BC Clinical Research Informed Consent Form Guide and Template

How to use this document

This document is intended to assist investigators in producing consent forms that meet the requirements of the following UBC-affiliated and BC regional health authority REBs/RRC:

- BC Cancer Agency REB
- Children's & Women's REB
- Providence Health Care REB
- UBC Clinical REB (CREB)
- Fraser Health REB
- Interior Health REB
- Northern Health Research Review Committee (not currently a constituted REB)
- Vancouver Island Health Authority Clinical REB

Adherence to these guidelines may not be sufficient, however, and investigators should also refer to the guidance notes and policies of the individual REBs (see Appendix I).
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 for amendment.

The appendices provide more detail on specific aspects of the consent form creation.
Appendix I includes links to REB guidance notes, policies, and forms.
Appendix II includes general style and formatting guidelines.
Appendix III includes general directions to those responsible for obtaining consent.

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 is highlighted in yellow.
3. Recommended wording is in regular font.
4. Instructions are provided in *italics*.
5. Once you have completed your draft:
    a. Delete all italic content
    b. Remove colour highlighting from the remaining text
    c. Finalize the footers and remove the headers.
    d. Remove template appendices
6. Consent forms must be saved on the appropriate letterhead, as follows:
    a. BCCA REB requires BCCA letterhead.
    b. C&W REB requires UBC and/or Hospital/Program Department letterhead.
    c. PHC REB requires UBC and Providence Health Care/Providence Clinic Letterhead.

d. UBC CREB requires UBC Department letterhead or VCH or VCHRI letterhead, if appropriate.
e. FH REB requires Fraser Health Authority letterhead.
f. 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.
g. NH prefers not to have its logo on the letterhead; the consent form should be on the principal investigator's institutional letterhead.
h. VIHA REB requires VIHA letterhead.

Consent Form Elements

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

Title of study
Principal investigator, co-investigator, sponsor, emergency contact

1. Invitation
2. Your participation is voluntary
3. Who is conducting the study? (includes conflict of interest disclosure)
4. Background
5. What is the purpose of the study?
6. Who can participate in this study?
7. Who should not participate in the study?
8. What does the study involve?
9. What are my responsibilities?
10. What are the possible harms and discomforts?
11. What are the potential benefits of participating?
12. What are the alternatives to the study treatment?
13. What if new information becomes available that may affect my decision to participate?
14. What happens if I decide to withdraw my consent to participate?
15. Can I be asked to leave the study?
16. How will my taking part in this study be kept confidential?
17. What happens if something goes wrong?
18. What will the study cost me?
19. Who do I contact if I have questions about the study during my participation?
20. Who do I contact if I have any questions or concerns about my rights as a participant?
21. After the study is finished
22. Signatures

Appendix I – Links to REB Guidance Notes, Policies, and Forms
Appendix II – General Style and Formatting Guidelines
Appendix III – General Directions to those Responsible for Obtaining Consent

Template content and instructions begin on the next page.

Participant [Subject] Information and Consent Form

An individual *recruited into a study should be referred to as the "participant." "Subject" may be used, but "participant" is preferred in TCPS2 (see chapter 2.A.).*

The chosen *term must be used consistently throughout the document, including in the Title of Study.*

[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.*

Study personnel
For BCCA and VIHA REB:
Principal Investigator must be identified.
One lead Principal Investigator for each additional participating BCCA or VIHA centre must be identified.
Co-Investigators are not required to be listed.
For IH REB: All co-investigators must be listed.
All other REBs require at least the PI to be included; listing other study personnel is optional.

Principal Investigator:	[insert name, degrees held] [insert UBC/PHC/CW/BCCA/IHA/NHA/VIHA Department] [insert institution/centre] [insert contact phone number(s)]
Co-Investigator(s):	[insert name(s), degrees held] [insert UBC/PHC/CW/IHA/NHA/VIHA Department] [insert institution/centre] [insert contact phone number(s)]
Sponsors:	[insert names of all sponsors, granting agencies, and 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.*

***Required wording for BCCA REB**. Note that the researcher is responsible for ensuring that emergency numbers are provided and correct. For non-emergency contact numbers, insert the appropriate contact information from Sections 19 and 20 (Who do I contact…?).*

For emergencies only: Call the centre nearest you and ask for your study doctor or, if he or she is not available, ask for your usual oncologist or the oncologist on-call.

Vancouver Centre	(604) 877-6000
Vancouver Island Centre	(250) 370-8000
Fraser Valley Centre	(604) 581-2211
Abbotsford Centre	(604) 851-4700
Centre for the Southern Interior	(250) 862-4000
Centre for the North (Prince George)	(250) 645-7300

For non-emergency contact numbers: [insert contact numbers].

***For pediatric studies**: Place the following bolded 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**: Place the following bolded text above the Invitation.*

If you are a substitute decision-maker for someone who may take part in this study, permission from you and the agreement and the assent (agreement) of the potential research participant may be required. When we say "you" or "your" in this consent form, we mean the research participant; "we" means the doctors and other research staff.

1. Invitation

***Describe** the characteristics of the sample population that are important for the study, e.g. you have been diagnosed with high blood pressure.*

Recommended Text

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

2. 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?*

Recommended Text

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 services to 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.

If you wish to participate in this study, you will be asked to sign this form.

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

3. 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.*

Recommended Text

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.

BCCA REB conflict of interest statement is required if applicable.

The sponsors of this study may reimburse the BC Cancer Agency for all or part of the costs of conducting this study or they may provide the BC Cancer Agency some or all of the standard or experimental medications being used in this study. However, neither the BC Cancer Agency nor any of the investigators or staff conducting this study will receive any personal payments for conducting this study.

For all other REBs, the conflict of interest statement is required if applicable.

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 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 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.

4. Background

The background *section should be different from the "purpose" section below that will describe the specific goals of the study.*

Provide *a brief explanation of why the research is being done (explain the basis for the experimental intervention) so that the participant can understand why a particular health problem/intervention needs to be studied.*

Include *non-technical information on the prevalence or incidence of a disease, the problems associated with a disease, the poor outcomes for other treatment methods, previous studies, etc.*

This section *must include the standard/usual treatment(s) or care for participants who are eligible for this study and the likelihood of the known therapeutic effect and the duration of that effect, so that the participant can compare this to what is being proposed in the study.*

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

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*

For drug *or device studies, include the following Health Canada information, modified as necessary.*

Recommended Text

Health Canada has not approved the sale or use of [insert study drug/device] 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] 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.

5. 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) of this research project. The goal statement should specify 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.*

***Refer** to the TCPS2 Chapter 11 for information on clinical trial phases.*

[Insert goal statement]

For a pilot or feasibility study
***For BCCA** REB applications, please also follow the guidelines in the document "Elements Required for a Pilot or Feasibility Study.pdf" also posted on the BCCA REB webpage for New Applications.*

Recommended Text

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 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. Knowledge gained from pilot or feasibility studies may be used to develop future studies that may benefit others.

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.*

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.

For Expanded Access Protocols (EAP): See BCCA REB guidelines posted on the web page for New Applications.

6. 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.*

Recommended Text

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

- [insert criteria]

7. 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.*

Recommended Text

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

- [insert criteria]

***Required wording** for PHC REB studies (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.

8. 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.*

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

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 NOT millilitres).*
- ***Charts*** *are often helpful to summarize procedures and time commitments, especially for complex or long-term studies.*

Recommended Text

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.

Sub-Headings
If there *is more than one part to the screening visit, use sub-headings for each.*

Screening Visit/Initial Visit/Before You Begin the Study
[insert details]

Randomization Visit
[insert details]

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

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.*

See also *local REB Guidance Notes (links in Appendix I).*

Optional Studies

A separate section should be used to explain briefly about the availability of any optional studies that are not part of the main study and for which separate consent must be obtained, for example, 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.

Recommended Text

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

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.*

For BCCA *REB studies – see BCCA REB Interim Guidance on Mandatory Consent for Tissue Acquisition in Clinical Trials*

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.*

9. What are my responsibilities?

This section should list and specify any requirements of the study that the participant must comply with in order to participate, but avoid language of a contractual or legal nature. This may include requesting that the participant contact their research doctor before taking any medication other than the study drug. Avoid placing redundant information in this section. For example, if birth control

responsibilities are described elsewhere in the consent, they do not need to be repeated in detail here, although a brief reminder "to avoid pregnancy" may be included.

- [insert list]
-

10. 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.*

Disclose *all known risks and discomforts associated with study procedures, including social and psychological risks/discomforts, risks to others, reproductive risks (see recommended wording below), genetic risks (see required wording below), 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.*

Quantify *the risks/discomforts in percentages, or use an appropriate numerical estimate, wherever possible. Arrange by groups of likelihood. For example: "Very Common (approximately 50% or greater)…Common (20-50%)…Less Common (5-20%) Uncommon (2-5%)…Rare (less than approximately 1%-2%)…."*

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 *the role of any data safety monitoring board or committee (i.e., explain that an independent group of experts will be reviewing the data for safety at intervals throughout 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).*

For FH REB *format for inclusion of risk information see FH REB's Guidance notes for Initial Ethical Review Section #13, Harms.*

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.

Recommended Text

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.

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.

Recommended Text

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*** *if applicable. Disclose other genetic risks as applicable to the study.*

In addition to the risks of physical harms outlined in this consent form, there are also possible non-physical risks associated with taking part in this study. For example, disclosure of genetic or tissue marker research data could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. The chance that research data would be released is estimated to be small.

11. 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.*

Recommended Text

No one knows whether or not you will benefit from this study. There may or may not be direct benefits 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.

12. 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).*

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.*

Recommended Text

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:

- [Insert]
-

  If applicable, include in the list of alternatives:

- 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.

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

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

Insert required text if applicable.

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.

14. 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.*

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.*

Explain *that the investigator will retain any data collected up to the point of the participant's withdrawal from the study, such that the data itself cannot be withdrawn.*

For doubleblind *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.*

Recommended Text

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 data collected about you during your enrolment in the study will be retained for analysis. It is a legal requirement that these data cannot be destroyed [for Health Canada regulated or US federally funded research only]. If your participation in this study includes enrolling in any optional studies, you will be asked whether you wish to withdraw from these as well.

15. 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 or regulatory agency 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.*

Recommended Text

If you are not able to follow the requirements of the study or for any other reason, the study doctor may withdraw you from the study and will arrange for your care to continue. On receiving new information about the treatment, your research doctor might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health. 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.

16. 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.*

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 his or her designate by representatives of [insert here, if relevant, the name of the sponsoring company or cooperative group conducting the study,] 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 insure 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 above:

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

US FDA Regulated Study

For US FDA*-regulated studies only, include the following wording in separate paragraphs. The first paragraph is mandatory US FDA wording and cannot be amended.*

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.

Recommended Text

Because this study also falls under U.S. regulation, in the event of certain types of investigations of the study the U.S. Food and Drug Administration (US FDA) may need to copy and take away records that contain your personal information. By signing this consent form you are agreeing to this. In the event that this occurs, the study doctor will attempt to notify you. You should be aware that privacy protections of personal information may differ in other countries. Any study related data (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 personal information (for example the Patriot Act in the United States) may not be as strict as in Canada.

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).*

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, [insert (for e.g.) the Patriot Act in the United States] 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.

- [Insert organization/s]
-

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 BCCDC List of Reportable Diseases

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.

- [Insert example/s]
-

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

For BCCA REB and VIHA REB insert a statement in the consent that as a part of the study requirements the investigator will notify the participant's GP of the participant's participation in the study.

Your family physician will be notified of your participation in the study so that your study doctor and your family doctor can provide proper medical care.

For all other REBs, include the following (optional) notification section. This component cannot be used for BCCA REB or VIHA 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 applicable, collection of data on demographic features such as race/ethnicity, birthplace, gender, and sexual orientation must be justified in the ethics application and the reason for the collection

explained to participants and that providing this information is voluntary. (Note that the UBC Behavioural REB guidance notes may be helpful; see Sections 5.2 and 6.3.)

Recommended Text

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary.

17. 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.*

***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.

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].

Recommended text

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].

18. 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.*

Recommended Text

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

> ***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.*

[insert details]

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.*
>
> ***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.*

[insert details]

19. Who do I contact if I have questions about the study during my participation?

Recommended Text

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.

***BCCA REB** required wording*
For the Head of Program contact information, include only the telephone number of the applicable main switchboard, do not include this person's name or telephone extension.

In the event of a research related injury, please speak to your doctor (indicated above) or (after hours) call the BCCA centre nearest you and ask for your study doctor or, if he or she is not available, your usual oncologist or the oncologist on call.

Or, you can speak to the doctor who is the principal investigator, [insert name of PI] at (xxx) xxx-xxxx ext. xxxx.

Or, you can speak to the Head of [insert program name, e.g. the Systemic Therapy or Radiation Therapy] Program of the BC Cancer Agency. That person can be reached at (xxx) xxx-xxxx.

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

For UBC-affiliated REBs (BCCA REB, C&W REB, PHC REB, UBC CREB)

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).

For FH REB

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact Dr. Anton Grunfeld and/or Dr. Allan Belzberg, Research Ethics Board [REB] co-Chairs by calling 604-587-4681. You may discuss these rights with the co-chairmen of the Fraser Health REB.

For IH REB

If you have any concerns about your rights as a research participant and/or your experiences while participating in the study, we would be interested in hearing from you. Please feel free to contact the Chair of the Interior Health Research Ethics Board at (250) 870-4602 with your concerns.

For VIHA REB

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, or if you wish to verify the ethical approval of this study, you

may contact Karen Medler, Research Ethics Coordinator, or Dr. Marie-Térèse Little, Chair of the Clinical Research Ethics Board for the Vancouver Island Health Authority (250-370-8620).

21. 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.*

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.*

Recommended Text

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.

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.

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.*

Required *and suggested checklist items appear below.*

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) for clarification of assent policies and guidelines.*

[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 authorize access to my health records [insert if applicable 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.
- 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.]

Required wording *where participants who lack capacity are capable of assent.*

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in the research.

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

I consent to participate in this study.

"Participant's Signature" should be replaced with "Participant's or Substitute Decision-maker's Signature" if third party consent may be obtained from a legally authorized representative.

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date

***Where** applicable include the following elements:*

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 in the Consent Discussion	Printed Name	Date

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.

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.

Appendix I

Links to REB sites providing guidance notes, policies, and/or forms for UBC-affiliated and BC regional health authority REBs/RRC

UBC-affiliated Clinical REBs

- BC Cancer Agency REB (BCCA REB)
- Children's & Women's REB (C&W REB)
- Providence Health Care REB (PHC REB)
- Clinical REB (CREB)

Fraser Health REB (FH REB)

Interior Health REB (IH REB)

Northern Health Research Review Committee (NH RRC)

Vancouver Island Health Authority REB (VIHA REB)

Appendix II

General style and formatting guidelines for consent forms

1. Consent forms should be written at a Grade 7 level of understanding.
   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.
2. Type size: no smaller than the type on this page (12 point).
3. Improve readability by using headings, short paragraphs, and spaces between paragraphs.
4. 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/
5. 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).
6. Number the pages in the following manner: "1 of 3", "2 of 3", "3 of 3," etc.
7. 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.
8. All information required by the participant must be included in the informed consent form, with the exception of ancillary drug information sheets, if applicable.
9. The consent form submitted for review should be in its final form and on letterhead (as it will be seen by the participant).
10. Spelling, grammar and formatting must be corrected before submission to the REB.
11. 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.
12. References to "doctor" should be clarified to identify who is being referred to, e.g., the family doctor, study doctor, oncologist.

Appendix III

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.

2. 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.

3. 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.

4. A translator/interpreter should be a PHSA/BCCA 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 site.