# 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 research project is to create a biobank – the Tumour Tissue Repository (the "TTR") which is an initiative of BC Cancer, part of the Provincial Health Services Authority, and is managed by a custodian, Dr. Peter Watson. A biobank collects, stores and gives out to other researchers human samples (for example, tissue, saliva, blood, fluids, stem cells, stool, etc.), and health information connected to these samples. The TTR collects and stores tissue, blood, and health information. You are being invited to donate your samples and/or information to the TTR Biobank.

Researchers who are looking for new ways to detect, treat and maybe even prevent cancer, will access the samples and information that are stored at the TTR to conduct their own studies. Because cancer research is always progressing, it is unknown at this time what future research will be done on your samples or information, but some of these studies may lead to new products, such as drugs or tests for cancer, or may look at genes (the information needed to build and operate a human body) and how genes affect health or response to treatment.

## PARTICIPATION

You may participate in the TTR if you are 18 years of age or older, and you have received or will be having a medical treatment relating to a tumour.

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.

## WHAT IS INVOLVED?

### Tissue

No special test or procedure is required to donate your tissue. At the time of your surgery, your surgeon will remove whatever tissue is required for your treatment. Some of this tissue will be used for diagnostic purposes and stored by the Department of Pathology for future care and diagnosis. The remainder is usually discarded, but the TTR would like to collect and store this remaining material for researchers to use in future projects. The TTR may also collect some of the material stored by the Department of Pathology in the future, but only if a Pathologist determines that this material can be used without affecting your future care.

**Blood**
Blood samples may be collected in a single collection before your surgery or there may be two collections – one before surgery and one after. Whenever possible, the biobank samples will be collected as an extra blood sample (about 2 tablespoons of blood) at the same time as blood samples are being obtained from a vein in your arm for your clinical care. If we are unable to obtain an extra sample when your clinical samples are being obtained then we may ask you to provide a blood sample just for this research project. These blood samples are optional and you may still participate in this biobank even if you do not want to provide a blood sample.

**Excretory products**
Urine or stool specimens may be collected by the biobank. If you agree, you will be given instructions on how to self-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 to collect 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 self-collect these samples.

**Other samples**
It is possible that you may be asked for other samples that are not covered on this list. If this is the case, 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 collect information from your medical records including those records at BC Cancer and your hospital. Information may include results of tests, medical procedures, images (such as X-rays), and medicines you take. We may call you to get an update on your health status and review your medical records each year for as long as your sample is stored in the biobank.

## DURATION OF STORAGE
The samples will be stored securely and indefinitely until they have been entirely used up. It is important to do this because the research that can be conducted using your tissue and blood samples and/or data continuously improves.

## BENEFITS
You should not expect to get 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 or 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

In most instances, there are no additional physical risks to you as samples are collected at the same time samples for your clinical treatment are obtained, and any risks associated with individual procedures will be explained to you at the time the procedure is undertaken.

### Incidental (Unexpected) Findings Risk

The research that is planned is not designed to find information that will guide your current or future medical care for a tumour. However, it is possible that researchers will unexpectedly discover information that, if verified, could affect decisions about your health care. For example, they may find that you have an unexpected abnormality in a gene that makes you more susceptible to another disease. This is called an incidental finding (discovery of an abnormality that the researchers were not looking for) and is considered "actionable" if it can be prevented or treated effectively. You may choose to be informed or you may choose not to hear what the finding is or what could be done about it, in the rare event that the TTR is made aware of an incidental finding. Whatever you decide now you may change your mind at any time in the future and can be informed at that time. If you choose to hear about incidental findings the TTR will follow our plan to deal with potential incidental findings that involves discussion with the REB and your physicians.

### Hereditary Genetic Analysis Research Risks

When you donate your blood or tissue, you are not only sharing genetic information about yourself, but also about biological (blood) relatives who share your genes or DNA. In most cases the research that is planned is designed to analyse features just related to you and your cancer. However some research studies may be proposed that involve genetic analysis that identifies features in your genes that indicate features that might affect the health of people related to you and that may be inherited (passed on in families). This type of research involving genetic analysis will only be done if you are contacted and give your permission for it.

## CAN YOU STOP TAKING PART IN THE BIOBANK?

Participation in this biobank is entirely voluntary. You can withdraw from the TTR at any time for any reason without any consequences to your medical care.

If you want to withdraw, call the TTR at 250-519-5713 to let us know. We will destroy all samples and/or information that are in the custody of the biobank. Please note that 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?

The custodian of the TTR Biobank and the Research Ethics Board will determine what happens to the samples should the biobank have to close. You will be informed using the contact details you provided by a letter or email which will outline the closure plan. If you do not agree to the closure plan you will have the opportunity to request that your samples and electronic documentation 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 electronic consent form will be stored in the Provincial Health Services Authority BC Children's Hospital Research Institute's secured network in Vancouver, BC. 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. However, despite only sharing coded information, 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.

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 biobank is referred to as the 'study-related data'. This data may include your medical records, biological materials, genetic information, 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) 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**

We would like to use your email address to communicate with you about this research study and so you can return your completed consent form to us. The information you provide will be kept confidential by the research team. However, you should be aware that some webmail services (e.g. Gmail, etc.) may store the contents of your email account outside of Canada (for example, in the United States), where privacy and data security standards may be different than they are in Canada. Under the Freedom of Information and Protection of Privacy Act (British Columbia), we require your consent to send your personal information (such as your name and health information included in the consent form and in our communications) outside of Canada. Please carefully consider whether this email account is secure, whether other people have access to it, or whether you have concerns about the security of any information sent to this account. If you have any concerns about the use of your email address in research or would like to stop receiving research communication via email, please contact TTR Consent Personnel by phone at 250-519-5713 or by email at bbrs@biobanking.org

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

Researchers can ask to study the samples and information stored in the TTR. These researchers could be from BC Cancer, as well as from universities/academic institutes, hospitals/health institutions, or even

commercial companies (e.g. biotechnology or pharmaceutical companies) as research collaborations may be undertaken between or amongst these organizations. Some researchers will be from Canada, and some may be from other countries around the world. All researchers applying to access samples and information will be required to submit details of their project and their ethics approval and a science committee at the TTR will review each request. An ethics approval is to make sure that your welfare and rights are protected. Researchers may be charged a fee to help cover some of the costs of storage, release, and overall operation of the TTR. Research records and medical records identifying you may also be inspected in the presence of the custodian or his or her designate by representatives of national regulatory authorities and the BC Cancer Research Ethics Board for the purpose of monitoring the TTR.

## 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.

## WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions or desire further information with respect to the TTR before or during participation, you may contact the TTR Project Coordinator (250-519-5713).

You can contact the BC Cancer Research Ethics Board (REB) about your rights as a research participant at reb@bccancer.bc.ca, or 604-877-6284. Please provide the reference number H18-03344 when contacting the REB so the staff can better assist you.

Signing this consent form in no way limits your legal rights against the custodian, or anyone else involved in this biobank.

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

**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<br>I am willing to donate **only** the samples specified in the table below | **Initial here** |

| YES | NO | N/A | TYPE OF SAMPLE |
|---|---|---|---|
| | | | Tissue |
| | | | Blood |
| | | | Stool |
| | | | Urine |
| | | | Buccal Cells/Saliva/Sputum |
| | | | Other: |

In addition, please specifically address the below:

| YES | NO | |
|---|---|---|
| | | I agree to be contacted by my physician if researchers identify 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: |

| | | |
|---|---|---|
| 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 |