# HREBA Optional Research Consent Form Template

# Instructions for Informed Consent Form Development

## The informed consent form (ICF) is only a component of the informed consent process which includes an informed discussion with, and responses to, any questions raised by the participant.

**HOW TO USE THIS TEMPLATE:**

* The intent of this template is to include, where possible, all optional studies in one ICF document.
* Instructions from the template authors are indicated in *red italics*; DELETE from the final draft.
* *Blue italics* within sentences indicate that protocol-specific detailsneed to be inserted, such as drug/intervention name, descriptions, options for protocol details; REPLACE italics with regular font.
* Yellow highlightingindicates instructions for sites when creating their local forms.
* Suggested text/examples are provided throughout the ICF; they should be DELETED if they are not relevant to the specific protocol.
* All sections of this template are to be included in the final draft.
* DELETE this instruction page from final draft.

**TIPS FOR WRITING AND IMPLEMENTING THE CONSENT:**

* Use plain (lay), concise language that is easy for a non-medical person to understand:
  + Use short sentences and sections.
  + Aim for grade 8 reading level, ideally no more than grade 10.
  + Include simple words; avoid scientific/technical explanations; refer to lay [glossary](http://humansubjects.stanford.edu/new/docs/glossary_definitions/lay_language.pdf) as needed.
* Use a consistent font size that is easy to read; size 12 or larger is recommended.
* Eliminate repetitive information.
* Define all acronyms when they first appear and limit their use.
* Use the term [“participant”](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/) (TCPS2) when referring to the individual participating within the study.
* When referring to the individual responsible for the conduct of the research study (i.e., study doctor, researcher, investigator) choose the most appropriate title at the outset of the document and use it consistently throughout. Note that the TCPS2 refers to this individual as the researcher.
* Ensure that the final version of the form is properly formatted and free of spelling or grammatical errors.
* After all edits have been made, all text should appear black with no italic font.
* Place finalized consent form on approved site letterhead.
* If assistance is provided during the consent process, more information (including the role or relationship of the impartial witness/interpreter) should be noted in the individuals study record(s).

*Insert and Use approved letterhead for your institution where the research is being conducted.*

**Informed Consent Form for Participation in Optional Research**

*Study Title as written on the protocol*

*Non-technical lay title*

*This title should be short & convey the purpose(s) of the study.*

Protocol ID: *XXXX*

Researcher: Name

Department

Institution/Site

Contact Number

*If the funder and sponsor are different then use two separate lines.*

Funder(s)/Sponsor: *Name*

**INTRODUCTION**

In addition to the main study, you also are being invited to take part in optional research. Although it is optional, the study of human samples and data focusing on the prevention, diagnosis and treatment of cancer and other diseases is an important part of research. Taking part in this optional research is voluntary. You still can take part in the main study, and will continue to receive treatment and care even if you say “no” to *any or all of* this optional research now or later. This form and your discussion with the researcher/study staff will give you the information you need to make your decision.

**WHY IS THIS OPTIONAL RESEARCH BEING DONE?**

*Edit/remove/add bullets as applicable to the protocol (this is not an exhaustive list).*

The researchers conducting this research are interested in doing the following:

* *Biomarker research for the main study using tumour tissue / blood already collected*
* *Biomarker research for the main study using fresh tumour tissue / blood*
* *Genetic research for the main study using tumour tissue / blood already collected*
* *Genetic research for the main study using fresh tumour tissue / blood*
* *Bio-banking for use in future research using tumour tissue / blood already collected*
* *Bio-banking for use in future research using fresh tumour tissue / blood*
* *Completing questionnaires on your quality of life*

*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. 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. Bio-banking).*

*Suggestion for biomarker research (protocol-specific):*

As part of this optional research, the researchers would like to examine your *tumour* *tissue/blood* samples to look for any **biomarkers** (small “signature” molecules or indicators) in your cancer cells or circulating in your blood. These biomarkers might help predict which patients are most likely to be affected by the study drug. This is called biomarker research.

*Suggestion for genetic research (protocol-specific):*

As part of this optional research, the researchers would like to examine the genes (DNA) found in your *blood/tumour tissue*. The study of genes (DNA) is often called **genetic research**. Genes carry information about features, such as hair or eye colour. Researchers are interested in the way that changes in the genes found in your blood/tumour tissue affect how your body responds to treatment. They may look at this DNA to learn about changes in the body that happen after you were born (**non-inherited**). For example, being in the sun too much can cause changes in cells that lead to skin cancer.

*Include with genetic research paragraph above if protocol specifies hereditary genetic testing:*

This may include looking at changes found in your DNA (genes) and in the DNA of people related to you that may be **inherited** (passed on in families). This is called hereditary genetic testing. This type of research on DNA and blood cells may help to explain why some cancers run in families or why some people have side effects from treatment while others do not.

*Suggestion for Biobanking:*

Bio-banking is the collection, storage, and use of human body samples and related health information for future research. It provides an important resource for health research locally, across Canada, and around the world. The researchers doing the main study are also interested in storing your *tissue/blood* samples for future research. The research that may be done on your samples in the future is unknown at this time. It may be related to your condition or it may be used to address research questions that are unrelated.

Some of this research may be about genes. Genes carry information about features, such as hair or eye colour. This research may include looking at changes in genes found in you and in people who are related to you. These changes may be inherited (passed on in families). This is called hereditary genetic testing. Researchers also may be interested in the way that genes affect health and disease, or how your body responds to treatment.

*Suggestion for Quality of Life studies:*

The researchers doing this study are also interested in understanding how your treatment and illness affects your quality of life.

**WHAT WILL HAPPEN DURING THIS OPTIONAL RESEARCH?**

*Explain the process for collection of samples, including whether the samples have been previously collected or will be freshly taken. Suggestions are provided. If multiple samples are being collected for the same purpose, you may wish to edit the options to reduce duplication. 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).*

You may take part in all or some of the optional research described here, it is your choice. If you agree to take part:

*For previously removed tumour samples not leftover from the main study (i.e., removed as part of standard of care):*

* the samples used for this optional research have already been collected as part of your standard of care. No further biopsies or surgeries are needed for this purpose.

*For previously collected samples leftover from the main study:*

* the *blood/tumour* samples used for this optional research will be those left over or remaining from your participation in the main study. No further biopsies or surgeries are needed for this purpose.

*For tumour samples collected from future routine surgery or biopsy:*

* the samples used for this optional research will be collected from you in the future, as part of your usual standard of care. No further biopsies or surgeries are not required for this purpose.

*For study-specific tumour collection via biopsy:*

* the collection of the tumour samples for this optional research 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. Samples will be taken *specify the total number of samples to be taken and timing, e.g., before taking the study drug.*

*If applicable:*

If you have a biopsy or surgery at another institution, signing this consent form means that you are consenting to the transfer of your tissue sample, together with any related personal health information, from that institution.

*For blood samples:*

If you agree to take part in this optional research, blood samples of (about *XX* mL or *YY* teaspoons), in addition to the main 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 the total number of samples to be taken and 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 in this optional research, you will be asked to provide a urine sample(s). Urine samples will be collected *specify the total number of samples to be taken and 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 quality of life questionnaires:*

You will be asked to complete a questionnaire *provide information about purpose, number and timing of questionnaires to be completed e.g., before you begin the study and then every two weeks for a year*. Each questionnaire will take about *indicate estimated time to complete in minutes*.

The information you provide on questionnaires is for research purposes only. Some of the questions may be personal. You can choose not to answer questions if you wish.

*If questionnaires include medically relevant information, but won’t be reviewed, include the following:*

Even though you may have provided information on a questionnaire, these responses will not be reviewed by your health care or study teams - if you wish them to know this information please bring it to their attention.

Other Samples -

*In this section, describe sample collection that differ from those indicated above.*

**HOW WILL MY SAMPLES BE HANDLED?**

Describe where samples will be sent (location & name of facility), 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. Bio-banking).*

For sending to a laboratory; as per TCPS2 must indicate if in Canada or outside Canada.

Your sample(s) and some related health information already collected from your participation in the main study will be sent to a laboratory (name of facility), in Canada or outside of Canada for analysis. The samples and data 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.

For sending to a biobank; must indicate if inside Canada or outside Canada.

Your remaining sample(s) and some related health information already collected from your participation in the main study will be sent to a biobank (name of facility), in Canada or outside of Canada and stored. The samples and data will be kept indefinitely/ if other as per protocol, specify amount of time, or until they are used up, destroyed or returned to the hospital where you had your surgery or biopsy.

Describe who will have access, how access will be obtained and under what conditions access will be granted. Describe any potential for the transfer of samples and/or information outside the country. Specify if additional information will be collected in addition to or different from the main study data. 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).

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* and who have met regulatory requirements and secured ethics approval for their research*.* 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 these 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.*

Describe any return of results.

The results of research done on your samples will/ will not be added to your personal health records and you or the researcher will/will not know the results.

**WHAT ARE THE RISKS OF PARTICIPATING IN THIS OPTIONAL RESEARCH?**

Describe all reasonably foreseeable risks, harms, or discomforts. Include both physical and psychological/emotional risks as applicable to the research. It is not necessary to include the risks of procedures that the participant is already familiar with unless the procedure is being done solely for the purpose of the optional research. Suggestions are below, select those that apply.

Risks related to sample collection:

* 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 bruising, pain, bleeding, and rarely an infection at the biopsy site infection or blood clot underneath the skin.
* Since the tissue sample(s) already have 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 you participate in this study, it is possible that not enough tumour tissue will be left for other testing that may need to be done in the future. Please discuss this possibility with the researcher.

Discomforts related to the use of questionnaires:

* You may feel uncomfortable answering certain questions on the questionnaires. In this situation, you may choose not to answer.

Risks related to the disclosure of personal health information:

* There is a risk that someone could get access to the personal information in your personal health records or other information researchers have stored about you.
* There is a risk that someone could trace the information in a central *or public* database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
* New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.
* 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.
* There may be risks to eligibility for employment or insurance if the results of genetic testing were inadvertently disclosed to certain parties.
* Genetic information cannot be protected from disclosure by court orders.

**WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING IN THIS OPTIONAL RESEARCH?**

You will not benefit directly from taking part in this optional research. However, research done with your donated samples or health information may benefit other patients with your condition or other similar or related condition(s).

**HOW WILL MY PERSONAL INFORMATION BE KEPT PRIVATE?**

*Specify the measures employed to protect the privacy of and minimize risks to participants, and any anticipated linkage of biological materials with information about the participant. Suggestions are provided, selected those that apply.*

Your privacy is very important to the researchers and they will make every effort to protect it. Here are the steps they will take:

* When your sample(s) *is/are* sent to the *laboratory*, no information identifying you (such as your name, date of birth, health insurance number) will be provided or shared. Samples may be identified by *your study code, pathology identification number, initials*.
* When your sample(s) *is/are* sent to the *biobank*, no information identifying you (such as your name, date of birth, health insurance number) will be provided or shared. Samples may be identified by *your study code, pathology identification number, initials.*
* *At the biobank, these identifiers will be replaced by a biobank code.*
* *The samples that are provided to researchers by -* insert name of clinical trials organization/Lead Group/Biobank - *are identified only by that biobank code; researchers will not know who you are.*
* The list that links the samples to your personal identifiers (i.e., name) will be kept separate from your sample(s) and health information in a secure and confidential location at the main study site. If you change your mind about participating in this optional research, this list will be used to locate and return or destroy your samples. Decoding can only be done by the researcher or an individual authorized by the researcher.
* Study records will be kept for *X* years.
* A record of your participation in this optional study will be kept with your main study records and may be monitored for quality assurance.

*For all:*

Information that identifies you, will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available except as described in this document. If research results are published, your name and other personal information will not be used.

*If applicable, describe who will have direct access to the participant’s original medical/health information for verification of study data.*

Qualified representatives of the sponsor will make sure the study has been done properly by checking your records at the researcher’s site. Regulatory authorities, such as Health Canada and the U.S. Food and Drug Administration, (if applicable), and the applicable Research Ethics Board also may wish to check that the study has been done properly, and may also have direct access to your personal health information. Except as expressly stated in this section, all of the information provided in the main study consent form about confidentiality and direct access to your personal health information applies to this optional research consent form.

*If data or samples will be sent outside of Canada:*

Any samples *and/or information*, 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 samples *and/or information that* is transferred outside of Canada will be coded and undergo a process of de-identification so that your data or samples do not contain any personal identifying information such as your name, date of birth, address, health insurance number or contact information. Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

*For questionnaires:*

Questionnaires may be identified by your *specify e.g., study code and initials* and will be kept in your study record. Qualified representatives may have direct access to these questionnaires as described in the Confidentiality Section of the main consent.

**WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME DURING THE STUDY?**

*If incidental findings are anticipated as a result of the study, include the following section and describe the information that will be provided to participants. Consideration should be given to the nature of the study, the nature and likelihood of incidental findings, the study population/duration of the study, etc. If questions arise when drafting the consent, please discuss them with the stakeholders.*

During the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may *insert anticipated incidental findings e.g. find out that you have another medical condition.*

*Describe anticipated management plan. For example:*

If any new clinically important information about your health is obtained as a result of your participation in this optional research, you will be given the opportunity to decide whether you wish to be made aware of that information. The researcher will explain the process, which may include genetic counselling to help you understand what this result could mean for you or your blood relatives, such as your siblings and/or children.

**WILL THERE BE ANY COSTS OR COMPENSATION INVOLVED WITH THS RESEARCH?**

There are no costs to you. You will not be paid for taking part. No samples or information/data will be sold.

It is possible that the research conducted using your samples and/or my data may eventually lead to the development of new diagnostic tests, new drugs or other commercial products. There are no plans to provide payment to you if this happens.

*If a biopsy or other medical procedure is done solely for collection of samples for these purposes, include the two paragraphs below pertaining to compensation and treatment available to the participant in the event of study-related injury.*

In the case of research-related side effects or injury, medical care will be provided by your doctor or you will be referred for appropriate medical care.

Although no funds have been set aside to compensate you in the event of injury or illness related to the study procedures, you do not give up any of your legal rights for compensation by signing this form. This consent form does not relieve the researcher(s), the hospital, the sponsor, and their agents from their legal and professional responsibilities.

**WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS OPTIONAL RESEARCH?**

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

If you decide you no longer want your samples *or related health information* to be used, you should tell the researcher. Any sample(s) that remain(s) in the bank will be *specify e.g., destroyed (if blood/urine/slides) or returned to the hospital where you had your original biopsy or surgery (if tumour block)*. If tests have already been done on your sample and included in an analysis or publication, it will not be possible to withdraw these results.

You will be given a copy of this signed and dated consent form prior to participating in this study.

**IS THERE ANY CONFLICT OF INTEREST RELATED TO THIS OPTIONAL RESEARCH?**

*Include details of any actual or potential conflict of interest concerning the optional research study, if applicable****.***

**WHO DO I CONTACT FOR QUESTIONS RELATED TO THIS OPTIONAL RESEARCH?**

*Add more lines as needed.*

If you have questions about the use of your samples/data for optional research, or if you suffer a research-related injury, contact the researcher of this optional study:

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Name Telephone Number

*For the Cross Cancer Institute/Tom Baker Cancer Centers include the following.*

The researcher can also be paged through the *Cross Cancer Institute/Tom Baker Cancer Centre* switchboard at *(XXX) XXX-XXXX.*

*If applicable:*

A wallet card will be provided to you with information about how to contact the study staff when required.

If you have questions about your rights as a participant or about ethical issues related to this optional research and you would like to speak to someone not involved in its conduct, please contact the Office of the Health Research Ethics Board of Alberta – Cancer Committee at: 780-423-5727 or toll-free 1-877-423-5727.

**UNDERSTANDING AND SIGNATURES PAGE**

*Revise text as needed in order to reflect protocol-specific choices clearly; remove all those that do not apply. New concepts/options (not already provided in the document) should not be introduced in the checkbox options. Terminology should be consistent with the text above.*

Please circle your answer to show whether or not you would like to take part in the optional research:

*For any samples that were already collected -*

I agree that samples which were already collected *and related health information* may be used for the optional research described above.

YES NO

*For any fresh samples that are collected -*

I agree that fresh tissue samples may be collected and that these sample(s) *and related health information* may be used for the optional research described above.

YES NO

I agree that fresh blood samples may be collected and that these sample(s) *and related health information* may be used for the optional research described above.

YES NO

I agree that fresh *urine/hair/other* samples may be collected and that these sample(s) *and related health information* may be used for the optional research described above.

YES NO

###### For biobanking for future research -

I agree that my samples *and related health information* may be kept in a biobank for use in future health research related to my condition or may be used to address research questions that are unrelated.

YES NO

*For Quality of Life Questionnaire(s) -*

I agree to take part in the Quality of Life research.

Yes NO

*For Future Contact -*

I agree that the researcher, or their representative, may contact me or my physician to see if I wish to learn about results from this research.

YES NO

**SIGNATURES**

PARTICIPANT ACKNOWLEDGEMENT

* I understand the information within this optional consent form.
* All of my questions have been answered to my satisfaction.
* I am aware of the risks and potential benefits to me of participating in this optional research.
* I allow access to my personal health information and samples as explained in this form.
* I understand that I do not give up any of my legal rights by signing this consent form.
* I agree to take part in this optional research as described and where “YES” above has been circled.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant or Printed Name Date

Substitute Decision Maker

*If applicable -* (As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself (e.g., lack of capacity). If the participant gains the capacity to consent for him/herself, your consent for them will end.)

STUDY TEAM ACKNOWLEDGEMENT

I believe that the person signing this form understands what is involved in this optional research and has freely decided to participate.

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

Signature of Person Conducting Printed Name Date

the Consent Discussion

PARTICIPANT ASSISTANCE (IMPARTIAL WITNESS)

This section is to be completed only if the participant is unable to read the consent document. The individual assisting the participant must be impartial.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Impartial Witness |  | Printed Name |  | Date |

TRANSLATOR/INTERPRETER ACKNOWLEDGEMENT

This section is to be completed only if the participant requires the assistance of a qualified oral translator/interpreter. The interpreter must be impartial.

* The informed consent discussion was accurately explained to, and apparently understood by the research participant.
* A sight translation of the consent document was provided by the interpreter as directed by the research staff conducting the consent process.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Interpreter |  | Printed Name |  | Date |

**You will be given a copy of this signed and dated consent form prior to participating in this optional research.**