# 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.

This ICF template has been designed to meet current regulatory and ethical standards.

**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
* Eliminate repetition of 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
* 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 medical record and/or study record

**HOW TO USE THIS TEMPLATE**

* *Turquoise italicized highlighting* indicates instructions to consent form authors; DELETE from 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 italicized highlighting*indicates instructions for participating centres to follow when creating their local ICF. DELETE from final draft – i.e., retain in provincial ICF for deletion by centres
* When developing a local ICF, participating centres should insert the centre-specific information; the highlighting should be deleted from the local ICF
* Suggested text/examples are provided throughout ICF; they should be omitted if they are not relevant to the specific protocol
* DELETE this instruction page from final draft
* The Provincial ICF should NOT be on local letterhead, nor include local contact information and should follow the OCREB template. Centres should keep the version date of the APPROVED Provincial consent form, and add their local contact information and all pre-approved, centre-specific, consent form changes.

**Informed Consent Form for Taking Part in Optional Research**

*STUDY TITLE*

Study ID: *XX.XX*

Study Doctor: Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: *Sponsor name*

*If an REB approved French consent is not used at your institution you should remove the above statement.*

Le formulaire de consentement est disponible en français sur demande.

**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/research staff will give you the information you need to make your decision.

**PURPOSE**

*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 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*

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. 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:*

*Suggestion for biomarker research (protocol specific):*

The researchers doing the main study are interested in examining 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):*

The researchers doing the main study are interested in examining 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 also are 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.

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 interested in understanding how your treatment and illness affects your quality of life.

**STUDY PROCEDURES**

*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 any or all of the optional studies described here. If you agree to take part:

*For previously removed tumour samples (not leftover from the main):*

* the samples collected will be from your tumour 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/tumour* samples used will be left over from the main study. No additional procedures are required for this purpose.

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

* the samples will be collected from your tumour that will be removed as part of your usual cancer treatment. Extra surgeries or biopsies are not required for this purpose.

*For study-specific tumour collection via biopsy:*

* the collection of the tumour 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.

*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, 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*. Each questionnaire will take about *indicate estimated time to complete in minutes*.

**Handling of your 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):*

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 in Canada or outside of Canada for analysis. 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.

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 in Canada or outside of Canada and stored. The samples 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, under what conditions access will be granted, and whether data will be sold. 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.* 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.*

Describe any return of results

The results of research done on your samples will/ will not be added to your medical records and you or your study doctor will/will not know the results.

**Questionnaires**

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 team or study team - if you wish them to know this information please bring it to their attention.

**RISKS OF PARTICIPATION**

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:

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 your study doctor.

Discomforts related to the use of questionnaires:

* You may feel uncomfortable answering certain questions on the questionnaires.

Risks related to personal health information:

* There is a risk that someone could get access to the personal information in your medical 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.

**BENEFITS**

You will not benefit directly from taking part in this optional research study. Researchers might make discoveries that could benefit people in the future.

**CONFIDENTIALITY**

*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:*

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

* When your sample(s) *is/are* sent to the *lab*, no information identifying you (such as your name) will be sent. 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) will be sent. 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 name will be kept separate from your sample and health information in a secure and confidential location at the study site. If you change your mind about participating in this research, this list will be used to locate your samples.
* 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 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.

*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. If research results are published, your name and other personal information will not be used.

*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. Coded means it will not contain your personal identifying information such as your name, address, medical health 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.

*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.*

**WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT YOU?**

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*. *Your study doctor 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.*

**COSTS AND COMPENSATION**

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

It is possible that the research conducted using your samples and/or study 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 investigator, the hospital, the sponsor, and their agents from their legal and professional responsibilities.

**RIGHTS**

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 your study doctor. 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.

**CONFLICT OF INTEREST**

*Please include details of any actual or potential conflict of interest concerning this study*

**CONTACTS**

If you have questions about the use of your samples for research, or if you suffer a research-related injury, contact the study doctor:

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

Name Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact the Office of the Chair of the Ontario Cancer Research Ethics Board at: 416-673-6648 OR,

Toll free: 1-866-678-6427 ext. 6648.

**Consent to take part in this optional research**

*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 each option:

**For any samples that were already collected**

I agree that my samples that 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

###### **Biobanking for future research**

I agree that my samples *and related information* may be kept in a biobank for use in future health research.

YES NO

**Quality of Life Questionnaire(s)**

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

Yes NO

**Future Contact**

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

YES NO

**SIGNATURES**

* All of my questions have been answered,
* I understand the information within this optional consent form,
* I allow access to my medical records and samples as explained in this consent form,
* I do not give up any of my legal rights by signing this consent form,
* I agree to take part in this study where I circled “YES”.

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

Signature of participant Printed name Date

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

Signature of person conducting Printed name Date

the consent discussion

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Parent/Guardian |  | Printed Name |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Parent/Guardian |  | Printed Name |  | Date |

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 Interpreter printed name Date