

Informed Consent Form

Biobank:

Lung Central Tissue Bank - LUTTISSUE

A collection of tissue and data

Biobank Custodian: Dr. Barbara Melsoky

PURPOSE

The purpose of this research project is to create a biobank – the Lung Central Tissue Bank (“Lung Biobank”) which is an initiative of BC Cancer, part of the Provincial Health Services Authority, and is managed by a custodian, Dr. Barbara Melosky. A biobank collects, stores and gives out to other researchers human samples (for example, tissue, saliva, blood, fluids, stem cells, etc), and health information connected to these samples. The Lung Biobank is collecting and storing tissue, blood, DNA and health information.

Researchers who are looking for new ways to detect, treat and maybe even prevent cancer, will access the samples and information that are stored with the Lung Biobank 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 this study 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 Lung Biobank would like to collect some of the material stored by the Department of Pathology, but only if more than one tissue block is available and if a Pathologist determines that this material can be used without affecting your future care.

Blood

Blood samples may also be collected in a single collection. 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.

DNA

DNA that is remaining from previous clinical care may also be collected and banked.

Information

We will collect information from your medical records at BC Cancer. 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, blood and DNA samples continuously improves.

ACCESS TO SAMPLES/INFORMATION

Researchers can ask to study the materials stored in the biobank. This includes researchers from BC Cancer, as well as from other universities, the government, and drug- or health-related companies. Some researchers will be from Canada, and some may be from other countries around the world. All researchers applying will be required to submit details of their project and a science committee at the biobank will review each request. There will also be an ethics review. This kind of review is to make sure that your welfare and rights are protected.

BENEFITS

You should not expect to get direct health benefits from this research. Results obtained from research studies that include samples of your tissue, blood, DNA 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

There are no physical risks to you when the Lung Biobank collects tissue left over from clinical treatment. In most instances, the Lung Biobank obtains blood samples only when a clinical sample is obtained. But when blood is drawn, you may feel brief pain or have some bruising from the needle. Infection, light-headedness, and fainting are also possible, but unlikely.

Privacy

There is a risk that someone could get access to the data we have stored about you, or it could be revealed inappropriately or accidentally. The level of this risk and the nature of the data is similar to your medical records. 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 them. These efforts are described in Privacy and Confidentiality section below.

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 Lung Biobank 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 Lung Biobank will follow our plan to deal with potential incidental findings that involves discussion with the REB and your physicians.

Hereditary Genetic Analysis Research Risks (If applicable)

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 STUDY?

You can leave the study at any time for any reason without any consequences to your medical care. If you want to leave the project, call the Biobank at 604-877-6000 x 672509 to let us know. We will send you a form with several options so you can tell us what to do with your unused sample.

Please note:

- You cannot withdraw your samples and information from studies that have already begun.
- We cannot get back samples or information that we have already given out to researchers.

COSTS, REIMBURSEMENT and COMPENSATION

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

No tissue, blood or clinical information is used for commercial purposes. Researchers may be charged a fee to help cover some of the costs of storage, release, and overall operation of the Lung Biobank. Researchers who receive material and/or data must agree that material and/or data will not be sold or used for commercial purposes and will only be used to support cancer research.

PRIVACY & CONFIDENTIALITY

This study takes many steps to protect the privacy of people who take part. We will remove your name and any other information that could directly identify you from your sample and information. We will replace this information with a code number that is created from a master list which links your code number to your name. We keep this master list in a protected file and separate from your sample and information. Only study staff who have signed an agreement to keep your identity a secret can access this list, if and when necessary.

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. Only coded information will be shared with other researchers, placed into other scientific databases, published, or presented at scientific meetings.

We will keep the samples in locked storage units 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.

Authorized representatives of the following organizations may view your original (identifiable) medical/clinical or study records or receive information related to the study from your medical/clinical or study records for quality assurance purposes, to check that the research is ethically conducted and ensure that the information collected is correct and follows proper laws and guidelines:

- BC Cancer
- Canadian government agencies who are responsible for overseeing health research or equivalent international agencies who also fund our research
- The BC Cancer Research Ethics Board

All of the organizations that may review your records are required to have strict policies and procedures to keep the information they see or receive about you confidential (except where disclosure may be required by law), and they must comply with all applicable federal and provincial privacy laws.

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions or desire further information with respect to this study before or during participation, you may contact the Lung Biobank Project Coordinator (604-877-6000 x 672509).

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 H12-02105 when contacting the REB so the 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 custodian, BC Cancer, 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. The costs of your medical treatment will be paid by your provincial medical plan and/or by BC Cancer.

You will be given a copy of this signed and dated consent form prior to participating in this study, and a copy will be included in your biobank records. A copy of the signature page of this consent will be put in your medical/hospital record.

SIGNATURES

Lung Central Tissue Bank

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 samples and information.

In addition, please specifically address the below:

- I agree to be contacted by my physician if researchers identify an actionable incidental finding.
Yes _____ (Initials) No _____ (Initials)
- I agree to be contacted in the future to discuss participation in hereditary genetic research.
Yes _____ (Initials) No _____ (Initials)
- I agree to be contacted in future to discuss participation in other research.
Yes _____ (Initials) No _____ (Initials)

Signature of Participant

Printed Name

Date

Signature of Person Conducting

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