



**PARTICIPANT (SUBJECT) INFORMATION AND CONSENT FORM  
LUNG CENTRAL TISSUE BANKING STUDY**

**BCCA Principal Investigator:** Dr. Barbara Melosky  
Vancouver Centre  
Telephone: (604) 877-6000, Local 2742

**Sponsor:** **British Columbia Cancer Research Foundation**

Non-Emergency contact numbers are noted at the end of this document under the section heading "Contacts".

**INTRODUCTION**

You are being invited to participate in the Lung Central Tissue Banking Study. This study is led by Dr. Barbara Melosky, a Medical Oncologist at the BC Cancer Agency, and the study is sponsored by the British Columbia Cancer Research Foundation.

You are being asked to participate in this research because you have a diagnosis of lung cancer. Some tissue from your tumour which has already been removed from you during surgery or a biopsy is being sent to the BC Cancer Agency (BCCA). You are being asked if you would like to donate some of your tumour tissue and a blood sample to support cancer research.

The purpose of this research is to better understand patient factors that influence cancer and the response to treatment. Your participation is voluntary and you may decide to withdraw at any time. Your decision to participate will not affect your clinical treatment in any way. Your doctors will continue to provide the best available treatment for your disease whether or not you participate in this study. The purpose of this form is to provide you with information about this research study, and to ask if you will agree to participate.

**What material will the Lung Central Tissue Banking study collect and store?**

The study collects and stores some tumour tissue, available DNA, and a blood sample from you. The tissue is embedded in wax, made into a block and stored at room temperature. The blood and remnant DNA will be frozen and stored in a -80°C Freezer. All biospecimens are stored in a secure location: frozen biospecimens are stored at the BC Children's Hospital Biobank, Oak Street Campus, and tissue blocks are stored at BCCA. All tissue samples are coded with a unique study code. All information will be stored in the Lung Central Tissue Bank database. The samples and the associated information will be stored and used indefinitely, until the samples are used up for the research purposes described in this consent. Measures that will be taken to ensure the security of your donation have been reviewed by the UBC BCCA Research Ethics Board (REB). Any changes in these measures will be reviewed when they are made by the UBC BCCA REB, or annually. If the samples are moved to another location or given to a new set of researchers for research other than is described below, the new researchers must obtain the approval of the UBC BCCA or other recognized REB before that new research is conducted. If your sample is sent to a location outside of the BCCA, all biospecimens will be de-identified with the unique study code.

**What will be released to researchers and for what research projects?**

Researchers will be able to access samples in the Lung Central Tissue Bank database only if they apply

to the bank's Access Committee through a formal scientific review process, and if they also obtain approval for their research project from the UBC BCCA REB or an equivalent institutional REB. These materials and records will only be used for research into cancer, causes of cancer, cancer treatments and the effects of cancer treatments. The material provided may include samples of blood or products of the blood, such as DNA, that is de-identified. The research studies will involve testing blood and tissue samples for patient factors that influence cancer and the response to treatment. These factors may include features that indicate how well your immune system is working, the variation in genes that influence how drugs or other treatments work in your body, or the pattern of proteins that are associated with your response to therapy. If any other type of research study is proposed, such as one that involves genetic testing that can predict that a subject will definitely develop a disease, then it will only be done with the approval of the UBC BCCA or other recognized REB, and also after contacting you to ask for your specific permission.

### **Procedures**

If you give your consent to participate in the Lung Central Tissue Bank Biobank:

1. The tumour tissue that was previously removed during surgery will be made into one or more diagnostic blocks for review by a pathologist. We would obtain your consent to store one of these blocks in the Biobank. We will not collect a block for this study if sufficient tissue is not available for diagnosis and treatment.
2. A blood sample of approximately 6 teaspoons (30 cc) will be drawn from a vein in your arm. This blood sample will be obtained sometime after you have consented to participate in the study.
3. You may also be contacted in the future to ask if you are interested to participate in other specific studies related to cancer research.

### **Tissue and blood storage**

The blood and remnant DNA will be frozen and stored in a -80°C Freezer and stored at the BC Children's Hospital Biobank, Oak Street Campus. Tissue blocks are stored at BCCA. All tissue samples are coded with a unique study code. All samples sent outside of BCCA will only contain the unique identifier assigned and no personal identifiers will be included. All information will be stored in a safe database at BCCA. If you have a diagnosis of lung cancer, the sample and the associated information will be stored indefinitely, or until the samples are used up for the research purposes described in this consent form.

Researchers will only be able to access samples in the Lung Central Tissue Bank if they apply to the bank's Access Committee through a formal scientific review process and have obtained approval for their research project from the UBC BCCA REB or an equivalent institutional REB. These materials and records will only be used for research into cancer, causes of cancer, cancer treatments and the effects of cancer treatments. The material provided may include samples of blood or products of the blood, such as DNA that is anonymously coded. The research studies will involve testing blood and tissue samples for patient factors that influence cancer and the response to treatment. These factors may include features that indicate how well your immune system is working, the variation in genes that influence how drugs or other treatments work in your body, or the pattern of proteins that are associated with your response to therapy. If any other type of research study is proposed, such as one that involves genetic testing that can predict that a subject will definitely develop a disease, then it will only be done with the approval of the UBC BCCA REB and also after contacting you to ask for your specific permission.

If the samples are moved to another location or given to a new set of researchers for other research than described below, the new researchers must obtain the approval of the UBC BCCA REB before that new research is conducted.

### **What are the risks?**

There may be mild pain or discomfort or a small chance of bruising from the collection of your blood sample. There may be a risk that your privacy could be compromised. The Lung Central Tissue Banking team will strive to minimize this risk by ensuring that your donated samples and information are stored within a secure location in the BCCA. Samples will be stored in a manner that maintain confidentiality and security standards

### **Benefits**

The type of research that will be done with this tissue is to help understand how to better treat lung cancers in the future. There will be no direct benefit to you from participating in this study but your contribution to research may benefit future patients with lung cancer.

### **Confidentiality**

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent. Your identity will not be used in any reports about the study. All records from the research will be kept in password protected computer files. Reports about any research done with your samples will not be given to you or your family doctor. These reports will not be put in your medical records. The research using your samples will not affect your care.

Research records and medical records identifying you may be inspected by representatives of Health Canada, and the UBC BCCA Research Ethics Board for the purpose of monitoring the research. However, no records that identify you will be allowed to leave the centre. These organizations have policies of strict confidentiality and the individuals inspecting your records must sign a BC Cancer Agency confidentiality form (the form is not applicable to Health Canada or U.S. Food and Drug Administration officials, who have the legal right to inspect health records and are bound to confidentiality by specific laws).

In the future, people who do research with your sample may need to know more about your health. While the researchers coordinating the Lung Central Tissue Banking Study may give them reports about your health, they will not give them your name, address, phone number or any other information that will let them know who you are.

Please note that research related data and samples will not be sent outside of Canadian borders.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request from your study doctor or the UBC BCCA Research Ethics Board.

You will not be directly informed about the results of this research but results without your identifying information will be published in medical and scientific journals. The tissue material will be securely stored at the BCCA for 20 years, or until the sample is used up.

Your participation in this research is entirely voluntary. If you decide to withdraw or to have your tissue and/or blood and/or DNA removed from the bank, please state your request to the researchers conducting the study (contact information is provided below). Once you have withdrawn from this study no further research will be conducted using your tissue or medical records, however, any research that had been conducted prior to that time cannot be removed.

You will not be paid for participating in this study.

The samples will be used for research purposes only and will not be sold. The research done with your samples may or may not help develop commercial products. There are no plans to provide payment to you if this happens.

**Costs:**

There will be no cost to you for participating in this study.

**Remuneration:**

Sponsors of studies using the tissue bank may reimburse the BC Cancer Agency for all or part of the costs of conducting the study. However, the researchers conducting studies will not receive any personal payments for conducting them. In addition, neither the BC Cancer Agency nor any of the researchers or staff conducting studies will receive any direct financial benefit related to the studies.

**Time to complete the study:**

Participation in this study does not require any additional time beyond standard of care with exception of the blood draw, which takes approximately 30 minutes. When possible, the blood draw will be booked at the same time as any blood tests that are required for standard of care.

**Contact:**

For more information you may contact Barbara Melosky, MD, Telephone (604) 877-6000 x 2742, Email: [bmelosky@bccancer.bc.ca](mailto:bmelosky@bccancer.bc.ca) .

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at [RSIL@ors.ubc.ca](mailto:RSIL@ors.ubc.ca) or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

**Subject Consent:**

**LUNG CENTRAL TISSUE BANKING STUDY**

I understand that participation is entirely voluntary. I may choose not to have samples from my tumour tissue used for research purposes, or I may have the option in future to withdraw my permission to use my samples. Whatever choice I make, I will continue to receive the best available care. If I withdraw permission to use my samples they will be returned to the source from which they were obtained or destroyed. Although I cannot have access to test results directly related to my tissue samples, I may ask questions about the type of research being done.

I will receive a signed and dated copy of this consent form.

Optional:

I agree that I may be contacted in the future to ask if I am interested in participating in other specific studies related to cancer research.

Yes  No

I agree to the collection and storage of a blood and tumor tissue sample and to the use of these samples for research into cancer, causes of cancer, cancer treatments and the effects of treatments as described in this consent form.

\_\_\_\_\_  
*Subject's Signature*

\_\_\_\_\_  
*Printed name*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
Signature of  
Person Obtaining Consent

\_\_\_\_\_  
Printed name

\_\_\_\_\_  
Study Role

\_\_\_\_\_  
Date

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: \_\_\_\_\_

Was the subject assisted during the consent process in one of the ways listed below?

Yes  No

If yes, please check the relevant box and complete the signature space below:

- The consent form was read to the subject, and the person signing below attests that the study was accurately explained to, and apparently understood by, the subject (please check if subject is unable to read).
- The person signing below acted as an interpreter/translator for the subject, during the consent process (please check if an interpreter/translator assisted during the consent process).

\_\_\_\_\_  
Signature of Person Assisting  
in the Consent Discussion

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date