

Informed Consent

Harvard School of Public Health

Research into Bronchioloalveolar Cell Carcinoma (BAC) of the Lung

Purpose

You are invited to take part in a research study that looks at the characteristics of bronchioloalveolar cell carcinoma (BAC). BAC is a rare form of lung cancer. Although lung cancer is heavily studied, we know very little about BAC. This research study will help us to understand the epidemiology of BAC (i.e., who gets BAC, when do they get it, what are the risk factors), how we might develop ways of preventing it, and also about its specific characteristics to help develop more effective treatments.

Voluntary Participation

Your participation in this study is completely voluntary. You are free to participate or to stop at any time without any consequence to your regular health benefits or health care.

Procedures

Your participation in this study will involve three parts: (1) completing a questionnaire; (2) allowing the Harvard School of Public Health to obtain existing tissue samples and medical records information about your cancer diagnosis and treatment from your hospital or physician; and (3) providing a blood sample to Harvard for analysis. The following steps will occur:

- We will call you to ask you a few questions about the history of your diagnosis and to verify your address and contact information.
- We will then send you a packet that will include: a copy of this signed consent form, an Authorization to Release Medical Information form, a questionnaire, 2 pre-stamped envelopes, and a blood sample kit with instructions inside the kit.
- You will check that the information on the Authorization to Release Medical Information form (which allows us to obtain existing tissue samples and medical records) is correct, sign it and return it to us in the pre-stamped envelope. This paperwork will give us signed permission to obtain your medical records (information about your cancer diagnosis, testing and treatment) and a sample of your lung tissue from your hospital or clinic. You DO NOT need to provide a new sample of the tumor for this study. For our research, we will use tissue obtained from previous procedures and surgeries you may have had. Please note that your physician may ask you to sign an additional medical release form if they prefer to use their own.
- You will complete the questionnaire and return it to us in the pre-stamped envelope. The questionnaire contains questions about your diet, medical, job-related and environmental history and cancer treatments. The questionnaire should take about thirty minutes to complete. You are free to leave any question unanswered.
- You will provide us with a sample of your blood (two tablespoons) from a licensed phlebotomist. This can be obtained through your physician's office, clinical, lab or hospital, which we can help to coordinate. The blood sample kit will provide specific instructions for you to follow. Your blood will then be sent to Harvard for analysis.

Risks or Discomfort

- There is a slight risk of breach of confidentiality. Please be assured, however, that we will take every step reasonably possible to maintain your privacy and confidentiality.
- You will likely be able to provide a blood sample for this research at the time you get bloodwork done for your usual medical care. In that case, getting the blood sample needed for this study will not involve an additional needle stick. If you need to have a separate blood draw solely for the purposes of providing a blood sample for research, you should know that the risks associated with blood drawing are temporary pain and bruising where the needle enters the skin, and infrequently, fainting and/or infection.

Costs & Payments to You (Money Matters)

You will not be charged for any part of this study, including the blood draw procedure or analysis of your tissue sample. If the laboratory or clinic where you go for your blood draw wishes to charge you for the procedure, please let us know and we will coordinate the payment directly with the clinic.

We will cover any postage expenses, including the shipment of your sample and the questionnaires. If you downloaded this consent and sent it to us by mail, we will reimburse those postage costs. In addition, you will receive \$25 for your participation in this study after we receive your questionnaire, blood and tissue samples.

Benefits

Because much of this research is in its early stages, the research we perform will not impact on the treatment of your BAC, and we will not contact you to provide specific results relating to your blood or tissue samples. However, this study has a potential benefit to others since it will help us to gain a better understanding of BAC.

Confidentiality

We will make every reasonable effort to protect your privacy. Your identity and your relationship to any information that we obtain through your participation in this research study will be kept strictly confidential. Your tissue sample will be used for research purposes only. If, at any time, you wish for it to be removed and destroyed, please contact Dr. Christiani at the number below. The data that we collect from individuals will be used in group form and disclosed (without identifying individual participants) in scientific papers. Only authorized research personnel and ethical review boards (which are interested in protecting human subjects who are in research projects) will have access to your de-identified records.

In case of injury

It is highly unlikely that you would be physically injured as a result of participating in this study. If you are, however, medical treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Compensation is not available, and your insurance carrier may be billed for the cost of treatment.

Questions

Additionally:

- We may need to contact you by telephone at a later date regarding your answers to the questionnaire. We will not contact you for any other reason. Do you agree to this? Please check your option.

YES _____ NO _____

If at any time during the course of this project, you feel that you have not been well enough informed about the study's risks, benefits, alternative procedures, or your rights as a research subject, or if you feel that you have to continue against your wishes, the staff of the Human Subjects Committee is available to speak with you at 617-384-5480. In the event of a research related injury, please contact Dr. David Christiani at 617-432-1261. For more information about this study, please contact either Lia Shimada at 617-432-1261, or by e-mail at [lshimada@hsph.harvard.edu] or Dr. Geoffrey Liu at 617-724-4000, or by e-mail at [gliu1@partners.org].

David C. Christiani, MD, MPH, MS
Professor and Principal Investigator

Storage of Blood and Tissue Samples for Future Research

After we have studied your blood and tissue samples for this research project, we would like to store the sample for future research related to BAC. Your identity will remain strictly confidential, and samples would be stored indefinitely unless you contacted us and asked that your samples be destroyed.

Please check your option:

- I agree that my samples can be stored for future research related to BAC.

YES _____ NO _____

- I agree that my samples can be stored for any type of research

YES _____ NO _____

I have been informed about the above procedures, with their possible benefits, risks, and consequences. I recognize that I am free to ask any questions. I understand that participation is voluntary, and that I am free to withdraw from the study at any time without any consequences.

I will receive a copy of this signed consent form, which will be mailed to me. The Harvard School of Public Health maintains an "Institutional Assurance of Compliance," a document that explains how the School provides for the protection of human subjects, a copy of which is available upon request.

I hereby agree to become a subject in this investigation.

Subject's Signature and Date

Subject's Name (printed)

Contact information:

Daytime Telephone _____

Other Telephone _____

When is the best time to contact you: Day ____ Night ____

Other (specify): _____

Address (for the researchers to mail study materials, questionnaire, and compensation):

Number and Street

Town/City State Zip code

FOR RESEARCH STAFF USE ONLY. PLEASE DO NOT WRITE IN THIS BOX.

This consent form is designed to explain to the subject, _____, the nature and purpose of the procedures described and such risks that are involved in their performance. In addition, I have made myself available by telephone and by e-mail and have answered honestly and to the best of my ability any questions relating to this study and the subject's participation in it.

Investigator's Signature and Date