**BC Common Clinical Informed Consent Form**

**Template and Guidance**

**PART 1**

Consent Form Elements

(Click on the element to move to the corresponding section.)

1. [Title of study](#Title_of_Study)

2. [Principal investigator, co-investigator, sponsor, emergency contact](#Study_personnel)

3. [Invitation](#Invitation)

4. [Your participation is voluntary](#Your_participation_is_voluntary)

5. [Who is conducting the study](#Who_is_conducting_this_study)? (includes conflict of interest disclosure)

6. [Background](#Background)

7. [What is the purpose of the study](#What_is_the_purpose_of_the_study)?

8. [Who can participate in this study](#Who_can_participate_in_this_study)?

9. [Who should not participate in the study](#Who_should_not_participate)?

10.[What does the study involve](#What_does_the_study_involve)?

11. [What are the possible harms and discomforts](#What_are_the_possible_harms)?

12. [What are the potential benefits of participating](#What_are_the_potential_benefits)?

13. [What are the alternatives to the study treatment](#What_alternatives_to_the_study_treatment)?

14. [After the study is finished](#After_study_finished)

15. [What if new information becomes available that may affect my decision to participate](#What_new_information_becomes_available)?

16. [What happens if I decide to withdraw my consent to participate](#What_decide_to_withdraw_my_consent)?

17. [Can I be asked to leave the study](#Can_I_be_asked_to_leave_the_study)?

18. [How will my taking part in this study be kept confidential](#Confidentiality)?

19. [What happens if something goes wrong](#What_happens_if_something_goes_wrong)?

20. [What will the study cost me](#What_will_the_study_cost_me)?

*21.* [If I have questions about the study procedures during my participation, who should I speak to](#Who_do_I_contact_if_question_about_study)*?*

22. [Who do I contact if I have any questions or concerns about my rights as a participant](#Who_do_I_contact_if_questions_rights)?

23. [Signatures](#Signatures)

* Required wording for all REBs is highlighted in yellow.
* Required wording for Health Canada regulated trials is highlighted in green.

PART 2

[Appendix I](#Appendix_I) – How to Use this Document; General Style and Formatting Guidelines

[Appendix II](#Appendix_II) – General Directions to those Responsible for Obtaining Consent

[Appendix III](#Appendix_III) –Links to REB Guidance Notes, Policies, and Forms

Template content and instructions begin on the next page.

**Participant Information and Consent Form**

**1.** [**[Insert Title of Study]**](#Guidance_title)

**2. Study personnel**

*For studies undergoing harmonized review, please identify the lead Principal Investigator (as indicated on RISe). Site-specific Principal Investigators should be listed as such on local consent forms.*

*For UBC, IH, UVIC, SFU, and UNBC REBs:*

* *Principal Investigator of the overall study must be identified.*
* *One lead Investigator for each additional participating site must be identified.*
* *Co-Investigators are not required to be listed.*

*For FHREB:*

* *The Fraser Health (FH) Co-Investigator must be included if the Principal Investigator is not a Fraser Health employee or privileged physician.*

*All other REBs require at least the PI to be included; listing other study personnel is optional.*

**Principal Investigator:** [insert name, degrees held]

 [insert primary department]

 [insert institution/centre]

 [insert contact phone number(s)]

**Co-Investigator(s):** [insert name(s), degrees held]

 [insert primary department]

 [insert institution/centre]

 [insert contact phone number(s)]

**Sponsor(s) / Funder:** [insert names of all sponsors (i.e. those who claim ownership of the data), granting agencies, coordinating groups.]

**Emergency Telephone Number**

*A 24-hour, 7-day a week phone number is required for all studies that include non-minimal risk research procedures or interventions. Ideally, a person needing emergency assistance should not be required to go through a switchboard. If using a switchboard, ensure that requisite information is available and is kept current regarding referrals.*

*Refer to local REB policies for further guidance.*

Non-emergency Contact Number

***For pediatric******studies****:*

*Please insert the following text above the Invitation:*

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say “you” or “your” in this consent form, we mean you and/or your child; “we” means the doctors and other staff.

***For studies******that recruit adults who lack capacity****:*

*Please insert the following text above the Invitation:*

If you are 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. The agreement and the assent (agreement) of the potential research participant may be required. If the participant gains the capacity to consent for him/herself, your consent for them will end, and the participant will be asked to provide their consent for ongoing participation. Throughout this form, “you” means the person you are representing.

**For Researchers who receive Department of Health & Human Services (DHHS) Agency funding for studies involving human participants:**

Effective January 21, 2019, new US regulations came into effect. These new regulations mandate that specific information must be contained in the DHHS funded study informed consent form. They also require that if the study is a clinical trial\*, either the study funding agency (e.g. NIH or other agency), or the awardee (e.g. lead principle investigator) must post a copy of the clinical trial informed consent form, within a specified time frame, to [ClinicalTrials.gov](https://clinicaltrials.gov/) or to a docket folder on [Regulations.gov](https://www.regulations.gov/) (Docket ID: HHS-OPHS-2018-0021).

**Informed Consent Requirements**

Most of the mandated information in informed consents is already required information in informed consents reviewed and approved by UBC’s affiliated Research Ethics Boards. There are also some new requirements, the most significant of which is the requirement that informed consent forms must begin with a concise and focused presentation of the “key information” that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.

Detailed information on the mandated informed consent requirements can be found [here](https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/DHHS_consent_requirements.pdf).

**Posting Requirements**

Detailed information on the mandated posting requirement can be found [here](https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/DHHS_consent_posting_requirements.pdf).

**3.** [**Invitation**](#Guidance_Invitation)

You are being invited to take part in this research study because ***[insert details]***.

**4.** [**Your participation is voluntary**](#Guidance_your_participation_is_voluntary)

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other servicesto which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient, all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant, you and your doctor also must take into account the requirements for the research study. These may include procedures and treatments that are not part of standard practice or are not yet proven. This consent form describes the diagnostic and treatment procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

**5.** [**Who is conducting this study?**](#Guidance_who_is_conducting)

This study is being conducted/sponsored by the ***[name of research group, e.g. industry sponsor/granting agency]***.

*OR:*

This study is not receiving funds from an external agency or sponsor.

*The following conflict of interest statement is* ***required for industry-sponsored studies:***

The Principal Investigator ***[insert study personnel and/or institution]*** has received financial compensation from the sponsor ***[name the sponsor]*** for the work required in doing this clinical research [revise to be applicable: and/or for providing advice on the design of the study/travel expenses/etc.] Financial compensation to researchers for conducting the research is associated with obligations defined in a signed contractual agreement between the researchers, institution and the sponsor. Researchers must serve the interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Principal Investigator.

**6.** [**Background**](#Background)

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

*OR:*

***[Insert name(s) of product/agent/device]*** is a new type of ***[describe 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 (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]***. 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 has not approved the sale or use of ***[insert study drug/device/natural health product]*** to treat ***[insert disease, including stage of disease where relevant, for example, for cancer]***, although they have allowed its use in this clinical study.

*OR:*

Health Canada has approved the sale or use of ***[insert study drug/device/natural health product]*** to treat ***[insert type of disease]***, although they have not approved its use for ***[this disease/stage of disease, or at this dose, etc.]***, they have allowed its use in this clinical study.

**7.** [**What is the purpose of the study?**](#Guidance_What_is_the_purpose)

Describe the study goal(s) in lay language.

***For a pilot or feasibility study:***

A “pilot study” or “feasibility study” is done 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 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. Knowledge gained from pilot or feasibility studies may be used to develop future studies that may benefit others.

***For a Phase I Study:***

This is a Phase I study. A Phase I study is a trial of an experimental study drug or treatment which is tested in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. Phase I studies are neither expected nor intended to provide a direct personal benefit to participants.

*Include the following* ***if applicable*** *and modify accordingly:*

The purpose of this study is to find the highest dose of a new drug ***[insert agent]*** 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. Participants are given ***[insert agent]*** 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 more potential participants are asked to join this study and are given a higher dose of ***[insert agent]***. Participants joining this study later on will get higher doses of ***[insert agent]*** 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.

***For a Phase II Study:***

This is a Phase II study. A Phase II study is undertaken after preliminary safety testing on a drug or treatment. It is usually conducted on a small number of individuals (100-300 persons), and its goal is to begin to find out what effect it has on your ***[insert disease or condition]*** and to further evaluate its safety.

***For a Phase III Study:***

This is a Phase III study. A Phase III study is a study of an experimental drug or treatment which is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information to determine whether the experimental drug or treatment can be used safely.

***For a Phase IV Study:***

This is a Phase IV study. A Phase IV study is a study of an approved drug or treatment (also called “a post marketing study”) which is conducted to obtain additional information regarding the drug’s or treatment’s, benefits and optimal use.

**8.** [**Who can participate in this study?**](#Guidance_Who_can_participate)

You may be able to participate in this study if*:*

* [insert inclusion criteria the potential participant is likely to be aware of, and **only** criteria which has not already been covered as part of the screening process]

**9.** [**Who should not participate in this study?**](#Guidance_Who_should_not_participate)

You will not be eligible to participate in this study if:

* [insert exclusion criteria the potential participant is likely to be aware of, and **only** criteria which has not already been covered as part of the screening process]]

***Required wording for PHC REB studies only*** *(recommended wording for other REBs):*

Because we do not know if or how an unborn baby/fetus could be harmed, you should avoid becoming pregnant. Talk to your study doctor about the risks to your unborn baby/fetus if you did get pregnant. Work with your study doctor to find the best solution to make sure you do not get pregnant, if you wish to be in the study.

**10.** [**What does the study involve?**](#Guidance_What_does_the_study_involve)

*The following sections describe specific information that can be included in the consent form when applicable to the individual study:*

* **Overall design of the study**
* **If You Decide to Join This Study: Specific Procedures**

If you agree to take part in this study, the procedures and visits you can expect will include the following:

[*Insert procedures*]

*Additional recommended text for Blinded Studies:*

This study is double-blinded, meaning that neither you nor your doctor will know which study medication you take. However, this information is available in case of an emergency.

* **Screening Visit/Initial Visit/Before You Begin the Study**
* **Randomization Visit**
* **Study Visits**

*Tables are often helpful to summarize procedures and time commitments, especially for complex or long-term studies. Researchers can use the chart of study visits included in the protocol.*

* **Expected Follow-up**

*Describe the number of follow-up visits and their duration.*

* **Use of Data from Secondary Data Sources that use identifiable information.**

**Optional Studies**

The following studies are optional. For each optional study, you will be provided with a separate consent that describes the details, and which you will be required to sign if you wish to participate. You can take part in the main study and not take part in these optional studies. If you decide not to take part in any or all of the optional studies, your care will not be affected.

[**Mandatory/Optional Blood or Tissue Collection and/or Biobanking**](#Guidance_Mandatory_Banking)

**Future Use and Storage of Genetic Samples:**

Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information; this risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family, as they share some of your DNA profile. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have.

There is a risk that someone could get access to the samples or data we have stored about you.. There are laws against the misuse of genetic information, but they may not give full protection. To minimize the risk of someone linking your samples and data back to you, they will be coded (your name or other identifying information will be removed and replaced with a code).

We are asking your permission to use your (samples, genetic data) and health information for this particular study. However, we would also like you to consider sharing your samples and information/ will also (\*if required)) for other future research studies.

You will not share in any commercial value or profit derived from the use of your samples and/or information obtained from them

If you wish to participate, please indicate your answers to the following questions:

May we collect your coded (samples, genetic information) and health information to study [state specific research project]?

Yes   [ ]                 No [ ]

May we [share your coded (samples, genetic information) and health information with other researchers /use you coded (samples, genetic information)] to study [state specific disease or disorder]?

Yes   [ ]                 No [ ]

May we [share your coded (samples, genetic information) and health information with other researchers /use you coded (samples, genetic information)] for future research projects related to other topics?

Yes [ ]                   No [ ]

May we store your coded (samples) and health information in a biobank for future use? Other researchers would be able to use the materials stored in the Data/Biobank for approved studies. Researchers from universities, the government, and drug- or health-related companies can apply to use the materials. A science committee at the Data/Biobank will review each request. There may also be an ethics review. We will not give researchers your name or any other information that could directly identify you.

Yes     [ ]               No [ ]

*\*For studies where it is mandatory to have* [*open access to study data and samples*](#Guidance_Open_Access)*, please rephrase the language making it mandatory rather than optional.*

**11.** [**What are the possible harms and discomforts?**](#Guidance_What_are_the_possible_harms)

**Risks and Discomforts from Standard Treatment**

The risks and side-effects of the standard or usual treatment of ***[insert details]*** will be explained to you as part of your standard care. If you are unclear about what is standard of care and what is specifically part of this study, please discuss this with your study doctor.

**Reproductive Risks**

Because the effects that ***[insert study drug]*** may have on an unborn child are unknown, you should not become pregnant or father a baby while on this study. An effective method to avoid pregnancy should be used while you are on study treatment. ***[Explain if this extends for a period of time after treatment has stopped and specify how long it should continue.]*** Ask the study doctor about counseling and more information about preventing pregnancy. You should not breastfeed your baby while on this study ***[explain if this is only while taking the experimental treatment or extends for a period of time after treatment has stopped and specify how long]*** because it is possible the drugs used in this study may be present in your breast milk. ***[Include a statement about possible sterility when appropriate (e.g., “Some of the drugs used in the study may make you unable to have children in the future. Your study doctor will discuss this with you.”]***. If you (or your partner) become pregnant while you are on this study, you should notify your study doctor.

**Genetic Risks**

*Insert required text below* ***only if applicable****.* *Disclose other genetic risks as applicable to the study.*

“When you donate your blood or tissue for genetic testing or research, you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes or DNA.  The risk of your information being accidentally released in this study is estimated to be \_\_\_\_\_\_\_\_\_\_\_\_ (insert risk level as appropriate) A Federal (Canada-wide) law now prohibits anyone such as an employer or an insurer from requiring you to disclose the results of a genetic test or to take a genetic test as condition of providing services.  In addition, discrimination against individuals based upon genetic characteristics is now prohibited by the Canadian Human Rights Act.”

*If there is any foreseeable prospect of incidental findings, a plan for this needs to be disclosed to the REB and in the consent form.*

**12.** [**What are the potential benefits of participating?**](#Guidance_What_are_the_potential_benefits)

There may not be direct benefit to you from taking part in this study.

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease.

**13.** [**What are the alternatives to the study treatment?**](#Guidance_What_are_the_alternatives)

If you choose not to participate in this study or to withdraw at a later date, the following treatment options may be available to you ***[List those that are known.]***

You can discuss these options with your doctor before deciding whether or not to participate in this research project.

**14.** [**After the study is finished**](#Guidance_After_the_study_is_finished)

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

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

**Studies requiring Clinical Trials registration:**

***For studies requiring registration with ClinicalTrials.gov****, include the following wording in separate paragraphs.*

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**15. What if new information becomes available that may affect my decision to participate?**

*Insert required text* ***only*** *if applicable to your study (i.e. a study which is investigating a treatment).*

If you choose to enter this study and at a later date a more effective treatment becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study. You may be invited to sign an amended consent to indicate your continued consent to participate in the study.

**16.** [**What happens if I decide to withdraw my consent to participate?**](#Guidance_What_happens_if_I_withdraw)

***For research that is regulated by Health Canada or U.S. FDA:***

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, all information about you collected up to the point of your withdrawal ***[including, where applicable, information obtained from your biological samples]*** will be retained for analysis in order to protect the integrity of the research, which may benefit future research participants and patients. However, no further information will be collected. If you decide to withdraw, you may still be asked to come in for a final safety visit to ensure your safety.

***Additionally, include the paragraph below if samples have been collected:***

If samples have been collected before you withdraw, they will be destroyed or returned to the facility from which they were obtained. There may be exceptions where the samples will not be able to be withdrawn for example where the sample is no longer identifiable (meaning it cannot be linked in any way back to your identity).

***Include the paragraph below if applicable:***

If your participation in this study includes enrolling in any optional studies or long term follow-up, you will be asked whether you wish to withdraw from these as well.

***For research NOT regulated by Health Canada or US FDA:***

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you ***[and/or your samples]*** already collected. You have the right to request the destruction of your information ***[and/or samples]*** collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data ***[and/or samples]*** will not be able to be withdrawn for example where the data ***[and/or sample]*** is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data ***[and/or samples]***, please let your study doctor know. If your participation in this study includes enrolling in any optional studies, or long term follow-up, you will be asked whether you wish to withdraw from these as well.

**17.** [**Can I be asked to leave the study?**](#Guidance_Can_I_be_asked_to_leave)

You may be asked to leave the study if the study doctor judges it is not in your best interest to continue, or if you are unable to fulfill the requirements for the study, or for any other reason. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision. The study doctor will arrange for you to continue your care outside of the study. The study may also be stopped at any time by the sponsor or the Research Ethics Board ***[or Health Canada/other applicable regulatory agencies]*** if new information rises about the safety of the study treatment. The reasons for study stoppage will be explained to you by the study doctor.

**18.** [**How will my taking part in this study be kept confidential?**](#Guidance_Confidentiality)

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or designate and by representatives of ***[insert here, if relevant, the name of the sponsoring company or cooperative group conducting the study,] [insert here, if relevant, Health Canada], [insert here, if relevant, the U.S. Food and Drug Administration,]*** and ***[insert name of your REB]*** for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

*If planned disclosure of personal identifiers (e.g. birth date) is approved by the REB, amend the details in the required wording as follows:*

Your ***[insert personal identifier/s]*** will also be provided if requested by the sponsor or responsible regulatory agency.

**If data is being transferred out of Canada:**

*Clarify whether data and/or samples will be sent outside of Canada, and include the following wording:*

Any study related data [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 related data [and/or samples], that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information [and/or samples], to organizations located outside of Canada.

* [List name of entity and country location (only) for which data/biospecimens will be transferred to.]

**Reportable Diseases**

*Include the following required wording if your study will be testing for any reportable diseases in B.C.:*

Your personal information or information that could identify you will not be revealed without your express consent unless required by law. If facts become known to the researchers which must be reported by law to public health authorities or legal authorities, then your personal information will be provided to the appropriate agency or authority.

* Positive results for \_\_\_\_\_\_ will be reported

[Enter which specific disease will be tested.]

**Primary Care Physician(s)/Specialist(s) Notification**

***For studies which are using electronic medical records (EMRs) and will have the consent form as part of the EMR (e.g. Cerner), please include the following required wording.*** *Please note this wording should also be amended and used accordingly for studies where the hard copy consent form will be placed in the patient’s medical record****:***

Because this is a treatment study, your signed consent form will be included in your electronic medical record, and your healthcare team will be alerted that you are on a study. This is to ensure your healthcare team has a little information about the study so that they can treat you safely according to the study protocol.

*For all other REBs, include the following (optional) notification section.*

*This component cannot be used for BC Cancer REB.*

*Recommended Text*

Please indicate, by checking the applicable box, whether you want us to notify your primary care physician(s) or specialist(s) of your participation in this study. This is not a consent to release medical information.

⬜ Yes, I want the study investigator to advise my primary care physician(s) or specialist(s) of my participation in this study. My primary care physician(s) and/or specialist(s) name(s) is/are:

The name of the medical clinic I attend is:

 Participant Initials:

⬜ No, I do not want the study investigator to advise my primary care physician(s) or specialist(s) of my participation in this study.

 Participant Initials:

⬜ I do not have a primary care physician or specialist.

 Participant Initials:

⬜ The study investigator is my primary care physician/specialist.

 Participant Initials:

I understand that if I choose not to advise my primary care physician(s) or specialist(s) of my participation in this study, there may be potential medical consequences which may affect my comprehensive medical care or treatment. I understand that the study investigator may not be responsible for these consequences.

You may wish to discuss the consequences of your decision with the study staff.

**Disclosure of Race/Ethnicity**

*If you are conducting a study which requires the collection of demographic data, please include wording along the following suggestion:*

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because \_\_\_\_\_\_\_\_\_\_. You should be aware that providing this information is not mandatory.

**19.** [**What happens if something goes wrong?**](#Guidance_What_if_something_goes_wrong)

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan and/or by the study sponsor ***[insert name of sponsor]***.

In case of a serious medical event, please report to an emergency room and inform them that you are participating in a clinical study and that the following person can then be contacted for further information: Dr. ***[insert doctor’s name]*** at telephone number: ***[insert doctor’s telephone number]***.

*If the study involves an investigational drug / device / health product, subjects should be given a wallet card to carry with them in the event of an emergency.*

**20.** [**What will the study cost me?**](#Guidance_What_will_the_study_cost_me)

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

**Reimbursement**

*Clarify whether participants will be reimbursed for any expenses incurred, such as parking or transportation, as well as whether receipts will be required.*

**Remuneration**

*Clarify whether participants will be paid for their participation. NOTE: This is not the same as “reimbursement”, which is payment to reimburse expenses incurred by the participant.*

**21. If I have questions about the study procedures during my participation, who should I speak to?**

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact***[insert PI or his/her representative]***at ***(xxx) xxx-xxxx, ext. xxxx***.

**22. Who do I contact if I have any questions or concerns about my rights as a participant?**

*If this is a harmonized study, please include only the Board of Record’s contact details as necessary. Please note all studies which have Fraser Health affiliation are required to outline Fraser Health’s Complaint Line details, regardless of whether they are Board of Record*

*For UBC-affiliated REBs:*

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598.) Please reference the study number (Hxx-xxxx) when calling so the Complaint Line staff can better assist you.

*For Fraser Health REB*

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Fraser Health Research Ethics Board co-Chair by calling 604-587-4681. Please reference the study number (xyz123).

*For Interior Health REB*

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Chair of the Interior Health Research Ethics Board at (250) 870-4602. Please reference the study number (abc123).

*For Vancouver Island Health Authority REB*

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Vancouver Island Health Authority Research Ethics Office at 250-519-6726 or by email at researchethics@viha.ca Please reference the study number (xxx123).

*For Simon Fraser University REB:*

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, you may contact Dr. Jeffrey Toward, Director, Office of Research Ethics at jtoward@sfu.ca or 778-782-6593.

**23.** [**Signatures**](#Guidance_Signatures)

***[Insert full study title]***

**Participant Consent**

My signature on this consent form means:

* I have read and understood the information in this consent form.
* I have had enough time to think about the information provided.
* I have been able to ask for advice if needed.
* I have been able to ask questions and have had satisfactory responses to my questions.
* I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
* I understand that my participation in this study is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
* I understand that I am not waiving any of my legal rights as a result of signing this consent form.
* I understand that there is no guarantee that this study will provide any benefits to me.
* *[Insert any other research specific clauses that may be important to reiterate.]*

**If applicable to your study, the following bullet is also required:**

* I authorize access to my health records ***[insert “and samples” if applicable]*** as described in this consent form.

I will receive a signed and dated copy of this consent form for my own records.

I consent to participate in this study.

Participant’s Signature Printed name Date

 Signature of Person Printed name Study Role Date

 Obtaining Consent

**Investigator Signature**

*Some REBs may require an investigator signature for all consent forms. Check local REB requirements. As well, a signatory line for “investigator signature” (example below) must be added if required by the sponsor, but this may not replace the line for the “person obtaining consent” if this is a different person:*

Investigator Signature Printed name Date

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant’s signature was obtained.

**Parent/Guardian and/or Substitute Decision Maker Consent:**

*(This wording should be used* ***only when applicable****)*

This consent form was read by the parent(s)/guardian(s)/substitute decision-maker (legally authorized representative), and both the person reading this consent form and the investigator are satisfied that:

* The study information was accurately explained to, and apparently understood by, the child/participant.
* The child/participant was given an opportunity to ask questions, and all questions have been answered.
* The child/participant assents to participating in the research.

Participant Name

[Parent]/[Representative’s] Signature Printed name Date

 Signature of Person Printed name Study Role Date

 Obtaining Consent

**When a Substitute Decision Maker (SDM) becomes necessary during the course of a study: (‘Substitute Decision Maker –Ongoing Consent’)**

During a study, a person may lose the capacity to consent, either due to natural disease progression or some other circumstance.  In this case, you as their SDM may be asked to provide consent on their behalf to continue in the study. You should consider what the participant’s wishes are or were, and whether continuing in the study might be of benefit or harm. The participant may be able to provide their assent to continue in the study as well.

[**Use of Translators/Witnesses**](#Guidance_Use_of_Translators_Witnesses)

**Future Contact**

*If researchers wish to contact participants later to participate in other studies, include this request with an appropriate yes/no tick box. Researchers are encouraged to include this request if there is any chance that they may wish to ask participants to participate in future studies.*

**When participant regains capacity to consent**

**Participant’s Acceptance of Substitute Decision Maker’s Consent**

Your illness made it impossible for you to participate in the informed consent process, so your substitute decision maker’s (SDM) consent was obtained on your behalf. Your SDM agreed to your participation in this research study. Now that your condition has improved we would like to inform you of the details of the study and obtain your consent. The Participant Informed Consent Form will be reviewed with you and then you may agree or disagree with the decision made by your SDM.

My signature on this consent form means:

* I have read and understood the participant information and consent form.
* I have had the opportunity to ask questions and have had satisfactory responses to my questions.
* I understand that my participation in this study is voluntary
* I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
* I authorize access to my health record and samples as described in this consent form.
* I understand that I am not waiving any of my legal rights as a result of signing this consent form.

If you do not wish to continue participation in this study you may request that your study data be withdrawn. This request will be respected to the extent possible. Please note however that there may be exceptions where the data ***[and/or samples]*** will not be able to be withdrawn. You may discuss this further with the study doctor.

I will receive a signed and dated copy of this consent form for my own records.

I consent to participate in this study.

Participant’s Signature Printed name Date

 Signature of Person Printed name Study Role Date

 Obtaining Consent

**Appendix I**

How to use this document

This document is intended to assist investigators in producing consent forms that meet the ethical requirements of the following Research Ethics BC (REBC) Partner Organizations:

*
* [Children’s & Women’s Research Ethics Board](http://www.phsa.ca/researcher/ethics-approvals/research-ethics-approval/ubc-bc-childrens-and-womens-research-ethics-board) (C&W REB)
* [Fraser Health Research Ethics Board](https://www.fraserhealth.ca/health-professionals/research-and-evaluation/) (FHREB)
* [Interior Health Research Ethics Board](https://www.interiorhealth.ca/sites/Partners/Research/Pages/Research-Ethics-Board.aspx) (IH REB)
* [Northern Health Research Review Committee](https://www.northernhealth.ca/YourHealth/Research/NHResearchReviewCommittee.aspx)\* (NH RRC)
* [Providence Health Care Research Ethics Board](http://www.providenceresearch.ca/research-ethics) (PHC REB)
* [Simon Fraser University REB](http://www.sfu.ca/ore.html) (SFU REB)
* [UBC Clinical Research Ethics Board](https://ethics.research.ubc.ca/clinical-research-ethics) (UBC CREB)
* [University of Victoria Human Research Ethics Board](https://www.uvic.ca/research/conduct/home/regapproval/humanethics/index.php) (UVIC HREB)
* [Vancouver Island Health Authority Research Ethics Board](http://www.viha.ca/rnd/research_ethics/) (Island Health CREB)

\*NH does not currently have a constituted REB.

Adherence to these guidelines may not be sufficient. Investigators should also refer to the guidance notes and policies of individual partner organizations to ensure all requirements are met

All information required by the potential participant to make a free and informed decision to participate in the research must be included in the consent form. If any of the required sections have not been included, a consent document may be returned to the applicant with provisos.

Before you begin

1. To ensure you are using the most current version of this template, download a new copy each time you create consent forms. To use the template, you may copy this and use it as a guideline.
2. Required wording for all REBs is highlighted in yellow.
3. Required wording for Health Canada regulated trials is highlighted in green.
4. Recommended wording is in regular font.
5. Instructions and further guidance are provided in Part 2 of this document.
6. Once you have completed your draft:
	1. Delete all italic content,
	2. Remove colour highlighting from the remaining text,
	3. Finalize the footers and remove the headers,
	4. Remove template appendices.
7. Consent forms must be saved on the appropriate letterhead, as follows:
	1. BC Cancer REB requires BC Cancer letterhead.
	2. C&W REB requires UBC and/or Hospital/Program Department letterhead.
	3. PHC REBrequires UBC and Providence Health Care/Providence Clinic Letterhead.
	4. UBC CREB requires UBC Department letterhead or VCH or VCHRI letterhead, if applicable.
	5. FHREB requires Fraser Health Authority letterhead.
	6. IH REB requires Interior Health Authority letterhead if the study will be carried out by an IH site investigator. If the study is multi-jurisdictional, addition of the IH logo to another site’s letterhead is acceptable.
	7. NH prefers not to have its logo on the letterhead; the consent form should be on the principal investigator’s institutional letterhead.
	8. VIHA HREB requires VIHA letterhead.
	9. SFU REB requires Simon Fraser University logo.

There are some sections in a consent form which are not necessary to include in detail and add to the length of the form. The following is a list of sections the researcher should generally address in the body of the consent form, but may wish to elaborate on as part of a supplement to the consent form:

* Exhaustive list of study procedures (with a short summary and reference to appendix in consent form);
* Exhaustive list of study visits (with a short summary and reference to appendix in consent form);
* Optional procedures, when appropriate;
* Risk section, when there are several pages of risks: For industry-sponsored trials, check with your sponsor to see whether they have any requirements for all risks to be clearly outlined in the consent form. Basic risks should always be outlined; an exhaustive list of risks can essentially be referred to in a supplement to the consent form.

**General style and formatting guidelines for consent forms**

1. Consent forms should be written at a Grade 7 level of understanding.

2. In Microsoft Word, you can display the Flesch-Kincaid Grade Level Score by clicking on “Spelling and Grammar” in your tool bar. If the option to check for readability statistics is not viewable, ensure it is enabled. In Word 2013: Click the File tab, and then click Options. Click Proofing. Ensure “🗹 Show readability statistics” is selected.

3. Type size: no smaller than the type on this page (12 point).

4. Improve readability by using headings, short paragraphs, and spaces between paragraphs.

5. Use plain language; explain medical terms and jargon. Use non-scientific terminology. For assistance with finding lay language substitutes, refer to the Canadian Cancer Society Glossary of Terms: <http://info.cancer.ca/glossary/>

6. Acronyms should be avoided. If they must be used, they should be written out the first time they appear, e.g., Peculiar Acronym for General Use (PAGU).

7. Number the pages in the following manner: “1 of 3”, “2 of 3”, “3 of 3,” etc.

8. Include a footer ON EACH PAGE with the version number and date. Also include a brief reference to the study such as the protocol number or REB number or nickname of the study.

9. All information required by the participant must be included in the informed consent form, with the exception of ancillary drug information sheets, if applicable.

10. The consent form submitted for review should be in its final form and on letterhead (as it will be seen by the participant).

11. Spelling, grammar and formatting must be corrected before submission to the REB.

12. Use second person pronouns for the participant information part of the consent form (you/your). Use first person pronoun (“I”) only for the final Participant Consent portion of the form.

13. References to “doctor” should be clarified to identify who is being referred to, e.g., the family doctor, study doctor, oncologist.

**Appendix II**

*General directions to those responsible for obtaining consent*

1. The “person obtaining consent” must be sufficiently familiar with the study, the disease being treated and the process of informed consent to be able to obtain properly informed consent and, thus, will usually be the investigator or a designated research assistant.

 If a study doctor is also the treating doctor for the potential research participant, this must be clearly stated in the application to the REB. Include an explanation of efforts that will be made to mitigate the potential for undue influence over a potential participant when obtaining their consent to participate. In such cases best practice has been identified as having someone other than the study/treating doctor obtain consent, or receive the participant’s answer regarding their final decision. This does not preclude the study/treating doctor from providing information to the participant or answering any of their questions. See [TCPS2-Chapter 11.A: Duty of Care](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/#toc11-1a).

1. The investigator should independently document the obtaining of informed consent in the medical record, noting the date, the participant’s full understanding of the risks and benefits of enrollment and the voluntary nature of participation.
2. Translated Consent Documents: A translated consent document cannot replace the English language version but it can serve as an additional aid in the consent process. A translated consent document also does not replace the requirement for a translator/interpreter to be present during the consent process and throughout the study.The investigator should ask for the translated version to be independently reviewed for accuracy. The final version of the translated consent document must be submitted to the REB for approval along with a statement signed by the interpreter confirming that the translation is accurate, stating the name and version date of the document they translated and their qualifications. These documents may be submitted as an amendment after the REB has approved the English version. The participant will sign the translated consent.
3. A translator/interpreter should be a PHSA/BC Cancer or other such certified or qualified translator/interpreter. They should be impartial, that is, not a relative, study team member, or a person who might have influence over the participant. For more information see the [PHSA Provincial Language Services](http://www.phsa.ca/AgenciesAndServices/Services/Provincial-Language-Service/default.htm) site.

**Appendix III**

**1. [Insert Title of Study]**

*The title must be the exact title of the research protocol and include (if applicable) the protocol number.*

*A short simplified title may accompany the title if it is too difficult for a layperson to understand. The title should convey that the proposed intervention is for research rather than for educational, treatment, or other purposes.*

**3.** **Invitation**

*Describe the characteristics of the sample population that are important for the study, e.g. “You are being invited to participate in this study because you have been diagnosed with high blood pressure.”*

**4.** **Your participation is voluntary**

*This section should stress the voluntary nature of participation.*

*Procedures for study withdrawal are described in Section 14: What happens if I decide to withdraw my consent to participate?*

**5.** **Who is conducting this study?**

*Name all agencies contributing funds, including grants-in-aid, resources, and drugs and other products.*

*Declare any actual or potential conflicts of interest regarding remuneration received from the sponsor that are above or beyond reimbursement for costs to conduct the study, such as additional payment for conducting or being involved with any part of the study (e.g., study design) and/or possible benefits from commercialization of research findings.*

**6.** **Background**

*Within this section you want to clearly frame the research by providing an overview of the current state of knowledge/care and describe why there is need of change/improvement/research, and why the knowledge which will be gained is of interest to clinicians, patients, or administration. A well-framed research question is crucial. Make use of databases such as MEDLINE, EMBASE, Cochrane Library, and AMED.*

*Include a brief explanation of participants’ involvement in the study.*

*The background section should be different from the “purpose” section. The purpose section describes the specific goals of the study. The Background section describes the reasons why the research is being conducted.*

*Explain the background, describing specific information relevant to the study including (as applicable) the standard of care for the study population. Explain why the research is being done in non-technical language.*

*Include the prevalence or incidence of a disease, the problems associated with a disease, the poor outcomes for other treatment methods, relevant information from previous studies, possible deficiencies in the standard therapy, and the rationale for the investigational treatment (why the study drug/procedure has potential for participants).*

*When applicable, address the following key points:*

* *If placebo controls are being used, explain what a placebo is (i.e. explain that a placebo is an inactive substance, that it looks identical to the test drug/intervention but that it contains no therapeutic or experimental ingredients) and explain and why it is appropriate to use such controls*
* *Whether the research is being carried out for the first time in humans*
* *If the research is part of a larger multi-site clinical trial, indicate whether there are other Canadian sites and/or countries where the study will be conducted*
* *The total number of participants that will be recruited and the expected number at the local site*

**7.** **What is the purpose of the study?**

*This section should be distinguished from the “Background” section so that the participant can easily identify the specific goal(s) and primary objectives of this research project. The goal statement should specify in lay terms exactly what the study hopes to find out.*

*In addition, the purpose of Phase I, II, III, or IV clinical trials, pilot studies, extension studies, etc., must be explicitly explained in lay terms to participants, so that they can understand the current stage of scientific investigation of the therapy, and therefore, what scientific question(s) the study is trying to answer.*

*Note: Only descriptive statistics are appropriate. Neither the project description nor the consent document should imply that a definitive answer will result.*

***For a Phase I Study:***

*The language used throughout the study should make it clear that this is NOT a study in which efficacy will be determined. Phase I studies are neither expected nor intended to provide personal benefit.*

*Phase I-III clinical trials involving natural health products on human subjects must be authorized by Health Canada's Natural Health Products Directorate (NHPD) before commencement of the trial. This process requires the sponsor or a designated representative of the sponsor to submit an application package with detailed information about the proposed trial. https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/clinical-trials/forms-template.html*

*An Investigational Testing Application (ITA) must be submitted to Health Canada to conduct research with unapproved Class II, III, and IV medical devices. The consent form should clearly outline which Class of medical device is being used and what the researchers hope to discover.*

***For Expanded Access Protocols (EAP):***

*See BC Cancer REB guidelines posted on the web page for* [*New Applications*](http://www.bccancer.bc.ca/research-ethics-board-site/Documents/EAPGuidelines2005Mar13.pdf)*.*

*For more information on Clinical Trials Design and Registration, please refer to* [*TCPS2, Chapter 11, Section B*](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/#toc11-1b)*.*

**8.** **Who can participate in this study?**

*List, in point form, the major characteristics indicating eligibility to participate in this study. This list should be limited to inclusion* *criteria that the potential participant is likely to be aware of.*

*If the investigator wishes, an appendix can be added to the end of the consent form which clearly details the eligibility criteria.*

**9.** **Who should not participate in this study?**

*List, in point form, the major characteristics indicating ineligibility to participate in this study. This list should be limited to exclusions that the potential participant is likely to be aware of (e.g., illnesses and medical conditions).*

*Exclusion criteria should not be the opposite of inclusion criteria. They address the question: of those who meet ALL of the inclusion criteria, what characteristics/criteria/features are there ANY ONE of which would make an otherwise eligible participant ineligible?*

*If specific medications must be avoided by participants, indicate here and list them.*

*If participants must live within a certain distance of the centre, indicate this restriction and why it is necessary (e.g., because participants receiving experimental drugs must be able to come back to the hospital or center quickly if any severe or unexpected problem develops.)*

*If excluding due to reproductive risks specify. E.g., “If you are pregnant or of childbearing potential and/or a man who is able to father a child, you must agree to avoid pregnancy (and clarify for how long).” See details under Reproductive risks in Section 10, and PHC required wording below.*

*If breastfeeding is an exclusion, indicate here and for how long, (e.g. only while on treatment, or longer).*

*Further details regarding reproductive risks will be required under Section 10 of the consent.*

 **10.** **What does the study involve?**

*Explain in lay terms exactly what will happen to a participant who enrols in the study. Participants should be able to understand the extent of their involvement in the research and each step of their participation in it (e.g., screening procedures, treatment procedures, follow-up).*

*Describe the overall design of the study first, with respect to the different treatment arms/groups (should this apply), followed by a detailed description of the specific steps of the research, including the screening phase. A reference to the availability of any optional parts of the study can be included with an explanation that a separate optional consent will be provided with the details that they will need to sign if they wish to take part in the optional study.*

*It is also helpful to have a separate sub-heading for screening procedures used to determine eligibility for enrolment and to distinguish them from procedures that are part of the conduct of the study. This can follow the initial description of the overall design.*

*Research-related procedures may include standard or common investigations that would not normally be done in routine clinical care for the particular problem being investigated or that are done more frequently during the research than in routine clinical care for that particular problem. These should be distinguished from standard care. Standard care and related tests do not normally need to be disclosed unless they are being investigated as part of an experiment.*

**Overall design of the study:**

*This first section should include, as applicable, a description of the following specific information:*

* ***Any specific testing*** *which may be required to determine eligibility for the research (e.g. biopsy results, psychological tests, blood work, etc.)*
* ***The research*** *intervention: i.e. testing a new drug, undergoing surgery, review of records, undergoing specific diagnostic procedures (e.g. X-rays, MRI, taking blood), completing a questionnaire, answering questions in an interview, etc.*
* ***The different******treatment “arms”*** *(i.e. study groups). Ensure that the description of each is presented in such a way (e.g. separate paragraphs with sub-headings) that participants can discern the differences among the arms. A diagram of the different arms is often helpful.*
* *The differences between* ***standard therapy*** *and the* ***experimental procedures*** *and whether or not the participant will continue to receive standard therapy.*
* *How participants will be assigned to specific treatment arms (i.e.* ***randomization*** *– explain that this is like the flip of a coin so that there is an equal chance of being in any of the groups; double-blinding – neither the researcher nor the participant will know which group they are in). Note that a description of a placebo arm in lay terms should have been given earlier in the consent form – see Section 4).*
* ***Double-blinding*** *should include an explanation that the code can be broken in the case of an emergency so that the study drug can be identified;*
* ***The overall******duration*** *of the study and how this would differ from that of standard care, the number of visits, and the length of each visit (use a sub-heading to make this information easy for the participant to find);*
* *The number of* ***questionnaires*** *and/or* ***interviews****, the period of time over which these would be administered, and the length of time it may take to fill out questionnaires or participate in interviews. Include a statement that participants do not need to answer questions that they are not comfortable answering.*

**If You Decide to Join This Study: Specific Procedures**

*This section should describe in detail the research procedures that the participant would experience.*

* *Use sub-headings for each step in the participant’s involvement, including screening.*
* *Ensure that specific tests are spelled out initially before using acronyms.*
* *Describe the dosages of all study drugs.*
* *If applicable, specify the amount of blood/tissue to be taken each time as well as the total amount of blood/tissue to be taken (i.e. state the amount of blood to be taken in teaspoons/tablespoons or in millilitres).*
* ***Tables are often helpful to summarize procedures and time commitments, especially for complex or long-term studies. Researchers can use the chart of study visits included in the protocol.***
* **Study Visits**

*These can be described in a variety of ways depending on the research procedures, e.g.: Day 1, 2, 3; During the First Year of Your Participation in the Study; During the Remaining Years of Participation in the Study; First/Second/Third Visit; For Participants in Group 1/Group 2.*

* **Expected Follow-up**

*Describe the number of follow-up visits and their duration.*

* **Use of Data from Secondary Data Sources that use identifiable information.**

***If data*** *is collected from secondary data sources for the purposes of the study, the consent form must meet the requirements of* [*TCPS2 Ch.5 section D*](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1d)*.*

***See also*** *local REB Guidance Notes (links in* [*Appendix I*](#Appendix_I)*)****.***

**Open Access**

The potential for future use of data should be clearly disclosed in the consent form. There is an increasing trend in research requiring researchers to make their data publically available at the time of publication. This trend is both from the funder, e.g. Tri-Councils, and journals, who are refusing to publish papers unless the data is publically accessible. Researchers should carefully consider whether their research data could be made available in the future and in what form (de-identified or otherwise) and disclose this information in the consent form. Further considerations around privacy, confidentiality, and data management are required when data is sensitive or when there is future potential that data may be re-linked with other data to create identifiable information. It should be noted that many journals and funders will make exceptions to open access policies when it is not possible to make the data available in a way that protects the confidentiality of the participants or when sharing would erode the participants trust in the researcher.

**Needed Consent Form Disclosures:**

* A statement about the potential for future use and what that means within the context of the research.
* A statement about the nature of the data that will be publically available, e.g. de-identified. Ensure terms and definitions are defined in lay terms.
* If any, a discussion of any increased risk to participant, e.g. possibility of re-identification.
* If not already covered in the consent form, a statement that once data is made publically available, the participant will not be able to withdraw their data.
* If possible, a check box to opt out of future use.

**Optional Studies**

**Mandatory/Optional Blood or Tissue Collection and/or Biobanking**

*Mandatory tissue/blood collection must be limited to what is required for the conduct of the current study. Otherwise, it is considered optional and separate consent must be obtained.*

*See local REB policies and guidance notes for further information regarding consent requirements and tissue/biobanking consent templates.*

*Optional sub-studies should only be embedded within the main study consent form if the risks and procedures are not substantively different from those in the main study. Otherwise, a separate consent form for optional consents should be used. Examples of optional sub-studies that appropriate for inclusion in a main consent include additional questionnaires for optional cost-effectiveness studies, or additional collection of blood for purposes other than genetic testing or tissue banking when blood samples are already being taken for the main study.*

*Separate consent forms should be used for sub-studies that include genetic and DNA testing, tissue and blood banking studies, pharmacokinetic studies, use of individual data, records, or personally identifying information in another study, and analysis of secondary data from linked databases.*

*The consent form must clearly indicate which procedures are optional and that participation in the main study is not contingent on participation in the optional studies. The section on withdrawal should also explain what will happen to the data collected in optional studies.*

*Do not include check box options in the body of the consent. An additional signature line or checkbox for the optional sub-studies should be included in the signature section of the consent form.*

*If a separate consent form will be used for an optional sub-study, a reference to the sub-study can be included with an explanation that a separate optional consent will be provided with the details that they will need to sign if they wish to take part.*

*If mandatory tissue/blood collection is applicable, its use must be explained and assurance given that biobanking for unspecified, unrelated or genetic research will not occur.*

 *Use lay language to explain the scope of the research.*

*Explain how the samples will be identified, where they will be stored and for how long.*

*Explain that once these tests have been completed, any leftover samples will be returned to the facility from which they were obtained if needed, or destroyed (or if applicable; that they will be given an option to allow these to be used for other future research purposes, in which case they will be given a separate optional consent form to sign.)*

*If the tissue sample will be obtained from previously collected tissue, explain that no additional biopsy will be required.*

*Explain that the samples will only be used for the purposes described in this consent document and will not be sold.*

*Explain who will/will not receive reports about any research tests done on these samples and whether the reports will or will not be put in their health records.*

*Consider the use of flow charts or some form of graphic display to illustrate the handling and use of specimens; e.g. from initial collection of specimens, to banking, to distribution for future research. The chart could indicate when de-identification of specimens occurs and could show involvement of REBs in reviewing the use of specimens for future research.*

*If optional specimens will be obtained (tissue, blood, other material) for research, refer to the local REB’s consent form template for tissue and/or blood collection or other additional optional testing. Only tests that are required for participation in the main study should be described in the main consent. A statement may be made to indicate that an optional component is available and that a separate consent document will be provided and reassure the participant that they may choose not to participate in the optional part of the study and still participate in this main study.*

**11.** **What are the possible harms and discomforts?**

*The following information (and any other relevant information) should be included in this section where applicable:*

*Explain the risk that the participant’s condition may worsen.*

*The CIOMS standard frequencies for Risks are outlined as follows:*

*Very common (10% or greater)*

*Common (1% - 10%)*

*Uncommon (0.1% - 1%)*

*Rare (0.01% - 0.1%)*

*Very rare (less than 0.01%)*

*Frequency not known (cannot be estimated from the available data)*

*In cases where risks from human research is not readily available (for example, Phase I studies), please provide details of any relevant risks shown in previous studies conducted on animals.*

*Disclose all known risks and discomforts associated with study procedures, including social and psychological risks/discomforts, risks to others, reproductive risks, genetic risks, risks that require counselling (describe whether counselling will be made available), and risks related to testing for reportable diseases, and risks related to use of placebo or associated with drug washout periods.*

*Indicate whether the harms of the study drug may be severe, disabling, irreversible, or may cause death.*

*Indicate whether the risks are fully known and whether there may be unexpected harms/side effects, including unexpected effects of novel drug combinations or because the study drug is in an early stage of development. Provide previous study results if known.*

*Clarify**the risks to women should they become pregnant as well as any risks to potential fathers (see recommended wording below);*

*Instruct**participants that they should immediately inform their study doctor of any side effects they experience, if applicable;*

*Instruct**prospective participants to discuss the known side effects with their study doctor prior to their decision to participate in the study;*

*Clarify that participants assigned to the placebo group may experience worsening of their condition since they will not have their condition treated.*

*List in bold text any medications, supplements, or foods that should not be taken while on the study.*

*Disclose any potential loss of opportunity to receive standard care or the related known benefits from standard care.*

*For further information regarding describing risks to participants, refer to the local REB’s guidance notes (links in* [*Appendix I*](#Appendix_I)*).*

*For studies that involve questionnaires or surveys, include that there may be potential risks of feeling anxiety / sadness etc. and that the participant does not have to answer any questions that make them feel uncomfortable.*

**Risks and Discomforts from Standard Treatment**

*Risks and discomforts of standard treatment(s) are not normally listed, unless safety and/or efficacy of standard treatment(s) are being studied or standard treatment(s) is (are) being compared to experimental therapy, or if the standard treatment (drug) is being given in combination with an experimental treatment (drug). Side effects and other issues related to standard interventions should be explained following usual clinical practice. However, a statement should be included in the consent to explain this.*

**Reproductive Risks**

*If a pregnant partner consent is required, this should be submitted to the REB. This can be submitted later as an amendment, should a pregnancy occur.*

**12.** **What are the potential benefits of participating?**

*State that the participant may not benefit from being in the study.*

*Include relevant information about the nature of the potential benefits (how important are these benefits?) and the likelihood of these benefits occurring.*

*In research projects where there may be anticipated benefits to society or to a specific group, these potential benefits must be explained in a separate paragraph so as not to confuse potential benefits to others with potential benefits to the research participant.*

*Clarify – in addition – whether or not the investigators can provide the participant with their results from certain tests that would not otherwise be done if they were not participating in the study, which might be construed as a benefit.*

**13.** **What are the alternatives to the study treatment?**

*Describe, if applicable,**any alternatives (i.e. other standard treatments) to the treatment that participants would receive in the study.*

*State**if there are no such alternative therapies available.*

*Where applicable, palliative or best supportive care should be included as an alternative (see recommended wording below).*

Palliative Care or Best Supportive Care (BSC). This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the disease. It does not treat the disease directly, but instead tries to improve how you feel. Best Supportive Care tries to keep you as active and comfortable as possible.

*Describe alternative therapies, if they are available.*

*Recommend in the consent form that the participant discusses the alternative therapies with the study doctor or their personal physician before deciding whether or not to join this study.*

*Ensure that the participant understands clearly what treatment they may receive should they not participate in the study.*

*If applicable, include in the list of alternatives:*

**14.** **After the study is finished**

*Describe any information that may be given to the participant once their participation is concluded.*

*For example, this could include whether or not the participants will be able to continue treatment on the study drug. If not, include the following recommended wording below.*

*Explain that you will provide participants – where possible – with a lay summary of the study results.*

*Describe when the study and/or individual results are likely to be available and how they will be disseminated.*

*Inform participants, where relevant, of procedures for accessing those results.*

*If there is a possible open-label extension study, or if participants will continue to receive the study drug after the study, please explain the details here.*

*If the participant received a device, explain if they will keep the device or not (i.e., “The device that was implanted for this study will not be removed, but it will continue to be monitored as part of standard or usual care.”)*

*Note there is a requirement for studies listed on ClinicalTrials.gov to submit their results to the website; this information should be relayed to participants when applicable.*

*Include whether the research team plan to disseminate study data or results and the details around how this will occur. If a Newsletter will be disseminated provide the details of such.*

**16.** **What happens if I decide to withdraw my consent to participate?**

*Indicate that the participant may withdraw at any time without giving reasons, including withdrawal from optional study components.* ***Participants cannot be required to submit a request for withdrawal in writing only; the option to withdraw verbally must be presented as well.***

*Include the following when applicable:*

*Explain that participants have the option to withdraw from treatment but remain in the study for follow-up purposes. Describe what this will involve.*

*Explain that participants may remain in any optional studies.*

*Explain that examinations (e.g. physical, blood pressure, blood tests) may be recommended for or requested of the participant if they decide to withdraw from the study and that these would occur after the participant has been released from the study; explain why these examinations may be recommended or requested.*

*For double-blind studies, explain whether participants will be able to find out what treatment they were receiving.*

*Disclose if it will not be possible to undo the research-related intervention (e.g., somatic cell gene transfer, implantation of medical device [e.g. stent]). However, the participant may be able to withdraw from participation in the research (e.g. the ongoing evaluation) even though the procedures already performed cannot be undone.*

*Explain**what will happen to any data collected up to the point of the participant’s withdrawal from the study. For studies that are regulated by Health Canada or the US FDA, include the statement that such data will be retained and cannot be withdrawn. For studies not regulated by Health Canada or US FDA, the investigator must outline the factors that would lead to the participant’s request to withdraw their data being denied.*

*Remove**text in square brackets [ ] if biological samples (e.g., blood, tissue, etc.) are not being collected.*

Include a section that: *if you decide to withdraw, you may have a conversation with the study team to discuss your preferences in terms of your study data / samples disposition.*

**17.** **Can I be asked to leave the study?**

*Describe under what circumstances the study investigator would take the participant off the study, e.g. the study may be stopped by the sponsor, regulatory agency or Research Ethics Board if knowledge of any unexpected or unexplained serious adverse events that affect participant safety become known.*

*Include any specific instructions to the participant regarding what they need to do should they be withdrawn from the study.*

**18.** **How will my taking part in this study be kept confidential?**

*Procedures for coding participant information that are different from the required wording below (e.g., use of participants’ initials, PHN, etc.), and any related consent wording changes, will need to be explained and justified to the REB on the application.*

*If there is planned disclosure of personal identifiers (e.g. names, date of birth, or initials) outside the local study site, or if such personal identifiers are used on study documents or any research-related information or are part of the unique identifier, this must be justified to the REB on the application and, if permitted, the required wording below must be amended as necessary.*

*Placement of any research data or results in the participant’s health records must be disclosed to participants, and justified to the REB on the application.*

*Include what will happen to your data in terms of open access in the confidentiality section.*

**If data is being transferred out of Canada**

*Include the following information if data is being transferred out of Canada.*

1. *The participant information that will be sent outside of Canada.*
2. *A description of the coding of the data, if different from the coding described elsewhere in the consent form.*
3. *To whom the information will be sent (e.g. individuals, organizations, regulatory agencies).*
4. *Where the information will be sent (e.g. USA, UK, Australia).*

**Use of websites and/or third party applications:**

*If your study is collecting participant email addresses or other personally identifiable information, this needs to be disclosed. For example, if the participant is required to log in to a study website to create an account, clarify whether the website will be tracking the participant’s IP address, and ensure this is explicitly stated in the consent form.*

*The access to, or collection of, third party personal information without consent, and from a location outside of Canada, can be a concern. When using applications that have an option to access third party data (for example, Fitbit), please confirm whether the access to third party data by Fitbit can be disabled or turned off.*

*Participants should also be made aware of the privacy policies for the application or website in question. If data will be retained indefinitely by these organizations, or the study sponsor, this must be clearly outlined in the consent form.*

**Reportable Diseases**

*Disclose to participants if positive tests for communicable diseases are reportable to provincial health authorities (e.g. hepatitis B or C,* Human immunodeficiency virus *(HIV), West Nile virus, etc.).*

*Insert examples of any foreseeable instances where such reporting of communicable diseases may be required.*

*See* [*LIST OF REPORTABLE COMMUNICABLE DISEASES IN BC*](http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/Other/Epid_Guidelines_reportable_diseases_British_Columbia_July2009.pdf)

**19.** **What happens if something goes wrong?**

*If the person signing consent is doing so on behalf of a participant who lacks capacity add, “or the participant’s” after “any of your.”*

*The study sponsor must be prepared to cover the cost of medical treatment required for illness or injury as a result of the research if patient is uninsured.*

*As per ICH GCP* ***4.8.4****None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject’s legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.*

*The U.S. FDA also does not allow the use of exculpatory language through which the participant is made to waive or appear to waive any of their legal rights, or which releases or appears to release the investigator, sponsor or instigation from liability for negligence is not permitted on the consent form.*

*The name of the Sponsor is not necessary for non-regulated studies or unfunded studies.*

*For the definition of “Sponsor” refer to* [*ICH Good Clinical Practice Guidelines (ICH GCPs), article 1.53*](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a1.53)*.*

**20.** **What will the study cost me?**

*When applicable, begin this section with a general statement that research-related care and treatment will be provided at no cost to the participant.*

**Reimbursement**

*Stipulate whether the participant will incur any personal expenses as a result of participation.*

*State whether their expenses will be reimbursed, which expenses, and how they should claim for reimbursement. Otherwise, provide an explicit statement that there will be no reimbursement for study related expenses, if that is the case.*

*Researchers are encouraged to cover participants’ expenses such as parking, meals, travel, supportive care medications or other incidental costs over and above those needed for standard care they would not otherwise have been required to purchase. Include whether the participant is required to provide receipts.*

**Remuneration**

*State whether the participant will be paid for their participation (e.g. “You will not be paid for participating”).*

*If participants will be paid for participation, include the details of any honoraria/incentives to be provided.*

*For studies providing remuneration of $500 or more in one year, please check with your institution’s finance department to clarify whether they will need the participant’s Social Insurance Number to issue a T4. If so, disclose in the consent form. Please consult with your local Health Authority for guidance.*

*Such payments must not be weighted toward the end of the study, as an incentive to complete participation.*

*State that payments will be pro-rated if the participant withdraws from the study.*

**22.** **Signatures**

*This section of the consent form should start on a new page and include the full study title.*

*The participant is signing the form to indicate that he/she has read, understood and appreciates the information concerning the study. As such, use the first person pronoun (“I”) for this section.*

*Include a checklist of the issues most critical to making an informed decision.*

*Ensure that the checklist fits on the page with the signatures of the participants. The signatures should never be on a page by themselves.*

*Provide a copy of the signed and dated consent form to the participant.*

*Where third party consent is being obtained and participants have capacity to assent/dissent: refer to the local REB guidance notes (links in* [*Appendix I*](#Appendix_I)*) for clarification of assent policies and guidelines.*

**Use of Translators/Witnesses:**

*(This wording should be used* ***only when applicable****)*

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was the participant assisted during the consent process in one of ways listed below?

□ Yes □ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check “no”.]

If yes, please check the relevant box and complete the signature space below:

□ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read ).

□ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

 Signature of Person Assisting Printed Name Date

 in the Consent Discussion

**Witness Signature**

*Optional, except where an oral consent is necessary such as when the participant is illiterate or blind, or disabled, or for cultural reasons so that they either cannot or will not sign the consent form. In such circumstances, the witness must be independent of the Principal Investigator or designate. For blind or illiterate participants, an REB approved summary of what is to be said to the participant or his or her authorized representative must be signed by both the person providing the consent and the witness. In such circumstances, the signature of the witness is intended to attest to the fact, and to state, that what is included in the summary was actually said to the participant or legally authorized representative.*