

CTO Clinical Trial Informed Consent Form Template

Instructions:

This Clinical Trial Informed Consent Form (ICF) Template has been designed to meet current regulatory and ethical standards.

The study-wide (provincial) ICF template uploaded into the Provincial Initial Application should follow the prescribed structure and format as set out in this template.

How to use this template:

- Suggested text/examples in **blue font** may be omitted if they are not relevant to the specific protocol
- All text included in the study-wide ICF must be applicable/appropriate for that specific clinical trial
- Instructions are indicated in *italics/grey background*
- **Turquoise highlighting** provides a prompt to adapt text to the research study (e.g., to select from the available options highlighted)
- Text with **yellow highlighting** reflects instructions for participating centres to follow when creating their local ICF. This text, including the highlighting, should not be altered or removed from the ICF that is uploaded into the Provincial Initial Application through CTO Stream
- When developing their local ICF, participating centres should follow the instructions and insert the applicable centre-specific content. The instructions and highlighting should be deleted from the local consent form submitted to the REB of Record

When writing the consent, please remember to:

- Delete this instructional page
- Use plain (lay) language that is easy for a non-medical person to understand
- Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended)
- Define all acronyms and abbreviations when they first appear
- Use the term 'study doctor' when referring to physicians involved in the clinical trial, to ensure there is no confusion with the treating or primary care doctors
- Ensure that the final form is properly formatted and free of spelling or grammar errors.
- After all edits have been made, all text should be black

REMINDER:

The informed consent form is only a component of the informed consent process. Researchers still need to have an informed discussion with, and respond to any questions raised by, participants.

Informed Consent Form for Participation in a Research Study

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

Sponsor's Study ID: *Insert sponsor's study ID if applicable*

Study Doctor: *insert name, department and telephone or pager number*

Sponsor/Funder(s): *Insert the name of the Sponsor or, if applicable, the funder(s) of the research*

Emergency Contact Number (24 hours / 7 days a week): _____

Non-Emergency contact numbers are noted at the end of this document under the section heading "Contacts".

INTRODUCTION

For studies where consent is sought through a substitute decision maker, include the following paragraph:

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end. Throughout this form, "you" means the person you are representing.

You are being invited to participate in a clinical trial (a type of study that involves research). You are invited to participate in this trial because you have *explain the main features of the population to which the research applies*. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

If time permits

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

OR for clinical trials where participants must start intervention within a specific timeframe due to best practices for participant population/disease

The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care.

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IS THERE A CONFLICT OF INTEREST?

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

The *identify individual, e.g., study doctor, insert name*, is receiving personal financial payment from *Identify source of funds e.g., the study Sponsor* for *include reason for payment e.g., providing advice on the design of the study*. You may request details about this payment.

or

There are no conflicts of interest to declare related to this study.

or

The *insert recipient of funding e.g., hospital* is receiving financial payment from the *Sponsor/Funder* to cover the cost of conducting this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Describe the background information relevant to the study, including (as applicable) the standard of care for the population, the reason for conducting the clinical trial in lay language, and the nature of the application with Health Canada. Examples are provided below.

The standard or usual treatment for *specify condition* is *describe the standard treatment*.

Insert name(s) of product/agent/device is a new type of *describe, e.g., natural health product/drug/device* for *specify condition*. Laboratory tests show that it may *explain laboratory results in lay terminology*. For example, *[agent]* has been studied in a few people and seems promising but it is not clear if it can offer better results than standard treatment.

For studies under Health Canada oversight, include one of the following options, as applicable

Option 1: Approved product/agent/device for condition used outside of approved parameters (e.g., approved agent being used for new (not approved) condition, or being used outside of approved dosage/schedule)

Health Canada, the regulatory body that oversees the use of *natural health products/drugs/devices* in Canada, has not approved the sale or use of *insert name(s) of product/agent/device* for *specify change from approved parameters, e.g. this condition*. Health Canada has allowed *insert name(s) of product/agent/device* to be used in this study.

Option 2: product/Agent/device not approved by Health Canada

Health Canada, the regulatory body that oversees the use of *natural health products/drugs/devices* in Canada, has not approved the sale or use of *insert name(s) of product/agent/device*. Health Canada has allowed *insert name(s) of product/agent/device* to be used in this study.

WHY IS THIS STUDY BEING DONE?

Explain the purpose of the study in lay terminology

The purpose of this study is to *explain the purpose of the study, using suggestions below as applicable*.

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Suggestions: Pilot study:

The purpose of this study, called a pilot study or a feasibility study, is to test the study plan and to find out whether enough participants will join a larger study and accept the study procedures. This type of study involves a small number of participants and so it is not expected to prove safety or effectiveness. The results may be used as a guide for larger studies, although there is no guarantee that they will be conducted. Participation in a pilot study does not mean that you will be eligible to participate in a future larger study.

Suggestion: Phase I Studies:

The purpose of this study is to test the safety of a *describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device*, to see what effects it has on you and your *specify condition*. This is the first time this has been tested in people.

Or

The purpose of this study is to find the highest dose of a *describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device*, that can be tolerated without causing very severe side effects. This is done by starting at a dose lower than the one that does not cause side effects in animals. This is the first time this has been tested in people. Participants are given *insert name(s) of product/agent/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 *insert name(s) of product/agent/device*. Participants joining this study later on will get higher doses of *insert name(s) of product/agent/device* than participants who join earlier. *Include next sentences if applicable* This will continue until a dose is found that causes severe but temporary side effects. Doses higher than that will not be given.

Suggestion: Phase II Studies:

The purpose of this study is to find out what effects a *describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device*, has on you and your *specify condition*.

Suggestion: Phase III Studies:

The purpose of this study is to compare the effects on you and your *specify condition* of a *describe, e.g., natural health product/drug/device, insert name(s) of product/agent/device*, compared to other *natural health products/drugs/devices* which are commonly-used for *specify condition*.

Suggestion: Phase III Placebo Controlled Studies:

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

Suggestion: Phase IV studies:

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

WHAT OTHER CHOICES ARE THERE?

Explain the alternative options applicable to the study population, and their important potential benefits and risks. Refer to suggestions below as applicable.

Suggestion for therapeutic intervention studies (modify as applicable if there is no other alternative treatment available):

You do not have to take part in this study in order to receive treatment or care. Other options (in addition to the standard or usual treatment described above) may include, but are not limited to:

List applicable treatments available to participants (examples below may be used as applicable). The standard of care does not need to be repeated in this list

- no therapy at this time
- palliative care or Best Supportive Care (BSC). This type of care helps reduce pain, tiredness, appetite problems and other problems. It does not treat your condition directly, but instead tries to improve how you feel. Best Supportive Care tries to keep you as active and comfortable as possible.
- other research studies may be available if you do not take part in this study

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

Suggestion for studies using healthy volunteers

You do not have to take part in this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about *insert total number of participants* people will take part in this study, from research sites located in *indicate participating countries*.

This study should take *total length of study in months or years* to complete and the results should be known in about *time to anticipated analysis in months or years*.

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.

Example 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/one in three* chance of being placed in *either/any* group. Neither you, the study staff, nor the study doctors can choose what group you will be in.

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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.

Or (single-blind studies)

You will not know which group you are in, but the study doctor and study staff will.

Or (double-blind studies)

This is a double-blind study, which means that neither you, the study doctors, the study staff, nor your usual health care providers will know which group you are in. Your group assignment can be identified if medically necessary. Requests to reveal your assignment for your information or participation in other research studies will not be considered until this study has been completed and the results are known.

Example for trials with intervention assigned based on protocol-specific criteria

If you decide to participate 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 e.g. the treatment you have previously received*. 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 of the research sites combined, no more participants will be enrolled into the study at any site. It is possible that you may finish the screening phase and be ready to enter the intervention phase of the study, but not be enrolled into the study.

WHAT IS THE 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.

Suggestion for single arm studies

Experimental Intervention:

If you agree to take part in this study, you will *identify intervention, including description of method: e.g. be given [agent] by needle into one of your veins; you will take [agent] pills by mouth; you will complete X procedure. Include length of procedure/intervention for all non-oral interventions e.g., The procedure will take about <X> minutes. Include frequency of intervention for multiple study visits e.g., This will happen every <X> weeks for <X> months.*

Suggestion for multi-group studies. **Ensure that the Group/Arm names and descriptions are consistent with the protocol**

Group 1 (Experimental intervention): Standard intervention (*specify drug name/regimen/intervention*) plus experimental intervention (*specify drug name/regimen/intervention*)

If you are randomized to this group you will *identify intervention, including description of method: e.g. be given [agent] by needle into one of your veins; you will take [agent] pills by mouth; you will complete X procedure. Include length of procedure/intervention for all non-oral intervention e.g., The procedure will take about <X> minutes. Include frequency of intervention for multiple study visits e.g., This will happen every <X> weeks for <X> months.*

Group 2 (Non-Experimental Intervention): Standard intervention (*specify drug name/regimen/intervention*)

If you are randomized to this group you will *identify intervention, including description of method: e.g. be given [agent] by needle into one of your veins; you will take [agent] pills by mouth; you will complete X procedure. Include length of procedure/intervention for all non-oral intervention*

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e.g., The procedure will take about <X> minutes. Include frequency of intervention for multiple study visits e.g., This will happen every <X> weeks for <X> months.

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION?

Include the relevant information from the selection below

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

If participation in the 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 treatment options that participant would be excluded from* in the future.

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/may* not receive this usual 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.

WHAT ARE THE STUDY PROCEDURES?

Describe the procedures that are used in the study, including clear identification of those procedures that are experimental. It is not necessary to describe the risks associated with tests or procedures with which the participant population would already be familiar.

Non-Experimental Procedures

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

List the procedures and tests. Include a lay explanation of what each test involves.

-

If there are experimental procedures or medical tests, include the following section. Any standard procedures (e.g., MRI, blood draw, etc.) that are outside of standard of care should be included in the 'non-experimental procedures' section – this section is for procedures that are experimental (e.g., being tested as part of the research):

Experimental Procedures

Explain any risks of experimental procedures and medical tests in the risk section

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

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

-

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If focus groups are a mandatory component of the research, include the following section.

Focus Group

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 specify location. You will be asked to speak about explain topics of discussion e.g., your experiences with condition/intervention. Specify if there is any recording device(s) used e.g., The focus group sessions will be audio 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 section.

Questionnaires

You will be provided with a questionnaire provide information about the timing of questionnaires e.g., before you begin the study and then every two weeks for a year. The purpose of the questionnaire is include description of purpose e.g., to understand how the study intervention and illness affects your quality of life. Each questionnaire will take about indicate estimated time to complete in minutes to complete.

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

If the questions are of a sensitive nature, explain that they might experience emotional distress, explain 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 reviewed, include the following:

Even though you may have provided information on a questionnaire, these responses will not be reviewed by your health care team or study team - if you wish them to know this information please bring it to their attention.

If participant diaries are a mandatory component of the research, include the following section.

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

If central review is a mandatory component of the research, include the following section.

Central specify type of review e.g., Radiology/Radiotherapy/Surgical Review

If the research involves 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

Specify material being submitted e.g., Copies of your CT scans/Surgical specimens will be collected as part of this study. This is required for include description of rationale, e.g., quality assurance and data management. The copies will be sent to specify location conducting review, and kept until the end of the study monitoring period or specify other retention period

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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 limited to *specify which identifiers will be on the review material(s)*. If additional personal information is also being provided to the central review location (e.g., on additional forms provided with the review materials), include a description of the information provided.

If the research includes mandatory specimen collection, include this section.

MANDATORY SAMPLE COLLECTION

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

The researchers doing this study need to do tests on samples (described below) to *insert study-specific LAY explanation of the research purposes for all samples collected*.

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

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 *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 *specify condition* runs in families) will not be done on these samples.

Or

Hereditary genetic testing (to look at whether *specify condition* runs in families) **will/may** be done on these samples

If there is a possibility that a medically relevant sample will be exhausted:

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

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

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

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.

Tissue Collection (Required)

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 they may still participate if a sample is not available or whether a fresh tissue sample will then be required – see below.*

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If a fresh tissue sample is required

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

Identify location where specimens will be retained. For example:

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

Blood/Urine Collection (Required)

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

Urine will be collected *Specify number of samples to be collected and timing (e.g., specify if 24 hour collection) if multiple samples are required.* These urine samples will be sent to a laboratory at the *insert location* where they will be examined.

Blood samples will be taken by inserting a needle into a vein in your arm. These will be taken at the same time as your study related tests whenever possible, *describe sample timing e.g. at entry to the study and <X> weeks after you stop the study intervention.* *Specify amount of blood to be collected and timing if additional samples are required and the tests to be done on these samples.* These blood samples will be sent to a laboratory at the *insert location* where they will be examined.

How will samples be identified?

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

Despite protections being in place, there is a risk of unintentional release of information. Due to technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you.

Can I withdraw these samples?

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

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

If samples will be anonymized at a certain point

You can request withdrawal of your specimens until *insert expected anonymization point,* when the samples will be made anonymous. It won't be possible to return samples after this because the researchers will not know which sample is yours.

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

Optional Research

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

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

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

HOW LONG WILL PARTICIPANTS BE IN THE 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*. *If intervention length varies by group assignment, ensure this is specified.*

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

You will be asked to come back to the *specify location e.g., clinic/hospital specify time period e.g., 30 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.

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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 the study intervention early, we would like to keep track of your health for *define period of time to describe purpose of long-term follow-up e.g., look at the long-term effects of your participation on this study*. We would do this by *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*.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

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

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 oversight, include the following

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected or sent to the sponsor after you withdraw your permission.

OR If the participant can withdraw information collected prior to withdrawal

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the study doctor know if you choose this.

CAN 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 study 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 option for you
- The Sponsor decides to stop the study
- The Regulatory Authority/ies (for example, Health Canada) or research ethics board withdraw permission for this study to continue
- Your group assignment becomes known to you *if applicable* or others (like the study doctor or study staff)
- If you plan to or become pregnant

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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 this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

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

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. You should discuss these with the study doctor.

The study doctor will watch you closely to see if you have side effects. When possible, other medicine will be given to you to make side effects less serious and more tolerable. Many side effects go away shortly after the study intervention is stopped, but in some cases side effects can be serious, long-lasting, permanent, or may even cause death.

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 may be best treated by these clinics/hospitals. If you need immediate treatment and are unable to return to the clinic/hospital, the study doctor should be contacted as soon as possible.

Risks and side effects related to the experimental intervention *insert name of product/agent/device* we are studying include:

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

Suggested categories (may be presented in list or table format):

Very likely (21% -100%):

-

Less likely (5 – 20%):

-

Rarely (1 – 4%):

-

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

As of *insert date*, *specify number* people have been given this intervention and the side effects that have been reported are:

- *Specify number* experienced *specify side effect e.g., headaches*
- *Specify number* experienced *specify side effect e.g., diarrhea*

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 *list using lay language*.

If the study drug will be used in combination with standard treatment, the consent should include the following:

You will receive the standard treatment for the condition you have. An experimental intervention 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 the standard treatment alone. It could also mean that the standard treatment does not work as expected.

If a comparison arm includes standard of care treatment/intervention along, include the following:

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.

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

If participation in this study puts the participants at increased risk of long-term effects such as cancer, include the following

Long term effects of the *specify test/intervention* used in this study include an increased risk of developing *specify long-term risk e.g., cancer*.

WHAT ARE THE REPRODUCTIVE RISKS?

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

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

If there are known interactions or contraindications with specific methods, they should be included.

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

Women should not nurse (breastfeed) a baby *specify period e.g., while taking [insert name of product/agent/device] and for [identify post-intervention period] after the last dose* because the drugs used in this study might be present in breast milk and could be harmful to a baby.

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For trials with pregnancy reporting, include the following

If you become pregnant or father a child *specify period e.g., while taking [insert name of product/agent/device] and for [identify post-intervention period] after the last dose*, you should immediately notify the study doctor. The study doctor will ask if you/your partner are willing to provide information about the pregnancy as part of this study. If your partner becomes pregnant, she will be given a separate consent document to sign to give permission for the collection of this information. You or your partner may choose not to give consent for the collection of this information or may withdraw consent at any time without giving a reason. This will not impact your participation on the study and will not result in any penalty or affect your or your partner's current or future health care.

For trials with reporting of exposure through lactation, include the following

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

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Inform participants of potential benefits to themselves and in general that may arise. If there is no known clinical benefit, ensure this is stated.

If there is no likely medical benefit to participation (e.g., phase I study), include the following

There are no medical benefits to you for taking part in this study.

If the benefit is known, include

The expected benefit from taking part in this study is *specify*.

If the potential benefit is unknown, include

If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you.

For placebo controlled studies, include the following

You will not benefit from the placebo used in this study

If applicable, include

We hope the information learned from this study will help other people with *specify condition* in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

Note: *If there will be disclosure of personal identifiers, i.e., disclosed on any research-related information/documents including samples or 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 institutional and REB policies with respect to the disclosure of personal identifiers.*

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

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

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Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

Include only 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:

- *Insert sponsor name, the Sponsor of this study*
- The research ethics board who oversees the ethical conduct of this study in Ontario
- *insert research site name*, to oversee the ethical conduct of research at this location
- Health Canada (because they oversee the use of **natural health products/drugs/devices** in Canada) *include for studies under Health Canada oversight only*
- U.S. Food and Drug Administration (because they oversee the use of **natural health products/drugs/devices** in the United States) *include only if applicable (e.g., for studies with Ontario centres subject to US FDA oversight)*

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain your *disclose identifiers e.g., participant code, initials, sex, and date of birth.*

The following organizations may also receive study data:

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 their role in the research.

- *List other regulatory authorities* (because they oversee the use of **natural health products/drugs/devices** in other countries)
- *Identify any other organizations with permission to receive study data only*

If race/ethnicity information 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 **voluntary/required**.

If an autopsy report is being provided to the sponsor, include the following:

This study does not require that an autopsy be performed. However, if an autopsy is performed for other reasons, and a copy of the report is provided to the study doctor, this report will be sent to the study sponsor as part of the study data collected for this trial. This report may contain other health information that is not required for study purposes.

If health information is being collected for other research/database:

In addition to the data that will be collected for this clinical trial, the researchers will also be collecting the following personal health information:

- *List all additional information being collected*

This additional data is being collected to *insert purpose e.g. to help researchers better*

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understand common trends between your condition and other health problems. This additional information is not required for the purpose of this study, but for other research interests at *insert organization name*.

If identifiable data will be sent outside the institution:

This study requires the transfer of identifiable information to *insert name of institution/individual* for the purposes of *specify purpose*. The following information will be transferred:

- *Specify identifiable information to be transferred*

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this 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*. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of the study intervention.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

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

If data or samples will be sent outside of Canada

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

Include for US FDA-regulated studies (as per 21 CFR 312.68 and 21 CFR 812.145

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

For studies using smartphones, apps or applicable technology, describe any limits to the confidentiality. For example:

Data collected 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.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider *will/may* be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss this with the study team.

Or

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

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

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.

OR

All other clinical trials

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

WHAT IS THE COST TO PARTICIPANTS?

Inform the participant of any anticipated expenses associated with participation in the clinical trial

Include if the intervention is supplied for free

The [insert name\(s\) of product/agent/device/intervention](#) will be supplied at no charge while you take part in this study.

If applicable:

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

If applicable:

The costs of your medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available.

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 trials

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

- The intervention may not turn out to be effective or safe.
- The intervention may not be approved for use in Canada.
- Your caregivers may not feel it is the best option for you.
- You may decide it is too expensive and insurance coverage may not be available.
- The intervention, even if approved in Canada, may not be available free of charge.

The study doctor will talk to you about your options.

Include if participants who are benefiting from the experimental intervention will 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 trials.

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

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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. If you have private health care insurance, the insurer may not pay for these added costs.
- There may be costs associated with hospital visits. For example, parking or transportation, or snacks/meals during your stay.
- You may miss work as a result of participation in this study.

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.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

Describe compensation provided to participants, or state if no compensation is provided. Suggestions are provided below.

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 \$*specify amount of payment including indication of payment interval if applicable e.g., every three months.*

If you decide to leave the study, you will receive a prorated payment for participating in the study.

If there is re-imbursement of costs for participation

If you decide to participate in this study, you will be reimbursed \$ *enter actual or maximum dollar amount* for some study related expenses such as *list reimbursable expenses as applicable.*

If receipts or other documentation is required for re-imbursement, this must be described. For example:

You will need to provide your receipts for *insert expense types e.g., parking* 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.

In the case of research-related side effects or injury, medical care will be provided by *specify response e.g., your doctor or you will be referred for appropriate medical care.*

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH 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.

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Explain how the participant can obtain the results, for example: *If you would like to be informed of the results of this study, please contact the study doctor* or *If you would like to be informed of the results of this study, please let the study doctor know* or, *if the results will be publically available in the Clinical Trial Registry* The results of this study will be available on the clinical trial registry (see the “Will information about this study be available online” section for more details).

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

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

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

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

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

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

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

Name

Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

Name

Telephone

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SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to my medical records and specimens as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I understand that my family doctor/health care provider will/may be informed of my participation in this study
- I agree, or agree to allow the person I am responsible for, to take part in this study.

Signature of Participant/
Substitute Decision-Maker PRINTED NAME Date

Signature of Person Conducting
the Consent Discussion PRINTED NAME & ROLE Date

Complete the following section only if the participant is unable to read or requires an oral translation:

- The informed consent form was accurately explained to, and apparently understood by, the participant/substitute decision maker, and
- Informed consent was freely given by the participant/substitute decision maker

Signature of Impartial
Witness/Translator PRINTED NAME Date
*(If participant were unable to
read/required an oral translation)*

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.

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