Instructions for Informed Consent Form Development

The informed consent form (ICF) is one component of the informed consent process. Further guidance may be found in the HREB Guidelines for Consent for Research found under the Attachments tab in the Researcher Portal.

Brief instructions to consent authors are highlighted in this colour and/or [enclosed in square brackets]. This text should be removed prior to REB submission, i.e. not included in the consent form for participants.

Edit the text examples as necessary to make the language specific to the study question since many statements throughout the template are generic.

Examples are not given for every study situation. Consent authors should review all examples in a section, even if the example is for a different study type, to identify language that may apply to their study.

Participant Study Calendars: Consider providing an easy-to-read-and- understandable participant study calendar. A participant study calendar may be included as an appendix or included in the main consent document.

Eliminate repetitive information.

Define all acronyms when they first appear and limit their use.

Use the term ‘study doctor’ when referring to physicians involved in the clinical trial, to ensure there is no confusion with the treating or primary care doctors.

Please delete this instruction page from the consent forms prior to REB submission.

Insert Letterhead

Optional Study Consent Form

TITLE: Consent for Optional [Storage of Samples Biobanking/Biomarker/Genetic Research] for patients taking part in [lay title of main study].

PROTOCOL TITLE: Protocol [number]. [Full protocol title of main study]

STUDY DOCTOR (S): Phone Number:

In addition to the main study, you are being invited to take part in optional research. Taking part in (this optional study / these optional studies) is voluntary. You may choose to take part or you may choose not to take part in (this study / these studies). You may also change your mind at any time. If you choose to not to take part in (this optional study / these optional studies), you can still take part in the main study. Whatever you choose it will not affect your usual care and you will not lose any benefits to which you are entitled.

This consent form has important information to help you make your choice. It may use words that you do not understand. Please ask the study staff to explain anything that you do not understand. It is important that you have as much information as you need and that all your questions are answered. Please take as much time as you need to think about your decision to participate or not, and ask questions about anything that is not clear. You may find it helpful to discuss it with your friends and family. The study staff will tell you about the study timelines for making your decision.

1. What is the purpose of this study:

Edit/remove/add bullets as applicable for protocol (this is not an exhaustive list):
The researchers doing this study are interested in doing the following:

- Biomarker research for the main study using (*specimen e.g. tumor tissue / blood*) already collected
- Biomarker research for the main study using fresh *(specimen e.g. tumor tissue/ blood sample)*
- Genetic research for the main study using *(specimen)* already collected
- Genetic research for the main study using fresh *(specimen)*
- Bio-banking for use in future research using *(specimen)* already collected
- Bio-banking for use in future research using fresh *(specimen)*
- Completing questionnaires on your quality of life

This optional research will be described below.

Explain the purpose of the optional research, in lay terminology. Specify the types of samples to be used for each purpose (if applicable). Suggestions are provided.

Suggestion for biomarker research (protocol specific):
The researchers doing the main study are interested in examining your [specimen] to look for any biomarkers (small "signature" molecules or indicators) in your [specimen]. These biomarkers might

help predict which patients are most likely to be affected by the study drug. This is called biomarker research. No genetic testing will be done on this sample.

Suggestion for genetic research: This study will involve genetic research. Genetic research is a way for us to learn about the role of genes in human health and disease. Every person has their own unique set of genes, or "genome". Genes, which you inherit from your parents, are responsible for determining some of our individual traits, such as eye colour, height and skin tone. Genes may also determine why people get certain diseases and how medicines may affect them. Genes can affect how well you respond to certain types of treatment.

Genes are made up of DNA which are tiny packets of information that contain the instructions for how our bodies develop. The sequence of your DNA forms the blueprint of you. The DNA sequence of a gene can vary slightly between people. These differences in DNA sequence are called variants. These variants may or may not be harmful. We are continuing to learn new information about genes.

The researchers doing the main study are interested in examining the genes (DNA) found in your [specimen]. Please describe the type of genetic test (e.g. whole genome sequencing/whole exome sequencing/ a single gene panel test. Explain the genetic test and what the test will produce. Include any commercial uses (including when these may occur), and whether participants will receive reports. If applicable, will results be put in their health records and/or reported to participant's physician. As well, information re hereditary genetic testing, if applicable.

Suggestion for biobanking:
If you choose to take part in this optional study, [specimen] will be collected and stored for future research studies. This is called "biobanking." The biobank is being run by [insert name] in [insert location of biobank].

We don't know what research may be done in the future using your stored [specimen]. This means that: [Select from list below and adapt as appropriate]

- You will not be asked if you agree to take part in the future research studies. Your study doctor may not have any involvement in the research that is done on your samples.
- Researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.
- Any future research would require the approval of [approval body].
- Future research may include examining the genes (DNA) found in your [specimen]. Genetic research is a way for us to learn about the role of genes in human health and disease. Every person has their own unique set of genes, or "genome". Genes, which you inherit from your parents, are responsible for determining some of our individual traits, such as eye colour, height and skin tone. Genes may also determine why people get certain diseases and how medicines may affect them. Genes can affect how well you respond to certain types of treatment.

  Genes are made up of DNA which are tiny packets of information that contain the instructions for how our bodies develop. The sequence of your DNA forms the blueprint of you. The DNA sequence of a gene can vary slightly between people. These differences in DNA sequence are

called variants. These variants may or may not be harmful. We are continuing to learn new information about genes.

The researchers doing the main study are interested in examining the genes (DNA) found in your [specimen]. Please describe the type of genetic test (e.g. whole genome sequencing/whole exome sequencing/ a single gene panel test. Explain the genetic test and what the test will produce. Include any commercial uses (including when these may occur), and whether participants will receive reports. If applicable, will results be put in their health records and/or reported to participant's physician. As well, information re hereditary genetic testing, if applicable.

Include if relevant: Also, any health-related information will be linked and stored for future use in [insert location] such as your response to treatment, results of study tests, and medicines you took.

Suggestion for Questionnaires:
The researchers doing this study are interested in understanding how your treatment and illness affects [briefly state topic, e.g., your physical and emotional well-being].

2. What is involved in this optional [specimen] collection?

Explain the process for collection of samples, including whether the samples have been previously collected or will be freshly taken. If samples are being collected for multiple purposes, insert appropriate headers that can be used throughout the document (e.g. 1. Tissue samples, and 2. Blood samples; or 1. Biomarkers and 2. Biobanking):

See suggestions below. Edit as required.

If you agree to take part:
For previously removed tumour samples:

- the samples will be taken your tumor that has already been removed by biopsy or surgery. No further surgeries or biopsies are needed for this purpose.

For previously collected samples leftover from the main study:

- the [blood/tumor] samples used will be left over from the main study. No additional procedures are required for this purpose.

For study-specific tumour collection via biopsy:

- the collection of the tumor samples will require that you undergo a biopsy. This is a type of surgical procedure which will remove a piece of your tumour. You would not normally have this biopsy done, it would be done solely for the purpose of this optional research.

For fresh blood samples:
If you agree to take part, blood samples of [about *XX* mL or *YY* teaspoons], in addition to the study-related blood samples, will be taken from a vein with a needle. Whenever possible, these samples will be taken at the same time as your study related tests. Blood samples will be taken [specify timing e.g., before you take the study drug, 1 and 4 weeks after you start the study drug and 4 weeks after you stop the study drug].

For urine samples:
If you agree to take part, you will be asked to provide a urine sample. Urine samples will be collected [specify timing e.g., before you take the study drug, 1 and 4 weeks after you start the study drug and 4 weeks after you stop the study drug].

For questionnaires:
You will be provided with a questionnaire [provide information about the timing of questionnaires e.g., before you begin the study and then every two weeks for a year].
You will be asked to answer questions about [briefly state topic, e.g., your physical and emotional well-being]. Each questionnaire will take about [insert number] minutes to complete. It will ask about things like [briefly describe, e.g., pain, shortness of breath]. You don't have to answer any questions that make you feel uncomfortable.

3. What will happen to my samples?

Describe where samples will be sent, retention period, how they will be stored, and what happens at the end of the retention period (e.g., destroyed, returned). Indicate whether previously collected health information (study data) will be associated with the sample and the retention period and what happens to the data at the end of that period (if different from sample retention). If samples are being collected for multiple purposes, insert appropriate headers that can be used throughout the document (e.g. 1. Tissue samples, and 2. Blood samples; or 1. Biomarkers and 2. Biobanking):

If sending to a biobank, describe who will have access, how access will be obtained, under what conditions access will be granted, and whether data will be sold. Specify if additional information will be collected in addition to or different from the main study data.
Your remaining sample(s) and some related health information already collected from your participation in the main study will be sent to a biobank [in Canada/outside of Canada] and stored. The samples will be kept [specify amount of time, or until they are used up / destroyed or returned to the hospital where you had your surgery or biopsy].

Qualified researchers can submit a request to use the materials stored in the biobank. Your samples and related health information will be used only by researchers whose requests have been accepted by the sponsor/biobank. The samples and data may be sent to other countries. Your name or any other information that could directly identify you will not be given to researchers.

If information is being stored in a public central database, describe and specify the type of information (e.g., genetic and/or health information):
Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Your name or any other information that could directly identify you will not be included.

4. Length of time:

Taking part in this study will not require any added visits. The (specimen) will be collected during one of your regular study visits.

5. Are there risks to taking part in this study?

All potential risks, discomforts and inconveniences of being in the study – physical, emotional, social – should be explained. It is not necessary to include the risks associate with the standard of care/care that the participant will receive if not participating in this study

Examples of risks. Please edit as required.

Risks related to personal health information:

- There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Genetic information is the most identifiable form of information that can be collected from a person, and though the research database will not include your name this does not guarantee that the genetic information we collect from you can't be identified as yours. Recent advances in artificial intelligence (AI) have increased this risk, and, the risk will likely continue to increase in the future as people find new ways of tracing information. The potential future use of genetic information is therefore unknown and so future risks are also unknown.
- There is a risk of unintentional release of information if there is a security breach in the system that stores the data.
- The potential re-identification or unintentional release of your information could lead to loss of privacy and to possible future discrimination against you or your biological relatives.
- The potential psychological and social risks of participating and receiving genomic information are not fully known at this time. It may be upsetting to learn about genetic causes and medically actionable findings. Because parent(s) and children can share genetic variants, the discovery of harmful variants in your genome may lead to identifying the same variants in your family members' genome. It may be upsetting to learn that other members of your family share harmful genetic variants with you.
- Due to the rapid pace of technological advances, the potential future use of genetic information is unknown and therefore the potential future risks also are unknown.
- The potential future use of your [data/sample] is unknown and therefore not all potential future risks are known.
- Because the future use of your [sample/data] is unknown at this time, it may be used for research that you may not have chosen to participate in if asked.

Risks related to sample collection:

Examples:

- The needles used for sample collection might be uncomfortable. You might get a bruise, or rarely, an infection at the site of the needle puncture.
- The risks of a biopsy include (risks).
- Since the tissue sample(s) have already been collected (for the main study or as part of your standard of care), no additional physical risks are expected.

Risk related to future care [if using tumor tissue]

- If you participate in this study, it is possible that not enough tumor tissue will be left for other testing that may need to be done in the future. Please discuss this possibility with your study doctor.

Discomforts related to the use of questionnaires:

- During the questionnaires and/or the interview, you may become uncomfortable or experience some anxiety, emotional and/or psychological distress due to the nature of the questions. You

can skip questions, take a break or stop answering at any time.

- If your responses indicate that there is a serious risk of harm to yourself or others, confidentiality will be broken in order to protect you or another person. If we feel that you need urgent care as result of participating in this research study we will intervene according to routine clinical care practices.

6. What are the possible benefits of participating in this study?

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

If applicable, include: We hope that the information learned from this study can be used in the future to benefit other people with (disease/condition).

7. If I decide to take part in this optional study, can I stop later?

Note: requiring a written notification is not acceptable. It is the study team's responsibility to document the request. Verbal notification is sufficient. Parents/patients should not be asked to go through the additional burden of writing a letter for documentation purposes.
It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from the study will not have any effect on the care you (or your family, if applicable) will receive. If you decide to leave the optional study, you can remain in the main study.

Please describe the process for withdrawal and any limitations to the withdrawal. **You may select an option from the sample language below or edit to suit the study:**

- You may withdraw from this optional study. The study team will have a discussion with you about what will happen to the information about you [and/or your samples] already collected. Your study doctor will notify the sponsor who will ensure that the information/samples are [returned to the hospital from which they were obtained if needed, or destroyed]. You can request withdrawal of your specimens until [insert expected time point], at which point the code that links you to your sample will be removed. It won't be possible to return samples after this because the researchers will not know which sample is yours.
- You have the right to request the destruction of your information [and/or samples] collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

8. What about my privacy and confidentiality?

Edit as necessary
Please refer to the privacy and confidentiality section of the main study consent form as it is unchanged for this optional study.

9. Who will see my medical information?

Edit as necessary
Please refer to this section of the main study consent form as it is unchanged for this optional study.

10. What are my rights?

Edit as necessary
Please refer to this section of the main study consent form as it is unchanged for this optional study.

11. Commercialization:

Edit as necessary
It is possible that the research conducted using your samples and/or study data may eventually lead to the development of new diagnostic test or new drugs or other commercial products. You will have no right to any products that may be created as a result of this study or any future research studies using this research study data.

12. Declaration of financial interest:

Edit as necessary
Please refer to this section of the main study consent form as it is unchanged for this optional study.

13. Questions:

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

Insert Study Doctor's Name and Phone Number

You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

Research Ethics Office at 709-864-8871
Email: info@hrea.ca
Web : www.hrea.ca

After you sign this consent form, you will be given a copy.

Signature Page

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- 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, without having to give a reason, and that this will not change the quality of care that I receive.
- I understand that it is my choice to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of participating in this study.
- I do not give up any of my legal rights by signing this consent form.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I allow access to medical records and transfer of specimens and related personal health information as explained in this consent form.
- I understand that my family doctor will/may be informed of my study participation.
- I agree, or agree to allow the person I am responsible for, to take part in this study.
- [Insert any other research specific clauses that may be important to reiterate.]

Signature of participant	Printed name	Day Month Year
Signature of person authorized as substitute decision maker **[If applicable]**	Printed name	Day Month Year
Signature of person conducting the consent discussion	Name printed	Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant/substitute decision maker fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

Signature of investigator | Name Printed | Day Month Year

Signature Page for Parent/Guardian

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse for my child/ward to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that my child/ward receives.
- I understand that it is my choice for my child/ward to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of my child/ward participating in this study.
- I do not give up any of my child/ward's legal rights by signing this consent form,
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I allow access to my child/ward's medical records and transfer of specimens and related personal health information as explained in this consent form.
- I understand that my child/ward's family doctor will/may be informed of my study participation.
- [Insert any other research specific clauses that may be important to reiterate.]

I consent for my child/ward _____ to take part in this study.

Signature of parent/guardian | Name printed | Day Month Year

Signature of person conducting the consent discussion | Name printed | Day Month Year

Signature of witness **[If applicable]** | Name printed | Day Month Year

To be signed by the investigator:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the parent/guardian fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen for the child/ward to be in the study.

Signature of Investigator | Printed Name | Day Month Year

To be signed by the minor participant [if appropriate]
Assent of minor participant:

I understand the purpose of this research
I understand that it is my decision to take part in this study. I can stop taking part if I chose.
I understand that taking part in this research may not help me.
I understand that there may be risks to participating in this study.

I agree that I will take part in this study

Signature of minor participant | Day Month Year

Name printed | Age

Participant Assistance

Complete the following declaration only if the participant is unable to read:

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

Signature of Impartial Witness | Printed Name | Date

Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:

- The informed consent discussion was interpreted by an interpreter, and
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter Declaration and Signature:
By signing the consent form I attest that I provided a faithful interpretation for any discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

Signature of Interpreter	Printed Name	Date