Study Information and Consent Form

Study Title

Protocol Number: [insert number here]

 **Principal investigator:** Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[insert name, degrees held]

[insert BC Cancer Department]

[insert institution/centre]

[insert contact phone number(s)]

**Sponsor/Granting agency/Coordinating group: [insert name here]**

**PURPOSE**
We are inviting you to take part in this research study because you have [insert condition here]. The purpose of this study is to investigate/explore ­­­­­­­­­­­\_\_\_\_\_\_\_\_ (provide a brief explanation here including objectives/goals).

**BACKGROUND BEHIND THIS STUDY**

Please provide a brief explanation for the background for this study.

e.g. Lymphomas are among the most common cancers found in ­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_

**WHO IS CONDUCTING THIS STUDY?**

This study is being funded by [insert sponsor/ grant/funder name here]. This means that BC Cancer has received funding to do the study. However, none of the study researchers or staff will receive any personal payments.

**PARTICIPATION**

Your participation is entirely voluntary. Please take as much time as you need to decide. The decision

you make, whether to participate or not, will have no effect on your medical care.

This study does not provide treatment for your­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­ [insert condition here].

Your alternative is not to be in this study. Your decision to take part in this study will not change the medical care you receive from your regular doctor according to the accepted standard of care.

Approximately [insert worldwide overall number] participants will take part in this study world-wide with [insert number of patients at BC Cancer] taking part from BC Cancer.

**EXCLUSION CRITERIA**

Exclusion criteria for this study include:

List them here

**WHAT DO YOU NEED TO DO?**

If you agree to participate, the following tests/ procedures will be done as part of this study. Some of these may be done as part of your standard care, in which case the results may be used. Some of these tests/procedures may be done more frequently than if you were not taking part in this study and some may be done solely for the purpose of the study.

**STUDY VISITS AND SAMPLE COLLECTION SCHEDULE**

**TABLE A: Study visit schedule**
The total amount of time required for this research study, is [insert number of hours or minutes] a month, over [insert total number of months] months.

|  |
| --- |
| **INCLUDE VISIT SCHEDULE TABLE HERE** |
|  |  |  |  |  |  |  |

**TABLE B: Sample collection and tests (Tissue, blood and saliva collections, ECG etc.) schedule**

|  |  |  |  |
| --- | --- | --- | --- |
| **SAMPLE/TEST** | **WHEN** | **Blood taken** | **Comment** |
| **in ml** | **in tsp / cup** |
| Blood CBC, chemistry |  | 13 | 2.5 tsp |  |
|  |  |  |  |  |

**Questionnaires**

This study includes questionnaires. You will not have to answer any question that makes you feel uncomfortable.

**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.]*

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information, and any processes that can or need to be undertaken will be discussed with you. As an example, genetic counselling may be available in order to help you understand what this result could mean for you or your blood relatives, such as your siblings and/or children.

**BENEFITS**

You should not expect to get direct health benefits from taking part in this study. What is learned from this study may help patients in the future.

**RISKS and SIDE EFFECTS**

The risks and side effects of procedures usually done as standard of care will be explained to you as part of your usual care.All of the risks and side effects that go along with taking part in this study are described 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 \_\_\_\_\_\_\_\_\_\_\_.

Risks related toGenetic research

* When you donate your blood or tissue for genetic testing or research, you are not only sharing genetic information about yourself, but also about biological (blood) relatives who share your genes or DNA. The risk of your information being accidentally released in this study is estimated to be small.

**CAN YOU STOP TAKING PART IN THE STUDY?**

Participation in this study is entirely voluntary. You can leave the study at any time for any reason without any consequences to your medical care, please call <insert number and name (if appropriate)> to let us know.

You will be given a number of withdrawal options to consider like returning samples to the facility where they were obtained, and opting out of future access to your medical records.

If you choose to stop taking part in the study, all of the information collected up to the point of your withdrawal will be kept for analysis in order to protect the integrity of the research. In addition, it will not be possible to withdraw data and samples that have been anonymized and can no longer be linked back to you.

**HOW LONG WILL STUDY-RELATED DATA and SAMPLES BE KEPT?**

Your study records including confidential information about you collected during the study will be kept at a secure location for at least xx years after study completion. Biological materials used for this study will be kept for [insert length of time, how they will be preserved, location of storage (e.g., in Canada, outside Canada), and process for disposal, if applicable]. Any anticipated linkage of biological materials with information about the participant should also be indicated.]

**COSTS, REIMBURSEMENT and COMPENSATION**

There are no costs to you for taking part in this study. You will not be paid for taking part in this study. The research using your biological materials and data may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

**PRIVACY & CONFIDENTIALITY**

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

However, there is a risk that someone could get access to the information we have stored about you, it could be revealed inappropriately or accidentally, and the risk of someone identifying you may increase in the future as people find new ways of tracing information. Depending on the nature of the information, such a release could upset or embarrass you, or be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse in Canada, but they may not give full protection, and laws in other countries may not be as strict as those in Canada, so when your information and samples are sent to places outside of Canada, you may not be afforded the same rights. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us, and we will make every effort to protect these as described below.

**Study-related data and coding:**

* All information gathered for use in the study is referred to as the ‘study-related data’. This data may include your medical records, biological materials, genetic information, completed questionnaires and/or diaries, etc. The study-related data will be transformed into datasets that can be analyzed. You will be assigned a unique code that will be used to track your study-related data. This unique code does not include any personal information that could identify you, and will be used on all study-related data that leave BC Cancer unless otherwise specified in this form (this is referred to as ‘coded data’).
* Coded data (including genetic information) from this study may be pooled and shared with researchers from around the world for future studies that are unknown at this time. It may also be added to public databases, published, or presented at scientific meetings. The aim of these future studies is to benefit people by improving our understanding of health conditions like cancer.

**WHO WILL HAVE ACCESS TO YOUR STUDY-RELATED DATA?**

Your study-related data will be reviewed by the sponsor of this study, or their representatives at BC Cancer. The BC Cancer Research Ethics Board or regulatory authorities and auditors may also look at your study-related data for the purpose of overseeing the conduct of the study. By signing this form you are authorizing such access. The Table below sets out the organizations that may access your study-related data and for what purposes.

**Access to your study-related data**

|  |  |  |  |
| --- | --- | --- | --- |
| **WHO** | **WHAT** | **WHERE** | **PURPOSE** |
| Health Canada | Study-related records and data (including your medical records) that include information that can identify you  | Canada | Oversight of the use of drugs in Canada |
| U.S. Food and Drug Administration (FDA) | Study-related records and data (including your medical records) that include information that can identify you  | Canada (may be copied and taken to USA) | Oversight of the use of drugs in the United States of America |
| Insert organization  | Blood and tissue samples | Location  | Biomarker, HRD testing, PK, immunogenicity testing  |
| Insert organization | Personally identifiable information – if applicable  | Location | Insert reasons  |

**STUDY RESULTS**

The study results will be shared with you when the study is complete. [Please describe who will communicate the results, as well as the method of communication]

**WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?**

* **For questions about the study:** If you have any questions or desire further information with respect to this study before or during participation, you may contact the < NAME > Project Coordinator <INSERT CONTACT NUMBER>.
* **For privacy related questions or questions about your rights as a research participant:** You can contact BC Cancer Research Ethics at reb@bccancer.bc.ca, or 604.877.6284. Please reference the study number Hxx-xxxx when contacting Research Ethics so staff can better assist you.

By signing this form, you do not give up any of your legal rights and you do not release the sponsor, Principal Investigator, researchers, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you.

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

**SIGNATURES**

**[insert study TITLE]**

**My signature on this consent form means:**

* I have read and understood the information in this Study Information and Consent form.
* I have been able to ask questions and have had satisfactory responses to my questions.
* I understand that my participation in this study is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
* I understand and accept that there may not be a benefit to me as a result of participating in the study.
* I authorize access to my medical records, biological material, and/or genetic information, as well as my study-related data as described in this consent form.
* I am not waiving any of my legal rights by signing this Study Information and Consent Form.
* I hereby consent to participate in the study as described in this Study Information and Consent Form.

 **Return of clinically important information:**

I agree to be informed by the study team if researchers identify any new clinically important information about my health.

Yes \_\_\_\_\_\_\_\_\_\_ (Initials) No \_\_\_\_\_\_\_\_\_ (Initials)

**Leftover samples:**

I agree that my leftover samples that were already collected for this study may be usedfor future research studies that are unknown at this time.

Yes \_\_\_\_\_\_\_\_\_\_ (Initials) No \_\_\_\_\_\_\_\_\_ (Initials)

**Xenografting:**

I agree that my samples may be used for the purposes of xenografting.

Yes \_\_\_\_\_\_\_\_\_\_ (Initials) No \_\_\_\_\_\_\_\_\_ (Initials)

Signature of Participant Printed Name Date

Signature of Person Conducting Printed Name Date

the Consent Discussion

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 the discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

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

Signature of Interpreter Printed Name Date