To be on Investigator letterhead

***OPTIONAL* GENETIC TESTING AND/OR biobanking**

**ATTACHMENT to THE MAIN STUDY INFORMATION AND CONSENT FORM**

**Title of Study:**

**Principal Investigator:** *[include phone number]*

**Introduction**

You are being asked to take part in an optional [specify e.g., genetic testing, biobanking] research study, because you are already participating in the [specify Main Study Title].

Optional means that you do not have to to take part in this part of the study to still be included in the main study.

Before you make a decision one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

**Why Is This Optional Study Being Done?**

***Provide rationale for this optional study, examples:***

**Genetic Testing or Genetic Research**

Cells in your body contain what is called *deoxyribonucleic acid*, or DNA for short. Your DNA contains the plans for how your body is built and functions.  These plans are held in sections of our DNA known as genes.  For example, your genes provide the plans for things like your eye and hair colour as well as how tall you are. We inherit our genes from our parents and everyone has two copies for each gene, one from each parent. Some genes that are inherited may affect a person’s chance of developing certain diseases. “Genetic testing” or “genetic research” studies are studies that look for these inherited genes that may cause certain diseases. By studying the genetic changes, researchers hope to understand the causes of different diseases, and eventually develop new ways to prevent, detect and treat them.

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](http://www.biobankcentral.org/resource/glossary.php#Biomaterials) 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”. This biomarker research may help researchers understand:

* how your disease may behave with or without treatment,
* what kind of side effects a person will have when they receive different kinds of treatment,
* how your condition might respond to the study treatment,
* 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 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, 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<disease site>.

***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 LIST SAMPLE HERE 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]

***Describe the potential to discover incidental findings and the choices participants may have in regards to this..***

## Incidental Unexpected finding and Genetic Research:

***This section should articulate whether the research conducted as part of this optional research may result in potential secondary findings (ie. things you were not looking for but found).  Secondary findings may be medically actionable. Medically actionable secondary findings mean there is a high chance of a health problem AND treatment and/or screening is available for this health problem.***

***If results arising from this optional testing may possibly yield medically actionable secondary findings - provide details as to your plan to manage the information revealed through the research (ie. How will participants be informed of these medically actionable findings and how will you support referrals for their follow up).  The consent form should clearly identify this as a possibility and clearly outline the follow up for participants. And provide text in the consent form to allow participants to make informed choices about whether they wish to receive the information about themselves and/or potentially their biological relatives (Article 13.3 of TCPS2) related to these findings.(ie. If participants do not want to participate in a study where medically actionable secondary findings are a possibility, they should not to join the study.***

***If results arising from this optional specimen testing are NOT anticipated to yield medically actionable findings - please advise the REB as to whether you plan to tell prospective participants of these results, and ensure that this is clearly reflected in the consent form as well. Example text:***

Medically non-actionable findings:In genetic research, there are also medically non-actionable findings. These findings may indicate there is a high chance for a disease but there is currently no treatment and/or screening available (e.g., Alzheimer’s or Huntington’s Disease). In this study, we will not return these findings to you; we do not return information on incidental findings that are not medically actionable. We will also not place this information into your medical records at this Institution.

**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 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.

**What are the Risks of This Optional 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.

In May 2017 the Genetic Non-Discrimination Act (GNA) was passed into law in Canada. GNA protects individuals from the disclosure of genetic test results for purposes such as insurance and employment.

**Other Risks:**

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 Study?**

Because this research is on-going and will take many years, you will not 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?**

***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 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 the applicable 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.

***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 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?**

Taking part in this optional sample 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 do not have to agree to be in this optional study to be in the main study.

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.

**Whom Do You Call If You Have Questions?**

If you have questions about this study, donating your samples, any study-related injury, contact the study doctor at:

If you have questions or concerns about the conduct of the research contact the University of Alberta Research Ethics Office at reoffice@ualberta.ca.

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

## **Consent To Participate in this Optional Research**

## My signature on this consent form means that:

## This optional study has been explained to me, I have been given the chance to discuss it and ask questions. All of my questions have been answered to my satisfaction,

## I have read each page of this form,

## I am aware of the risks to me of participating in this optional study,

## I agree to allow access to my personal health information as explained in this form,

## I agree to allow collection of my samples and study data for the research purposes explained in this form,

***This section should be added or deleted based on the kind of research you have outlined:***

**PLEASE INITIAL YOUR CHOICE BELOW BEFORE SIGNING:**

|  |
| --- |
| \_\_\_\_ I agree to allow my samples to be banked for future use for research INCLUDING genetic testing.  \_\_\_\_ I agree to allow my samples to be banked for future use for research EXCEPT FOR genetic testing. |

## I voluntarily consent to take part in this optional study as outlined above.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Participant (Print) |  | Signature of Participant |  | Date(yyyy-mmm-dd) |

## ***Person Obtaining Informed Consent:***

## *My signature below signifies that I have explained the nature and purpose of the study and the risks involved to the study participant, and I have answered all questions to the best of my ability.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Person Obtaining Informed Consent (print) |  | Signature of Person Obtaining Informed Consent |  | Date(yyyy-mmm-dd) |