

Guidance Document	HSREB Optional Genetic Biomarker Sub Study Consent Form
Effective Review	Delegated & Full Board
Version Date	Sept 6, 2017

STUDY TITLE

Provide an informative and meaningful title that full and accurately describes the study being conducted. This should be consistent among all items pertaining to the submission.

NAME OF PRINCIPAL INVESTIGATOR (STUDY DOCTOR)

Insert the full name, title, qualifications of the Principal Investigator

CO-INVESTIGATORS

Listing Co-Investigators is optional. If you choose to enter the names and titles of Co-Investigators keep in mind that at any point there is a change in the co-investigator, the consent form will require revision, review and approval by the REB.

CONTACT INFORMATION

Insert contact information of the study team for the participant.

NAME OF SPONSOR

INTRODUCTION

Introduce the research, why the participant is being approached, and why this sub study is being done. If there are incompetent participants or if the participants are minors, the letter should address the participant, rather than the substitute decision maker (SDM) or parent/guardian who is signing the consent form on behalf of the participant.

If SDM involved, insert:

In this Consent document, “you” always refers to the study participant. If you are a substitute decision maker (SDM) (i.e. someone who makes the decision of participation on behalf of a participant), please remember that “you” refers to the study patient. If an SDM is needed for this study, you will be asked to review and sign this consent form on behalf of the participant.

As part of the clinical study [name], you are being invited to take part in an optional [specify] research study. Optional means that you may refuse to take part in this optional study and still are in the main study. This study is voluntary and will include only people who choose to take part. Please take your time to make your decision.

Before agreeing to take part, it is important for you to understand all of the information related to this optional research study. Please ask the study doctor or study staff to explain any words in this document that you don’t understand, and make sure that all your questions have been answered to your satisfaction before signing this consent form. Feel free to discuss the information in this document with your friends and family or your family doctor.

WHY IS THIS OPTIONAL SUB STUDY BEING DONE?

Provide rationale for this optional study, examples:

Genetic Testing or Genetic Research

Your samples will be used for genetic research. Genetic research is the study of DNA. DNA is what your genes are made of. Research with genes involves studying changes that are inherited (passed on in families). Heredity is the passing of genetic information and traits (such as eye colour) from parents to their biological children. Studying DNA can help explain why some people respond to some medications and others do not. It can also explain why some people get some diseases and others do not.

If you agree to allow genetic testing, researchers may study your sample and examine your DNA and to compare it with the information already collected about you in the main study. [*specify if additional information will be collected in addition to or different from the main study data*]

Biobanking for Future Research

This optional study involves the collection of your [*specify - e.g., blood, urine, or tumour*] samples to store for future use. The storage of these samples for future research is called “biobanking”. A biobank is a type of facility that receives, stores, processes and distributes biological samples as well as the study data related to those samples. Biobanks provide **scientists with access** to the samples and study data to conduct research.

Describe the anticipated research/uses of the samples and study data and provide as much detail as possible, e.g.:

If you agree to donate your samples to a biobank, the research done on your samples may include looking at certain proteins called “biomarkers” that are believed to be important [*specify*]. This biomarker research may help researchers understand:

- how your [*specify*] may behave with or without treatment,
- what kind of side effects a person will have when they receive different kinds of treatment,
- why people may respond differently to [*specify*]
- who will benefit the most from this type of treatment.

It is not possible to predict all of the ways in which biobanks might be used in the future, so it is not possible to tell you exactly how your sample will be used. However, this future research may also include genetic research.

The study sponsor has no obligation to conduct this research, or any additional research on your samples or DNA.

WHAT IS INVOLVED IN PARTICIPATING IN THIS OPTIONAL SUB STUDY?

Describe specimen type, amount to be taken (per sample and total), when, from where and how it will be taken. See options below for samples already collected or for new collection of samples.

Option 1 - If the samples have not been collected at the time of the main study please insert information about the collection here. Examples:

If you agree to take part, a tube of blood [specify e.g., about XX mL (or YY teaspoons)] will be taken with a needle from a vein in your arm. Blood samples will be taken [specify – 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.].

OR

If you agree to donate your samples, whenever possible, these samples will be taken at the same time as your study-related tests (e.g. at entry to the trial). This means that in addition to the study-related blood and urine samples, [4] extra blood samples of [specify – e.g., 5 mL (1 teaspoon); 20 mL (4 teaspoons) in total] will be taken with a needle from a vein in your arm, and [2] extra urine samples will be collected. Blood samples will be taken [specify – 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.].

OR

If you agree to take part, a section of your [specify] will be removed during your surgery. [specify] cells from the extra tissue that is not needed for diagnosis will be collected for this study.

OR

If you agree to take part, the collection of the fresh tissue samples will require that you undergo a biopsy. This is a type of surgical procedure [specify] which will remove a piece of your [specify].

Option 2 - If some or all of these samples already have been collected at the time of the main study please insert this information here and reference the main study consent for the specific procedures). Examples:

If you agree to take part, the samples collected will be from your [specify] that has already been removed by biopsy or surgery. No further surgeries or biopsies are needed for this purpose.

OR

If you agree to take part, whenever possible, these samples will be taken from samples already collected during the main study.

WHAT WILL HAPPEN TO YOUR SAMPLES AND STUDY DATA?

Describe where samples will be sent, how long they will be kept, how they will be stored, and what happens to them at the end of that period (e.g., destroyed). Indicate if health information (study data) will be collected.

Your [samples will be sent to [specify laboratory name, city, province, country], owned by [specify] and stored for future research with similar samples from other people. 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].

The sponsor may send your study data collected in the main study to the [biobank] along with your sample. [specify if additional information will be collected in addition to or different from the main study data]

WHO WILL HAVE ACCESS TO YOUR SAMPLES AND STUDY DATA?

Describe who will have access, how access will be obtained and under what conditions access will be granted and whether samples will be sold. Describe any potential for linking with any other databases or registries and the possibility transfer of samples and/or information outside the country.

Your samples and study data will be used only by scientists approved by the sponsor and will not be sold. Your sample and your study data, including how you have responded to the medicine, might be sent to other countries. If this happens, the sponsor will make sure that your sample and study data will be treated with the same strict confidentiality as described in the section on confidentiality.

OR

Your samples and your study data may be given or sold by the biobank to qualified researchers in the international research community (which may include national and international researchers from academia, charitable organisations and ‘for-profit’ private companies, such as drug companies).

Researchers who would like to do future research using your samples will sign agreements that control use of the study data and the samples. They will not be permitted to disclose or to transfer study data or samples to anyone else. They will also not be permitted to use samples or study data for purposes other than those included in the agreements. Researchers will also agree that they will not attempt to re-identify you from your study data and samples.

The information from the biobank will be available only to researchers who have received prior scientific and Research Ethics Board approval for their research.

If applicable, define database and describe the type of database access

- **Open-Access:** Information in this database will be publicly accessible but will not contain information that can be used to identify you. In other words, all identifiers, which would allow you to be retraced, will be removed.
- **Controlled-Access:** Information in this database will not contain information that can be used to identify you. In other words, all identifiers, which would allow you to be retraced, will be removed. The information in this database will be available only to researchers who have received scientific and Research Ethics Board approval for their research.

WHAT ARE THE RISKS OF THIS OPTIONAL SUB STUDY?

Describe the risks, especially for genetic research (e.g., risk of linkage to the participant and potential for discrimination, how the use of the sample/data could affect privacy, that genetic information cannot be protected from disclosure by court order, that there are unknown risks with unknown potential future use)

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.

There is a risk that information gained from genetic research could eventually be linked to you. This potential re-identification of the information (e.g., to an employer or insurer) could lead to loss of privacy and to possible future discrimination in employment or insurance, against you or your biological relatives.

You should be aware that genetic information cannot be protected from disclosure by court order.

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.

Other Risks:

List as applicable

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 speak to your study doctor to discuss this possibility.

The needles used to take blood or inject substances might be uncomfortable. You might get a bruise, or rarely, an infection at the site of the needle puncture.

AND/OR

The risks of a biopsy include bruising, pain, bleeding, and rarely an infection at the biopsy site infection or blood clot underneath the skin.

OR

Since the [blood, tissue] sample will be collected from other samples already collected in the main clinical study [or is tissue that was already collected as part of your standard care], no additional risks are expected.

ARE THERE BENEFITS TO PARTICIPATING IN THIS OPTIONAL SUB STUDY?

Because this research is on-going and will take many years, it is unlikely that you will get any direct benefit from taking part in this study. The study sponsor will not make any results available to you or to your study doctor. This research may lead to better diagnosis and treatment in future for patients who have the same or a similar condition as you.

WHAT ABOUT CONFIDENTIALITY? (SEE CONSENT FORM GUIDANCE DOCUMENT FOR ADDITIONAL RECOMMENDATIONS)

Specify the protections/security measures that are in place for collection, transfer and storage of samples and study data and safeguards to protect the individual's privacy and confidentiality. State what identifiers are collected and stored, their traceability, and how and when samples/data are de-identified (if applicable). Indicate if samples will be coded, with a link maintained, or double-coded, or other (specify).

To protect your identity and privacy your samples will be labeled with a unique study number or 'code' before they are sent to the study sponsor, but not with any personal identifiers such as your name or initials [or [specify if any identifiers will be used e.g., initials, full date of birth, your hospital pathology identification number](#)]. The code linking your personal identifiers to the sample will be kept by the study doctor in a secure and confidential location at the study site [[hospital, clinic](#)]. Decoding can only be done by the study doctor or an individual authorized by the study doctor. If you change your mind about participating in this [[genetic/biobank](#)] research, this link will be used to locate and to destroy any of your remaining samples.

Specify if and when samples will be de-identified with no link, example:

As an added level of security, the samples will be de-identified. The study doctor may include specific information with the sample (such as your age, your gender, or certain clinical, pathological or demographic data, etc.); however, this information would not likely allow you to be identified or retraced.

You should know that the removal of some or all of your personal information from the study data is known as de-identification. This de-identification of the study data is intended to protect your privacy. Even with de-identification there remains some chance that the information could be re-identified, though the likelihood of re-identification is very small.

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

Qualified representatives [specify who] of the sponsor and the laboratory involved in this sample research may receive some of your study data for analysis purposes. This information will not be labeled with your name or with other personal identifiers such as your address or hospital number. It will be labeled with a unique study number or ‘code’ [specify if other identifiers will be used].

Qualified representatives of the sponsor will make sure the study has been done properly by checking your personal health information at the study doctor’s site. Regulatory authorities, such as Health Canada and the U.S. Food and Drug Administration, (if applicable), and Western Universities Health Sciences Research Ethics Board also may wish to check that the study has been done properly, and will 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 consent form.

Describe what will happen with the results

Evaluation of the results will only be performed as a group and not by individual patient. The medical implications of the results of this testing, if any, will only be known after many studies like this one are done. Reports about any research done with your samples will not be given to you or to your study doctor, or put in your personal health information records. The research using your samples will not affect your care.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published.

Describe how long information collected for the study, including their samples, will be kept.

If applicable, indicate whether or not the participant could agree to be re-contacted about the use of their sample

WILL YOU RECEIVE ANY COMPENSATION PARTICIPATING IN THIS OPTIONAL SUB STUDY?

You will [specify, not be paid, you will be reimbursed....] to participate in this study.

Potential discoveries including any commercial uses

It is possible that future research conducted using your samples and/or study data combined with the samples and study data from others will eventually lead to the development of new diagnostic tests, new drugs or other commercial products. Should this occur, you will not receive any part of the profits generated from such products. The rights to the commercial products will belong to the sponsor, collaborators or future unknown researchers.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT? (SEE CONSENT FORM GUIDANCE DOCUMENT FOR ADDITIONAL RECOMMENDATIONS)

Taking part in this optional sub study is entirely your choice. You can choose not to take part, or you can change your mind at any time for any reason. Your decision will not affect your medical care or your relationship with your study doctor in any way. You may refuse to take part in this optional sub study and still be in the main study.

If you take part in this optional sub study and then decide that you no longer want your samples to be used, let your study doctor know so the samples will be destroyed.

If you withdraw your consent before your sample is sent to the sponsor, your study doctor will arrange to have these destroyed. If you withdraw your consent after your sample has been sent to the biobank, the unused samples will either be destroyed [if blood], or returned to the hospital where you had your surgery [if tumour tissue]. If you choose to withdraw from this optional study, the study sponsor is not obliged to destroy results of any research that has already been done. [*If applicable: You will not be able to remove your sample or study data specify when – e.g., once the link to you is destroyed*]

The study sponsor will not make any results available to you, any insurance company, your employer, your family, the study doctor, or any other physician who treats you now or in the future.

For studies involving genetic testing and if applicable to the study participant population:

If you are a First Nations or an indigenous person who has contact with spiritual 'Elders', you may want to talk to them before you make a decision about this research study. Elders may have concerns about some genetic procedures.

You do not waive any legal rights by signing this consent document.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS?

Instructions on whom (name and phone number) to contact regarding any questions or concerns that may be raised by participating in the study or questions that may be raised by being a research participant. The 24 hour contact number can be repeated here if determined to be needed for the study (e.g. blinded study).

You must also include:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics (519) 661-3036, 1-844-720-9816, email: ethics@uwo.ca. The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential.

or

If this is a study that requires Lawson oversight:

The Letter of Information should include the following language for St. Joseph's Health Care London as a contact outside of the research team:

If you have any questions/concerns about your rights as a research participant or the conduct of this study, please contact: St. Joseph's Health Care London Patient Relations Consultant at 519-646-6100 ext. 64727

The Letter of Information should include the following language London Health Science Centre as a contact outside of the research team:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Experience Office at LHSC at (519) 685-8500 ext. 52036 or access the online form at: <https://apps.lhsc.on.ca/?q=forms/patient-experience-contact-form>.

You will receive a signed copy of this form to keep.

CONSENT (Include what is applicable)

Include this section with the rest of the consent document, but on its own page.

This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to take part in this study.

If including more than one option, include YES/NO check boxes for each. For example:

___ I agree to allow my samples to be banked for future use for [specify] INCLUDING genetic testing.

___ I agree to allow my samples to be banked for future use for [specify] EXCEPT FOR genetic testing.

If you are including people with communication difficulties, insert the following:

Was the participant assisted during the consent process? YES NO

If YES, please check the relevant box and complete the signature space below:

The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator Signature Date (DD-MMM-YYYY)

Language

If you are including illiterate people (those who cannot read English, add the following:

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness Signature Date (DD-MMM-YYYY)

Relationship to Participant

If you are including people who require a substitute decision maker, insert the following:

Your signature on this form indicates that you are acting as a substitute decision makers for the participant and the study has been explained to you and all your questions have been answered to your satisfaction. You agree to allow the person you represent to take part in the study. You know that the person you represent can leave the study any time.

Print Name of Substitute Decision
Maker

Signature

Date (*DD-MMM-YYYY*)

Relationship to Participant