

**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. 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).

4. 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.

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

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

7. Please delete all blue text as you draft your consent document. Blue text is intended to give further direction to researchers only (not participants).

8. Note that some of the text in this document is locked. This is because it is considered standard wording and should not be amended/altered by researchers.

**Participant Information and Consent Form**

**[Insert Title of Study]** *Note that this must match RISe (Box 1.7)*

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

 [insert primary department]

 [insert institution/centre]

 [insert contact phone number(s)]

*\*Note that you are not required to list Co-Investigators, but should you choose to the list must match RISe, Box 1.3*

*If applicable, sponsor/funder must be listed on the first page (and must match view 2 of the application:*

**Sponsor(s)/ Funder:** [insert sponsor/funder]

Study Contact Number: [insert the appropriate contact person and their number]

**Invitation**

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

**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.

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.

**Who is conducting this study?***Choose the relevant option, note this must be consistent with the funding outlined in view 2 of the application.*

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.

*OR (required wording for industry sponsored/for-profit 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 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.

**Background**

*Insert a brief background (2-3 short paragraphs at most) about the study in lay language (Grade 7 reading level recommended*)

*Include total number of participants to be recruited to this study and at this site (if different). Must match the enrollment numbers entered in 7.2 of the application.*

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

*Insert a description of the study goal(s), written in lay language for participants*

**Who can participate in this study?**

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

* *Insert a bullet point list of 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*
* *Remember to enter it as lay language (Grade 7). Avoid technical or medical jargon* for *participants from the general population.*

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

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

* *Insert a bullet point list of 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*
* *Do not repeat criteria already listed above*

**What does the study involve?**

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

* **Study Visits**

*Insert a description of what will occur at each visit and the time requirements for each visit. Do not include descriptions of procedures that are not being performed for research purposes (i.e., standard of care). As in all other areas of the consent, this must be written in lay language (explain any medical or research jargon or replace with lay language equivalents)*

*IF you have a complex study, please spend some time organizing this information in a way that is meaningful for potential participants. Some additional tips:*

*- Use small paragraphs and short sentences. Spaces between paragraphs/bullet points are a helpful way to break up dense sections of text.*

*- Whenever possible, replace technical/medical jargon with a lay language equivalent (always much easier for participants to read)*

*- Similar visits can be grouped together when helpful to do so*

*- Repeated procedures do not need to be described each time (first time only)*

*- Study tables can also be useful, but should be simplified as much as possible and written in lay language (rows/columns)*

*IF your study involves questionnaires or interviews, include specific examples of questions that will be asked so that participants have a clear sense of what to expect.*

*IF your study includes the collection of blood samples clarify for subjects:*

*- How much blood will be taken (list in mL and teaspoons/tablespoons)*

*- Brief lay language description of how their blood sample will be used*

*- Where the blood sample will be stored and who will be in charge of it*

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

*Sample wording:*

-There are no known risks for this study.

-You do not have to answer any questions that you are uncomfortable answering.

-The risks of blood draw include pain and/or discomfort, bruising, fainting and/or light-headedness, and the rare possibility of infection.

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

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].

*For studies requiring registration with ClinicalTrials.gov, include the following wording:*

**After the study is finished**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

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

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, you have the right to request the withdrawal of your information [and/or your samples] collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data 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 the principal investigator of the study know.

**How will my taking part in this study be kept confidential?** *This is required wording for all clinical research conducted in BC and has therefore been locked.*

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 the UBC Providence Health Care Research Ethics Board [and (name of sponsor if relevant)] 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 the study team.

*IF data is being transferred out of Canada, include the following required 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]

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

**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.

* Positive results on [list the reportable disease: for e.g., HIV, Hepatitis B and C] testing will be reported.

*Include the following wording IF your study will ask participants to provide their race/ethnicity (note this should also be justified in 8.4.B of the application):*

**Disclosure of Race/Ethnicity**

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/treatments/insert as appropriate]. You should be aware that providing this information is not mandatory.

**What happens if something goes wrong?** *\*****IF*** *this study does not involve any possibility of illness/physical injury, include ONLY the first sentence (otherwise this paragraph is considered required wording)*

By signing this form, you do not give up any of your legal rights and you do not release the principal investigator, 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)].

**What will the study cost me?**

All research-related procedures 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. This must match the application (Box 6.5.A)*

**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. This must match the application (Box 6.5.B)*

**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]

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

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.

**[page break]** *\*Signatures must begin at the top of a new page*

**Signatures**

**[Insert Title of Study]** *Note that this must match RISe (Box 1.7)*

**Participant Consent**

My signature on this consent form means:

* I have read and understood the information in this consent form.
* I have been able 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.
* 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.

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

* I authorize access to my health records **[**and samples**]** 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

**Additional consent sections which may be applicable:**

1. **Open Access:**

*\*Researchers may be required to make their data publicly available at the time of publication. Please see the guidance notes for full details and note that if data will be made available this needs to be disclosed in the consent form:* [*https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes/guidance-notes-behavioural-applications*](https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes/guidance-notes-behavioural-applications) *(see section 8.6: Future Use of Data).*

If the above is applicable, here is a list of the necessary 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 publicly 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 publicly available, the participant will not be able to withdraw their data.*

2. **Use of Translators/Witnesses:**

*This wording should be used* ***only when applicable*** *(i.e., if provisions for consent have been outlined in Box 6.11):*

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