**Clinical Informed Consent Form Template For Biobank/Registry Study at UBC**

\*\*Before you begin

* Required wording is highlighted in yellow.
* If applicable to your study, required wording is highlighted in blue otherwise remove the blue text.
* *Italicised text are instructions to researchers*
* Amend text in square brackets [ ]
* Consent forms should be written at a reading level appropriate for the target audience.
* For participants from the general population:
	+ **Grade 7 reading** level
	+ Use plain language; explain medical terms and jargon. Use non-scientific terminology.
	+ For assistance with lay language substitutes, see <http://info.cancer.ca/glossary/>
* Text size: no smaller than 12 point.
* Acronyms should be avoided. **No more than 3** and if used, write it out at first use.
	+ e.g., Peculiar Acronym for General Use (PAGU).
* Once you have completed your draft:
	+ Delete this instruction page, all italic text, square brackets [ ], and delete comments.
	+ Remove colour highlighting from text
* Use second person pronouns (“you”/”your”) throughout the form except the signature page where you use first person pronoun (“I”).

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

1. Sample wording is in regular font.
2. Improve readability by using headings, short paragraphs, and spaces between paragraphs.
3. Number the pages in the following manner: “1 of 3”, “2 of 3”, “3 of 3,” etc.
4. Spelling, grammar and formatting must be corrected before submission to the REB.

\*\* Please enter your study number in the footer. This can be found in the RISe application↓

**[🡪Insert Institutional logo(s)]**

**Participant Information and Consent Form**

**1. [🡪Insert Title of Study-*must match RISe box 1.7*]**

**2. Study personnel**

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

 *[insert primary department]*

 *[insert institution/centre]*

 *[insert contact phone number(s)]*

**Sponsor(s) / Funder:**

Study Contact Number:

***(If applicable) For pediatric******studies*** *: Please also see assent templates* [*here*](https://ethics.research.ubc.ca/clinical-research-ethics/creb-forms-templates) *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.

**3. Invitation**

You are being invited to take part in this research study because\_\_\_\_\_\_\_\_\_\_\_

**4. 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.

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

This study is being conducted/sponsored by the \_\_\_\_\_\_\_ [*Insert name of research group/ sponsor/granting agency]*

*OR:*

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

OR:

*If applicable, The following conflict of interest statement is* ***required for Industry-sponsored (eg. Pharmaceutical company) studies:***

The Principal Investigator **[insert if applicable text:** “study personnel and/or \_\_\_\_\_\_institution”***]*** has received financial compensation from the sponsor \_\_\_\_\_\_***[insert 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.

**6. Background**

*Insert a brief background (2-3 short paragraph max) about the study in lay language (Grade 7 for the general population*)*.*

*-Amend blue text*

It is increasingly common for researchers to invite participants to bank their data and samples for use in future research studies. Often the exact nature of these studies is not entirely known because of new discoveries lead research in new and not always foreseen directions. For this reason, participants are asked to consider storing the data and samples into a registry (ie, databank) /biobank for future studies that are as yet undetermined.

If in the future, other researchers not involved in this study request your information, they may be given access only to the coded data and/or samples but they will not know your identity. All future studies will also need to get proper research ethics approval to be allowed access to the registry/biobank.”

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

*Describe the study goal(s) in (\*note this should be lay language for participants from the general population)*.

The purpose is to create a registry/biobank, a collection of data and samples for future research purposes.

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

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

* *[insert inclusion criteria the potential participant is likely to be aware of]*
* *[List* ***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.

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

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]*
* Do not repeat criteria already listed in section 8.

**10. 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:

*[Insert time requirements for each 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.*

**Registry/ Biobank specific information that should be included:**

1. State the entity or person who have custodianship of the data and the location of the registry

2. Who will have access to the registry (including access to personal information maintained there)

3. Whether the registry will be used for commercial purposes

4. Who the registry data/samples (de-identified) will be shared with

5. The length of time data/samples will be kept

6. For Biobanks only: The researcher’s plan for handling results and findings, including clinically relevant information and incidental findings.

**11. 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.

Genetic analysis samples wording if applicable:

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 recently passed 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.

**12. 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.

**13. After the study is finished**

*Indicate what results or reports will be provided to participants if applicable.*

**14. 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.

OR For US FDA or Health Canada regulated studies:

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).

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

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 UBC’s Clinical Research Ethics Board and [***🡪insert here, if relevant, the name of the sponsoring company conducting the study, or Health Canada or US FDA],***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.

*For U.S. Regulated Studies:*

*Include the following wording if your study falls under U.S. Regulations:*

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 research 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) may not be as strict as in Canada.

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.

**If data/samples are being transferred out of Canada:**

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

**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 on *[🡪 list the reportable disease*: for eg, HIV, Hepatitis B and C] testing will be reported.

**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. You should be aware that providing this information is not mandatory.

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

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]***.

**17. 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.*

**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.*

**18. 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]***

**19. 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.)

**20. Signatures**

***[🡪Insert full Study title- 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

**Future Contact**

Are you interested in learning about other studies conducted by Dr. \_\_\_\_\_\_\_ in the future?

□ Yes □ No Initials\_\_\_\_\_\_\_\_\_\_\_

Note that for any future studies, a separate consent form will be provided to you for review.

*Include the below Only when applicable:*

**Witness Signature\_**

Witness Signature Printed name Date

*Include the below only when applicable*

**Parent/Guardian Consent:**

This consent form was read by the parent(s)/guardian(s), 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]/[Guardian’s] Signature Printed name Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Person Printed name Study Role Date

 Obtaining Consent

*Include the below only when applicable*

**Use of Translators**

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

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.

□ The person signing below acted as an interpreter/translator for the participant, during the consent process.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Person Assisting Printed Name Date

 in the Consent Discussion