

**Participant Information and Consent Form
Optional Sample or Tissue Collection and Banking**

Early Detection of Lung Cancer – A Pan-Canadian Study

BCCA Principal Investigator: Dr. Stephen Lam, Vancouver Center
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1-888-675-8001 local 8090

Co-Investigators: Dr. Annette McWilliams, Vancouver Center
Dr. Don Sin, iCapture Center, St. Paul's Hospital

Sponsor: Terry Fox Research Institute

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

You are being invited to participate in this optional genomics research study, to store your already drawn blood and or biopsy samples, because you are participating in the main study noted above.

Genomics refers to the study of the genetic material contained in the cells of your body (also known as DNA). Our long-term goal is to discover new knowledge that will improve prevention, early detection and treatment of lung cancer. As part of this goal, we are conducting research at the BC Cancer Agency in collaboration with our partners across Canada to identify genes, changes in genes and the proteins they produce. Changes in normal genes and proteins may be involved in cancer development or may make a person more likely to develop lung cancer. To make this research possible we need to collect and study a large number of samples of blood and tissue from people with different types of cancer, as well as pre-cancerous conditions.

During your participation in the early lung cancer detection study, you will be asked to provide blood samples so that we are able to measure several markers to predict the presence of lung cancer. With your permission, the DNA from the white blood cells in your samples will be taken out. The non cellular part of blood (plasma or serum) and the DNA will be stored for future research such as testing of other early detection tests that may be developed.

Also, if you have a bronchoscopy during your participation in the study, small tissue biopsy specimens (about 1 mm in size) may be taken. Cells and fluid samples will also be collected by washing or gentle brushing of the bronchial tubes. Most of the cells, biopsy and bronchial fluid samples will be used for clinical diagnosis. With your permission, any leftover specimens from any of the pathology examinations and laboratory studies will be stored for future research. No additional biopsies are needed for this purpose. We would also like to obtain and store any blood samples or tissue samples taken during any surgery you may have for lung cancer if there is any left over after confirming your diagnosis or making treatment decisions.

The donated tissue and/or blood will be given a study code for identification. This code would allow your samples to be used without anyone knowing that they are your samples just by looking at the label. These samples will be kept in secure freezers at the BC Cancer Agency for later use and may be stored forever. Because research continues to improve and new research questions become important the researchers are seeking your permission to keep the samples forever or until they are used up. The samples will be used for research purposes only and will not be sold.

Researchers within the Canadian Early Lung Cancer Study Group and at other institutions may also one day ask for a part of your sample for use in their related studies.

How Do Researchers From Other Institutions Access The Samples?

Researchers from universities, hospitals and other health organizations, such as our own, conduct research using blood/tissue. They may contact the Central Coordination Center at the BC Cancer Research Center and request samples for their studies. The Steering Committee of the Canadian Early Lung Cancer Study Group will decide if the request has scientific merit and if so, the appropriate tissue and amount will be released. If the samples are given to a new set of researchers for other research, the new researchers must obtain the approval of their own Review of Ethics Board in advance before that new research is conducted.

Benefits

Results from just one specimen do not give the researchers very much information. They need to be compared to results from a large number of normal and cancerous specimens from people with and without lung cancer. Although you may not directly benefit, your participation may increase our chances for a successful research outcome. It might help other people who have cancer or at risk for cancer and other diseases in the future.

Some future studies may be for testing the genes you inherited from your parents (also known as genetic testing). If a researcher finds that future test results may be useful for your health care, you will be contacted and given the choice to learn the test results. At that time you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or family conflicts from learning unknown information about your parents or blood relatives. No test results from these future studies will be put into your medical record unless you choose to learn the results of the testing. Sometimes results may be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information.

If our studies find that there is a possible medical benefit to you in the future, we will contact you to inform you of these new findings. For this reason, we ask you to give us, at the end of this form, the name, address and phone number of someone (perhaps a relative) who will know where you are if you move. By signing this form you give permission to contact that person in order to find you. In addition, we ask your permission to contact you directly or through this contact person if we wish to conduct other studies on your samples than the ones described in this consent form.

Compensation

There is a very small chance that some commercial value may result from the use of your sample. In the long-term if a diagnostic or therapeutic product or service is developed, you will not receive a financial benefit. Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else.

Withdrawal and Termination

Participation is voluntary. The decision to let us store tissue and blood sample for future research is up to you. Your decision **will not** affect your future care. You may continue to participate with the Early Lung Cancer Detection Study even if you decide not to have your tissue/blood stored.

If you decide to have your tissue/blood stored for future research, you are free to change your mind at any time. If you do change your mind please let us know that you no longer want your specimens stored or used for future research. Information or samples used up to that point will still be included in the analysis, however, any remaining samples will either be destroyed or returned to the Pathology department at the BC Cancer Agency.

Confidentiality

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent. Before leaving the BC Cancer Agency, the tissue and blood samples will be assigned a code number. Your birth date will be provided if requested by the sponsor or responsible regulatory agency. Personal information that may be linked to you such as name or health insurance number will be removed. Information that links you to samples will be accessed only by Dr. Stephen Lam, Dr. Annette McWilliams and their data manager and will be stored securely and separately from all other study information.

Your identity will not be used in any reports about the study. Records or samples that leave this centre will be identified by a study code only. All information associated with this study will be kept behind locked doors or in secure computer files.

The results will not be put into your health records. Reports about research done with your tissue will not be given to you or your doctor. Research records and medical records identifying you may be inspected in the presence of the Principal Investigator or his designate, by representatives of Health Canada, the Terry Fox Research Institute, the UBC BCCA Research Ethics Board or the Vancouver Island Health Authority for the purpose of monitoring and checking the accuracy of 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 confidentiality form is not applicable to Health Canada who has 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 this study may give those 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.

Information that directly discloses your identity will remain only with the Principal Investigator. Information that could be used to “link” your identity will not be released without your knowledge or consent unless required by law or regulation. You understand that by agreeing to participate in this study, anonymized information about you will be provided to the other members of the Pan Canada Early Lung Cancer study group.

Your rights to privacy are legally protected and guaranteed by federal and provincial laws. These laws require safeguards to insure that your privacy is respected. You have 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 to the investigator or the UBC BCCA Research Ethics Board.

Contact

If you have any questions or desire further information with respect to this study, you can speak with Dr. Annette McWilliams who is the principal investigator at 604-675-8090, 604-675-8089 or 1-888-675-8001 local 8090.

If you have any concerns about your treatment or rights as a research participant you may contact the Research Subject Information Line at the UBC Office of Research Services at the University of British Columbia at 604-822-8598, or Dr. Peter Kirk, Regional Director of Research and Academic Development, Vancouver Island Health Authority at 250-370-8620..

Participant Consent:

I understand that participation is entirely voluntary. I may choose not to have samples collected from me, or to withdraw my permission to use my samples and still participate in the main study. If I withdraw this permission to use my samples they will be destroyed or returned to the Pathology department at the BC Cancer Agency and will not be used for any future research. 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 copy of this consent form including all attachments, for my own records.

a) I agree to the collection, storage and use of my **blood and/or tissue** samples (as described in this consent document) for research related to:

(i) lung cancer prevention or treatment (such as the identification of genes, changes in genes and the proteins they produce. These genes and proteins may be involved in cancer development or make a person more likely to develop lung cancer).

Yes _____ No _____ Initial _____

(ii) other tobacco smoke related lung diseases such as chronic obstructive pulmonary disease.

Yes _____ No _____ Initial _____

b) I agree to be contacted in the event that the my samples are to be used in studies other than those described in this consent form.

Yes _____ No _____ Initial _____

c) I give permission for the study staff to contact my alternative contact person. Before contacting this person, all efforts will be made to contact me using the information I have already provided.

Yes _____ No _____ Initial _____

Participant's Signature

Printed name

Date

Witness' Signature

Printed name

Date

Signature of Person Obtaining Consent

Printed name

Date

Study Role

Alternative Contact: **Please give us the name, address, and phone number of a relative or close friend who will know your whereabouts should we lose contact with you.**

Name: _____

Address: _____

Phone Number: _____

Was the participant assisted during the consent process in one of 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 participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant.

The person signing below acted as a translator for the participant, during the consent process.

Signature of Person Assisting in the
Consent Discussion

Printed Name

Date

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