BC CANCER
Provincial Health Services Authority

# Study Information and Consent Form

***Biobank:***

***Tumour Tissue Repository***

***A collection of tissue and data***

**Biobank Custodian: Dr. Peter Watson**

## Purpose

The purpose of this project is to create a biobank. A biobank collects and stores human samples (such as tissue, saliva, blood, fluids, stool, etc.) and health information related to these samples. Researchers will access the samples and information that are stored in the biobank to conduct their own studies. They may be looking for new ways to detect, treat or maybe prevent cancer.

The Provincial Health Services Authority (PHSA) BC Cancer biobank is called the Tumour Tissue Repository (TTR). Dr. Peter Watson is the person responsible for the activities of the TTR.

You are being invited to donate your samples and information to the TTR.

Cancer research is always progressing. It is not known at this time what future research will be done on your samples or information. The research may look at genes (the information needed to build and operate a human body) and how genes affect health or response to treatment. Research may also lead to new products, such as drugs or tests for cancer.

## Participation

You may participate in the TTR:

- If you are 18 years of age or older
- You have received or will be having a medical treatment relating to a tumour

Your participation is entirely voluntary. You can take as much time as you need to decide whether or not you will donate. Whether you choose to participate or not in this research biobank will not effect your medical care.

## What is Involved?

### Tissue

No special test or procedure is required to donate your tissue.

When you have surgery, your surgeon will remove tissue when this is required for your treatment. Some of the removed tissue will be used for clinical diagnosis. The remaining tissue is usually discarded or stored by the Department of Pathology. The TTR would like to collect and store some of the remaining tissue for researchers to use. This will only be done if a Pathologist says that this would not affect your future care.

### Blood

Blood samples may be collected at one or two times, for example before your surgery and after. When it is possible, blood samples for the TTR will be collected as an extra blood sample (about 2 tablespoons of blood) at the same time you are having blood taken for your clinical care. If the biobank sample cannot be collected at the same time as your clinical samples then we may ask you to provide a blood sample just for the biobank.

Blood samples are optional. You may still participate in the biobank even if you do not want to provide a blood sample.

**Excretory products**

Urine or stool samples may be collected by the biobank. If you agree, you will be given instructions on how to collect these samples.

**Buccal (inside your cheek) cells or saliva or sputum sample(s)**

A buccal sample is obtained from the painless brushing of the inside of the cheeks. This collects cells from the lining of the mouth that are normally shed and grow again. You may be asked to provide a saliva or sputum sample that is collected by 'spitting' into a container. If you agree, you will be given instructions on how to collect these samples.

**Other samples**

You may be asked for other samples that are not covered on this list. If this happens, the sample type and collection procedure will be clearly outlined to you and recorded on this consent form.

**Information**

We will ask you for some basic information. This may include things like name, age, sex, and race or ethnic group. We will also collect information from your medical records including records at BC Cancer, the PHSA, and your hospital. Information may include results of tests, medical procedures, images (such as X-rays), and medicines you take.

We will review your medical records each year and may call you to get an update on your health status, for as long as your sample is stored in the biobank.

If you feel comfortable with providing it, we will collect your racial, ethnic and geographic location data. This data can help find out if there are differences in:

- Access to health care
- Treatments received
- Health care outcomes

By collecting this information, we can also better understand how different populations may experience health conditions like cancer. This will help to understand differences that may happen because of bias and discrimination. It will help make research that is more inclusive.

## Duration of Storage

The samples will be stored securely. They will be stored until they have been entirely used up or are no longer of scientific value.

## Benefits

There are no direct health benefits from donating to the TTR. Results obtained from research studies that include samples of your tissue, blood, or data will not be given to you. They will not be entered into your medical record. The main reason you may want to take part is to help researchers find new ways to prevent, detect, and treat cancer.

## Risks

### Physical Risks

There are no additional physical risks to you. Samples are collected for the biobank at the same time samples for your clinical care are collected. Any risks related to individual procedures will be explained to you at the time the procedure is happening.

### Incidental (Unexpected) Findings Risk

The research that is planned is not looking to find information that will guide your current or future medical care.

However, it is possible that researchers will unexpectedly discover information that could affect decisions about your health care. For example, they may find that you have an unexpected abnormality in a gene. This could make you more susceptible to another disease. The discovery

of something that the researchers were not looking for is called an incidental finding. It is considered “actionable” if it can be prevented or treated effectively.

If the TTR is made aware of this type of rare finding by a researcher studying your samples, you may choose to hear about it or not to. Whatever you decide now you may change your mind at any time in the future. If you choose to hear about this type of finding, the TTR will follow our plan. This plan involves talking with the Research Ethics Board and your physicians to communicate to you.

**Hereditary Genetic Analysis Research Risks**

When you donate your blood or tissue, you share genetic information about yourself and biological (blood) relatives. In most cases research that is planned is designed to look at features just related to you and your cancer.

Research studies may be proposed that involve genetic analysis. This identifies features in your genes that indicate risk of conditions that might affect the health of people related to you. These gene features may be inherited (passed on in families). Research involving genetic analysis will only be done if you give your permission for us to contact you and if you give permission for it.

## Can You Stop Taking Part in the Biobank?

Participation in this biobank is entirely voluntary. You can stop taking part in the TTR at any time for any reason. There would not be any effect on your medical care.

If you want to stop taking part, call the TTR to let us know. We will destroy all samples and/or information that are in the care of the biobank. We cannot get back samples or information that we have already given out to researchers.

## What Happens to My Samples if the Biobank has to Close?

Dr. Peter Watson and the Research Ethics Board will determine what happens to the samples. You will be notified by letter or email using the contact details you provided. If you do not agree to the closure plan, you can ask for your samples and information to be destroyed.

## Privacy and Confidentiality

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

- The TTR collects and holds some personally identifying information such as name, contact information, date of birth, etc.
- Any signed consent form will be stored in the Provincial Health Services Authority environment according to provincial standards for privacy and security. Only authorized personnel will be able to access it.
- We will keep the samples in a locked laboratory within locked buildings.
- We will keep health information and research data on secure computers. These computers have many levels of protection.
- Despite all the security and privacy standards used by the biobank, the possibility of someone identifying you can never be completely eliminated.
- Researchers will always have a duty to protect your privacy and to keep your information as confidential as possible.
- There is a risk that someone could get access to the information we have stored about you.
    - It could be revealed inappropriately or accidentally.
    - 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. Laws in other countries may not be as strict as those in Canada. 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 because of the precautions that we take. We cannot make guarantees. Your privacy and the confidentiality of your data are very important to us. We will make every effort to protect these.

**Study-related data and coding:**

- All information gathered for use in the biobank is referred to as the 'study-related data'.
  - This data may include your medical records, human samples, genetic information, etc.
  - The study-related data will be transformed into datasets that can be studied.
  - Your information and samples 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. It will be used on all study-related data that leaves BC Cancer. This is referred to as 'coded data'.
- Coded data (including your whole genome sequence and information about features of your genes) resulting from analyses being done on samples from this biobank:
  - 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.

**Email**

You may use email to communicate about this research study. The research team will use best efforts to keep your information confidential. However, there are always some risks of disclosure when using email and you should be aware that some email services may store the contents of your email account outside of Canada, where privacy and data security standards may be different than they are in Canada. If you have questions or would like to stop receiving research communication via email, please contact [Dr Peter Watson, Biobank Custodian, TTR@bccancer.bc.ca, 250-519-5713]

## Who Will Have Access to Your Study-Related Data?

Researchers can ask to study the samples and information stored in the TTR. Researchers may be from Canada or other countries around the world. They could be from:

- Universities/academic institutes
- Hospitals/health institutions
- Commercial companies (e.g. biotechnology or pharmaceutical companies)

Research partnerships may happen between these organizations.

Researchers that want to study samples and information from the TTR have to provide details about their project. They have to provide their ethics approval. An ethics approval is to make sure that your welfare and rights are protected. A science committee at the TTR will review each request.

If a national regulatory authority wanted to monitor the TTR they could look at research records that identify you. This would happen in the presence of the custodian (or their designate) and the BC Cancer Research Ethics Board.

## Costs, Reimbursement and Compensation

There are no costs to you for taking part in the TTR. You will not be paid for taking part in this Biobank. Research done with your samples and data may lead to the development of new tests, drugs, or other medical products that may have commercial value. If it does, you will not get any payment.

Researchers who wish to use samples and data in the biobank may be charged a fee to help cover some of the costs of storage, release, and overall operation of the TTR.

## Who Can You Contact If You Have Questions?

If you have any questions, want more information or want to update your contact information call the TTR at 250-519-5713 or toll free at 1-866-898-0887.

You can contact the BC Cancer Research Ethics Board (REB) about your privacy rights and your rights as a research participant at reb@bccancer.bc.ca, or 604-877-6284. Please use the reference number H18-03344.

Signing this consent form does not limit your legal rights against anyone involved in this biobank.

You will be given a copy of this signed consent form if you decide to participate in the TTR. A copy will be included in your biobank record. A copy of the signature page may be put in your medical/hospital record.

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**SIGNATURES**

**BIOBANK - Tumour Tissue Repository**

**My signature on this consent form means**

- I understand**:**
  - the information in this consent form
  - that participation is voluntary
  - that participation in the biobank will not provide any benefits to me
  - I am free to withdraw from this study at any time
  - I am not waiving any of my legal rights
- I have had satisfactory responses to my questions.
- I have had time to think about the information provided.
- I authorize access to my information.

| | | |
|---|---|---|
| I am willing to donate **any** of the samples described in this consent form | ☐ | **Initial here** |
| OR | | |
| I am willing to donate **only** the samples specified in the table below | ☐ | **Initial here** |

| Yes | No | Type of Sample |
|---|---|---|
| | | Tissue |
| | | Blood |
| | | Stool |
| | | Urine |
| | | Buccal Cells/Saliva/Sputum |
| | | Other: |

**In addition**, please initial yes or no to the below:

| Yes | No | |
|---|---|---|
| | | I agree to be contacted by my physician if researchers find an actionable incidental finding |
| | | I agree to be contacted in the future to discuss participation in hereditary genetic research |
| | | I agree to be contacted in the future to discuss participation in other research |
| | | I agree to be contacted in the future if the TTR needs an update on my health status |
| | | If you are willing to provide your email address, please do so here: |

Which ethnic group(s) would you use to describe yourself? (Please check all that apply)

☐ I prefer not to answer

☐ Black (African, African Canadian, Afro-Caribbean descent)

☐ East Asian (Chinese, Japanese, Korean, Taiwanese descent)

☐ Indigenous (First Nations, Inuk/Inuit, Métis descent)

☐ Latin American (Hispanic or Latin American descent)

☐ Middle Eastern (Arab, Persian, West Asian descent, e.g. Afghan, Egyptian, Iranian, Kurdish, Lebanese, Turkish)

☐ South Asian (South Asian descent, e.g. Bangladeshi, Indian, Indo-Caribbean, Pakistani, Sri Lankan)

☐ Southeast Asian (Cambodian, Filipino, Indonesian, Thai, Vietnamese, or other Southeast Asian descent)

☐ White (European descent)

☐ Other; Please specify: _____

☐ Do not know

What are the first 3 digits of your postal code?

☐ I prefer not to answer

☐ _____

| Signature of Participant | Printed Name | Date |
|---|---|---|
| Signature of Person Conducting the Consent Discussion | 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 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 |