide payments to you as part of this study and the study staff will provide *[list the information that will be provide to the third party]* to *[name of third party].*

Your personal data will kept confidential and will not be used for direct marketing or any other purpose other than providing services as part of this study.

*Provide an explanation of the options if they decide not to allow these services. If a service is mandatory this needs to be stated and the applicable check box below should be removed. If a service is not referred to above the applicable check box below should be removed.*

I understand that the use of Service Providers is optional and I agree that my name and contact information can be shared with Service Providers in order for them to complete the services related to this study:

* Delivery of study drug:

❑ YES ❑ NO

Participant’s Initials: \_\_\_\_\_\_\_\_

* Home visit by nurse:

❑ YES ❑ NO

Participant’s Initials: \_\_\_\_\_\_\_\_

* Delivery by courier:

❑ YES ❑ NO

Participant’s Initials: \_\_\_\_\_\_\_\_

* Providing payments:

❑ YES ❑ NO

Participant’s Initials: \_\_\_\_\_\_\_\_

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*If data or samples will be sent outside of Canada:*

Any study-related information *[and/or samples if applicable]* 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 *[and/or samples if applicable]* that is transferred outside of Canada will be Coded 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.

*For studies using smart forms, apps, third party payors, or applicable technology, describe limits to the confidentiality, add the following:*

Data collected *[insert specific purpose – ie. E-Diary; Questionnaires]* using the *[insert app/tool/device name]* resides on the *[insert name, e.g., Apple]* servers, and no assurance can be made about its confidentiality or that it will only be used for research purposes if accessed contrary to applicable law or otherwise improperly.

*If race/ethnicity is collected as part of the study, identify this and provide a rationale. See suggested text or modify as applicable*

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 *[as applicable, voluntary/required]*.

*If applicable:*

A copy of the consent form that you sign to enter the study willbe included in your health record/electronic health record/hospital chart.

**WILL MY HEALTHCARE PROVIDER(S) BE INFORMED OF MY PARTICIPATION IN THIS STUDY?**

Your family doctor/health care provider will be able to learn from your electronic medical records or other medical records that you are taking part in a study. You may want to discuss your study participation with your doctor/healthcare provider so that you can be provided with appropriate medical care.

**WILL THERE BE ANY COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?**

*Inform the participant of any anticipated expenses associated with participation in the research.*

The Alberta Health Care Insurance Plan will not be billed for any visits, treatments or procedures related to the conduct of this study.

*Include if the intervention is supplied for free:*

*[name of product/agent/device]* will be given to you free of charge while you take part in this study.

*If applicable:*

It is possible that the *[name of product/agent/device]* may not continue to be supplied while you are on the study. Although not likely, if this occurs, the study doctor will talk to you about your options.

*If participation could result in additional costs, include an explanation of these potential costs. Ensure that examples of extra costs are consistent with the research project.*

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

* 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;
* There may be costs associated with hospital /clinic visits. For example, parking, transportation, or snacks/meals during the study;
* You may miss work as result of participation in this study.

*Or if participation will not result in any costs, include the following:*

Participation in this study will not involve any additional costs to you or your private health care insurance.

Possible Costs After the Study is Complete

*If applicable, include if participants who are benefiting from the experimental intervention will NOT continue to receive the intervention after the study is finished. Wording may be altered according to the type of study or drug, or omitted in the case of adjuvant therapy:*

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 discuss these options with you.

## *If the study drug is not yet approved for use in Canada, this section must conclude with the following statement, where appropriate (e.g., in Phase I, II and some Phase III studies, where the prescribing indications for drug usage may be changing from investigational to approved for use):*

We will assist you in ensuring that appropriate treatment for your condition continues once the study has been completed and/or the drug is no longer available through the study. There is no guarantee that the drug will be available to you at that time. If the drug has been approved for marketing, you or your health insurance may have to pay for it.

**WILL I RECEIVE ANY PAYMENTS FOR PARTICIPATING IN THIS STUDY?**

*Describe compensation provided to participants, or state if no compensation is provided. Suggestions are provided below. There should be* ***no*** *statements that could result in coercion or inducement.*

*If there is no payment for participation*

You will not be paid for taking part in this study.

*Or if participants are paid, revise as applicable to the study*

If you decide to participate in this study, you will receive $*[include amount and basis of payment (e.g. for each study visit) and the payment interval if applicable (e.g., every <X> months)]*. If you decide to leave the study, you will receive payments for each study visit *[or specify the applicable basis of payment]* that you have completed in the study.

*If there is re-imbursements of costs for participation*

If you decide to participate in this study, you will be reimbursed for study-related expenses such as *[e.g., parking, meals, etc.]*. *This statement may be removed/revised as per study requirements.*

You may be eligible for reimbursement of reasonable, out-of-pocket expenses related to your participation in this study. Please speak with your study doctor if this is the case.

*If receipts or other documentation are required for re-imbursement, this must be described:*

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

*If applicable (alter as needed to fit the research):*

It is possible that the research conducted using your 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.

*If applicable:*

In the case of research-related side effects or injury, as a direct result of participating in this research, you will receive all medical treatments or services recommended by your doctors.

*If applicable:*

Payments will be made by *[specify, cheque, EFT, etc.] [include payment interval if applicable e.g. every month or <X> months]*.

**WILL I BE COMPENSATED IF I AM INJURED?**

*Explain who will determine whether an injury is study related. Where the policy is to have the study doctor and the sponsor (or sponsor’s representative) make this determination, it must be clear how conflicts among the decision-makers are to be resolved. If an injury is determined by both the study doctor and sponsor, please clarify that if there is a disagreement, who will make the final determination (study doctor, sponsor or independent third party).* *The Committee suggests that where there is a disagreement between the sponsor and study doctor as to whether an injury is study-related, an independent third party should make the final decision.*

**WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?**

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. If you would like to be informed of these results, please contact the study doctor.

*If the results will be publicly available*

The results of this study will be available on a clinical registry; refer to the section titled “Where can I find online information about this study?”.

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 hospital, investigators, sponsor, involved institutions for compensation or their agents, nor does this form relieve these parties from their legal and professional responsibilities.

**WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME AS A RESEARCH PARTICIPANT?**

*If incidental findings are anticipated as a result of the study, include the following section and address what information will be provided to participants.*

During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may *[insert anticipated incidental findings e.g., find out that you have another medical condition]*.

*Describe anticipated management plan. For example:*

If any clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity at that time to decide whether you wish to be made aware of that information.

**wHERE CAN i FIND oNLINE INFORMATION ABOUT THIS STUDY?**

*For US FDA-regulated studies (Do NOT modify text)*

A description of this clinical trial will be available on <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.

The study registration number to use this website is: *[XXXXXXXXXXX]*

*Or*

*All other clinical trials*

A description of this clinical trial will be available on *[web address]*. This website will not include information that can identify you. You can search for this website at any time.

**WHO DO I CONTACT FOR QUESTIONS?**

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to the study doctor, co-investigator or study nurse. These person(s) are:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name |  | Telephone |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name |  | Telephone |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name |  | Telephone |

*If applicable:*

A wallet card will be provided to you with information about how to contact the study staff when required.

If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, you should contact The Health Research Ethics Board of Alberta – Clinical Trials Committee at 780-423-5727 or toll-free at 1-877-423-5727. An REB is an independent committee established to protect the rights of research participants.

**Signatures**

Your signature on this form means that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive. Your continued participation should be as informed as your initial consent. You will be informed in a timely manner if information becomes available that may affect your willingness to continue participating in this study. You should also feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact:

**Part 1** - to be completed by the potential participant.

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Do you understand that you have been asked to take part in a research study? | 🞎 | 🞎 |
| Do you understand why this study is being done? | 🞎 | 🞎 |
| Do you understand the potential benefits and risks of taking part in this study? | 🞎 | 🞎 |
| Do you understand what you will be asked to do should you decide to take part in this study? | 🞎 | 🞎 |
| Do you understand the alternatives to participating in this study? | 🞎 | 🞎 |
| Do you understand that you are free to leave the study at any time, without having to give reason and without affecting your future health care? | 🞎 | 🞎 |
| Do you understand who will see your records, including health information that identifies you? | 🞎 | 🞎 |
| Do you understand that by signing this consent form you are giving us permission to access your health information and specimens if applicable? | 🞎 | 🞎 |
| Do you understand that by signing this consent form that you do not give up any of your legal rights? | 🞎 | 🞎 |
| *If applicable* Do you understand that your family doctor/health care provider will/may be informed of your participation in this study? | 🞎 | 🞎 |
| *If applicable* Do you understand the risks of becoming pregnant or fathering a child during this study? | 🞎 | 🞎 |
| Have you had enough opportunity to ask questions and discuss this study? | 🞎 | 🞎 |

*If a potential participant has answered “no” to any question above, please make sure to go over the relevant information with them until they do understand it.* ***Only once they are comfortable with all the information can you accept their decision to participate in the study.***

*If the study is taking place in Connect Care clinics or hospitals, please include the below statement.*

By signing this consent form, you understand that the research team will have access to your individually identifying information for research purposes.  In cases where the study involves an intervention such as a research-related medication, device, or other therapy, or the project includes research-specific lab tests and/or imaging, your signed consent will also be included in your electronic medical record(s), and healthcare staff will know that you are in a research study.

*Or*

Your signed consent form will be included in your electronic medical record(s) and your participation in the study will be visible to healthcare staff.

By signing this form I agree to participate in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Participant |  | PRINTED NAME |  | Date |

*[If the Participant is not able to physically sign this form]* By signing this form I confirm that I am authorized to sign on behalf of Participant [insert printed name] and that Participant agrees to participate in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Authorized Agent |  | PRINTED NAME |  | Date |

**Part 2** - to be completed by the study doctor or designee who conducted the informed consent discussion.Only compete this section if the potential participant has **agreed** to participate.

I believe that the person signing this form understands what is involved in the study and has freely decided to participate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Person Conducting the Consent Discussion |  | PRINTED NAME |  | Date |

**Part 3** - to be completed only if the participant is unable to read or requires assistance of an oral translator/interpreter.

* The informed consent form was accurately explained to and apparently understood by the participant*.*
* Informed consent was freely given by the participant.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Impartial Witness/Interpreter |  | PRINTED NAME |  | Date |

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

*To be completed by the study doctor or designee who conducted the informed consent discussion.**Only compete this section if the potential participant has* ***agreed*** *to participate.*

Person Conducting (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

the Consent Discussion

Signature of Person Conducting \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

the Consent Discussion

*The following signatures are optional, only include if you are using*

Witness’ Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness’ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

A copy of this form has been given to you to keep for your records and reference.