# UVA Informed Consent

# Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

**Participant's Name**_____ **Medical Record #** _____

**Principal Investigator:** Christopher Moskaluk, MD, PhD
Department of Pathology and Department of Biochemistry & Molecular Genetics
University of Virginia
PO Box 800214
Charlottesville VA 22908
Office: 434-924-8588

**Sponsor:** Department of Defense

## What is the purpose of this form?

This form will help you decide if you want to be in the research study. You need to be informed about the study, before you can decide if you want to be in it. You do not have to be in the study if you do not want to. You should have all your questions answered before you give your permission or consent to be in the study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will get a copy of this signed form.

## Who is funding this study?

This study is funding through a grant to the University of Virginia from the United States Department of Defense Congressionally Directed Medical Research Program (CDMRP).

## Why is this research being done?

The purpose of this project is to *collect* and *store* biologic specimens from people who have lung cancer for use in *future research studies* to help better diagnose and treat this disease.

Lung cancer is the leading cause of cancer related death in men and women today. Doctors and scientists need samples from patients with lung cancer in order to do research to help better understand and treat this problem. Often samples from lung cancer patients are not saved for research, and this has made it difficult to do some types of research. We are working to make a "bank" of specimens from patients with lung cancer to make this available to doctors and scientists to study. The types of specimens we want to collect include tissue samples (from the cancer and surrounding lung tissue), blood, saliva, urine, sputum, and/or bronchial washings (fluid which is collected during a procedure to "wash" or irrigate the lung and/or breathing passages).

You are being asked to be in this study, because you have been diagnosed with a known or suspected lung cancer. Up to 500 people will be in this study at UVA. Up to 1,500 people will be in this study at all places.

Specimens that are collected for this bank will be stored at the University of Virginia in a secure facility, called the **Lung Cancer Biospecimen Resource Network (LCBRN)**, and will be made available to researchers throughout the United States as they seek to improve the understanding, diagnosis, and/or treatment of lung cancer. There are methods in place to protect your privacy and confidentiality.

## What will be done if you agree to provide specimens?

If you agree to participate in this research, we may collect the following specimens from you which would be "left-over" after certain clinical procedures/surgeries which you might have:

**Tissue** – if you are having surgery for your lung cancer, we will collect tissue that is left over after all the clinical tests have been done. No additional tissue would be taken at the time of your surgery only for this specimen bank.

**Bronchial Washings** – if you are having surgery or a procedure where you will have your lungs flushed/ "washed" with water (such as a bronchoscopy or surgery to remove a portion of your lung), we would also like to save the fluid used after the washing as it may contain cells that would be beneficial for research.

The following specimens may be collected only for the purpose of this specimen bank ("extra" specimens that would not routinely be collected from you for your regular care):

**Blood** – We would like to draw up to 4 tablespoons of blood from you during your first year of study participation and then up to 1 tablespoon of blood every 6 months for a maximum of 5 years at times when you are returning to UVA for your regular care. This would be a maximum of about 12 tablespoons of blood over the entire 5 years.

**Urine** – we would like to collect 8 tablespoons of urine from you during your first year of study participation and then up to 2 tablespoons of urine every 6 months for a maximum of 5 years at times when you are returning to UVA for your regular care. This would be a maximum of about 24 tablespoons of urine over the entire 5 years.

**Sputum** – you will be asked to take a deep breath and cough hard until some sputum comes up into your mouth. You will be given a cup to spit the sputum in for donating this type of specimen. If you are not able to cough up any sputum, that is okay. You may be asked to give a sputum sample at two different times.

**Saliva** – we will give you a cotton swab to chew to help make saliva in your mouth. We will collect the swab with your saliva in a plastic tube. We would ask for a saliva sample at two different times.

Not all people will donate all kinds of specimens, and you do not have to donate all types of specimens in order to participate in this research. Your specimens will be identified using a special code. Neither your name or any other personal identifying information (like your initials or birthdate) will be kept with your specimen. The research team here at UVA will keep records that "link" you to your specimens, however this link will not be shared with researchers who receive specimens from the bank.

In addition to your specimens, you are also being asked to give your permission for the people in the specimen bank to record information about your medical history and your condition. We will review your medical record and record information about your medical history such as exposures to substances that may increase your risk for cancer, smoking history, previous medications, and environmental factors. This information helps the researchers to understand more about your specimen, and may be even more useful over time. Again, we will keep your identity private here at UVA, and will not release that to researchers who use specimens from the bank.

If you agree to be a part of this research, we would like to follow up with you either in the hospital after your surgery or at your regularly scheduled clinic visits during the first year and then every 6 months for up to 5 years to see how you are doing, and obtain follow up specimens as possible. You will not be asked to return to UVA specifically for the purpose of this research, however, we would like to obtain additional specimens from you during this time if you are returning to UVA for your care and treatment during the next 5 years. If you do not return to UVA, you may be contacted by telephone at these times to see how you are doing. We will also review your medical record during this time.

Your specimens and information will be stored for an unknown period of time (perhaps years) for future studies. The specimens and information will be destroyed when they are no longer needed.

### If you want to know about the results before the study is done:

Because the research will not have any effect on your care, you will not be given the results of any research performed with your specimen. In addition, no results will be placed in your chart. If information is learned that is believed to be important for your clinical condition, the study doctor at your hospital will be notified. He/she will determine if this information will change the care which you may already be receiving.

## What are the risks of being in this study?

The main risks to providing specimens for genetic testing and/or for future research may be the accidental release of information. An example of this would be if your name was released accidently with the stored specimens and/or the results of the tests run on your specimens. The release of this information that identified you could cause problems with insurance or future employment.

### Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

**Other unexpected risks:**
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

## Could you be helped by being in this study?

Information learned in this study may give useful information about the causes, risks, treatments and prevention of lung cancer which might help people in the future. There is no direct benefit to you for participating in this study.

## What are your other choices if you do not join this study?

You may choose not to participate in this research and not to donate your specimens. You can still receive care and treatment at UVA for your condition even if you do not participate in this research.

## Will you be paid for being in this study?

You will not get any money for being in this study.

## Will being in this study cost you any money?

Being in this study will not cost you any money. Your insurance company will also not be billed for donating your specimens.

## What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader or the sponsor of this study can take you out of the study. Some of the reasons for doing so may include

a) The study sponsor closes the study
b) You are unable to donate a specimen

Unless you notify us, this permission to use your specimen and the information does not expire. If you decide that you do not want us to use your specimens or information after you sign this form, please contact the study physician in writing to let us know that you are withdrawing your permission. The mailing address is:

Dr. Christopher Moskaluk
PO Box 800214
University of Virginia
Charlottesville, VA 22908

At this time, we will stop using your specimens and information.

## How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

## If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address, date of birth, social security number
- Your medical records and test results from before, during and after the study from any of your doctors or health care providers (including mental health care and substance abuse records, and HIV/AIDS records)
- Information needed to bill others for your care
- Tissue or blood samples if you agree to provide them for future research
- Tissue or blood samples if you agree to provide them for genetic testing

## Who will see your private information?

- The researchers to make sure they observe the effects of the study and understand its results
- People or committees that oversee the study to make sure it is conducted correctly
- People who pay for the study (Department of Defense), including insurance companies
- United States Army Medical Research and Material Command (USAMRMC), including the Office of Research Protections (ORP) and Human Research Protection Office (HRPO)
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA)

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

**What if you sign the form but then decide you don't want your private information shared?** You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation. UVa researchers will do everything possible to protect your privacy.

However, they will need to share your information with people who may not have to follow the rules described above. Some of those people may be allowed to share/release your information without your permission.

## Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)

- Leave the study before it is finished
- Express a concern about the study

  Dr. Christopher Moskaluk
  PO Box 800214, University of Virginia, Charlottesville, VA 22908
  Phone: 434-982-4408

## What if you have a concern about a study?

You may also report a concern about a study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

## Signatures

**What does your signature mean?**

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you understand the information given to you about the study and in this form. If you sign the form it means that you agree to join the study.

**Consent From Adult**

| PARTICIPANT (SIGNATURE) | PARTICIPANT (PRINT) | DATE |
|---|---|---|
| | | |

**Person Obtaining Consent**

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

| PERSON OBTAINING CONSENT (SIGNATURE) | PERSON OBTAINING CONSENT (PRINT) | DATE |
|---|---|---|
| | | |

# MUSC Informed Consent

# MEDICAL UNIVERSITY OF SOUTH CAROLINA
# CONSENT TO BE A RESEARCH SUBJECT

## Lung Cancer Biospecimen Resource Network - Biospecimen Collection

**Sponsor: The Department of Defense (DoD) and University of Virginia #5495**
**CTO# 101496**
**PI: Chadrick Denlinger, MD**



## A. PURPOSE AND BACKGROUND

You are being asked to volunteer to participate in a research study because you have lung cancer. The main purpose of this study is to *collect* and *store* biologic specimens from people who have lung cancer for use in *future research studies* to help better diagnose and treat this disease.

Lung cancer is the leading cause of cancer related death in men and women today. Doctors and scientists need samples from patients with lung cancer in order to do research to help better understand and treat this problem. Often samples from lung cancer patients are not saved for research, and this has made it difficult to do some types of research. We are working to make a "bank" of specimens from patients with lung cancer to make this available to doctors and scientists to study. We want to collect include tissue samples (from the cancer and surrounding lung tissue), blood, buffy coat, saliva, urine, sputum, and/or bronchial washings (fluid which is collected during a procedure to "wash" or irrigate the lung and/or breathing passages). The buffy coat is the upper, lighter portion of a blood clot occurring when coagulation (clotting) is delayed or when blood has been centrifuged (process in which white and red blood cells are separated by spinning the blood sample at high rate in a machine called a centrifuge).

Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

1,500 people will be in this study up to 500 of those patients will be enrolled at MUSC under the care of Chadrick Denlinger, MDr. This study is funded through a grant to the University of Virginia (UVA). The Department of Defense (DoD) is sponsoring this study grant.

## B. PROCEDURES

You are eligible to participate in this study because you have either been diagnosed or are thought to likely have lung cancer. Drs. Denlinger will explain the details of this particular study to you and answer any questions that you may have regarding your

potential participation. If you are interested in participating in this study, this consent form will be given to you to read and review in private. If you agree to participate, we will ask you to sign this consent form.

Importantly, your participation in this study will have no influence on the treatments that are provided for you at MUSC. You will receive the standard treatments that are appropriate for patients with lung cancer as determined by your teams of healthcare workers. Participation in this study will involve the collection of tissue samples that are "left-over" after certain clinical procedures/surgeries which you might have:

**Tissue** – if you are having surgery for your lung cancer, we will collect tissue that is left over after all the clinical tests have been done. No additional tissue would be taken at the time of your surgery only for this specimen bank.

**Bronchial Washings** – if you are having surgery or a procedure where you will have your lungs flushed/ "washed" with water (such as a bronchoscopy or surgery to remove a portion of your lung), we would also like to save the fluid used after the washing as it may contain cells that would be beneficial for research.

The following specimens may be collected only for the purpose of this specimen bank ("extra" specimens that would not routinely be collected from you for your regular care):

**Blood and Buffy Coat**– We would like to draw up to 4 tablespoons of blood and buffy coat from you during your first year of study participation and then up to 1 tablespoon of blood every 6 months for a maximum of 5 years at times when you are returning to MUSC for your regular care. This would be a maximum of about 12 tablespoons of blood over the entire 5 years.

**Urine** – we would like to collect 8 tablespoons of urine from you during your first year of study participation and then up to 2 tablespoons of urine every 6 months for a maximum of 5 years at times when you are returning to MUSC for your regular care. This would be a maximum of about 24 tablespoons of urine over the entire 5 years.

**Sputum** – you will be asked to take a deep breath and cough hard until some sputum comes up into your mouth. You will be given a cup to spit the sputum in for donating this type of specimen. If you are not able to cough up any sputum, that is okay.

**Saliva** – we will give you a cotton swab to chew to help make saliva in your mouth. We will collect the swab with your saliva in a plastic tube.

Not all people will donate all kinds of specimens, and you do not have to donate all types of specimens in order to participate in this research. Your specimens will be identified using a special code. Neither your name nor any other personal identifying information (like your initials or birth date) will be kept with your specimen. The research team here at MUSC will keep records that "link" you to your specimens; UVA will also have access to these records. This link, however, will not be shared with researchers who receive specimens from the bank.

In addition to your specimens, you are also being asked to give your permission for the people in the specimen bank to record information about your medical history and your condition. We will review your medical record and record information about your

medical history such as exposures to substances that may increase your risk for cancer, smoking history, previous medications, and environmental factors. This information helps the researchers to understand more about your specimen, and may be even more useful over time. Again, we will keep your identity private here at MUSC as will UVA, and will not release that your private identity to researchers who use specimens from the bank.

Your specimens and information will be stored for an unknown period of time (perhaps years) for future studies. Your specimens will be temporarily stored at MUSC prior to being transferred to UVA. The specimens and information will be destroyed when they are no longer needed.

## C. DURATION

If you agree to be a part of this research, we would like to follow up with you either in the hospital after your surgery or at regularly scheduled clinic visits during the first year and then every 6 months for up to 5 years to see how you are doing, and obtain follow up specimens as possible. You will not be asked to return to MUSC specifically for the purpose of this research. However, we would like to obtain additional specimens from you **if** you are returning to MUSC for your care and treatment during the next 5 years. Specimens would be collected at those visits. If you do not return to MUSC, you may be contacted by telephone at these times to see how you are doing. We will also review your medical record during this time.

## D. RISKS AND DISCOMFORTS

The main risks to providing specimens for genetic testing and/or for future research may be the accidental release of information. An example of this would be if your name was released accidentally with the stored specimens and/or the results of the tests run on your specimens. The release of this information that identified you could cause problems with insurance or future employment.

Research to identify genes that cause or contribute to a disease or trait is an increasingly important way to try to understand the role of genes in human disease. You have been given this consent form because the Medical University of South Carolina investigators want to include your tissue, cell or blood and buffy coat sample in a research project, or because they want to save such biological samples for future research. There are several things you should know before allowing your tissues, cells, blood or buffy coat to be studied or to be stored.

1. Your tissue, cells or blood and buffy coat samples will be stored under your name or some other type of identifier which could be linked to you. Sometimes these samples are shared for research purposes with other investigators at other research sites. If this is done, the other investigators would not know your name.

2. In addition to your name, other information about you might be connected to your blood, buffy coat or tissue sample. For instance, information about race,

ethnicity, sex, your medical history, and so forth might be available to investigators studying your tissue, buffy coat or blood. Such information is important for scientific reasons and sometimes for public health. It is possible that genetic information might come to be associated with your racial or ethnic group.

3. Genetic information about you will often apply (in one degree or another) to family members. It is not generally the University's policy to provide genetic information about you to your family members. However, certain studies, called "pedigree studies", share such information among family members. For this and related research you will be asked if you are willing to share your genetic information with your family members.

4, You have the right to refuse to allow your tissue, buffy coat or to be studied or saved for future research studies. You may withdraw from this study at any time and remove any samples that contain identifiers from research use after the date of your withdrawal. This means that while the University might retain the identified samples-the law often requires this-they would not be used for research.

5. South Carolina law, mandates that your genetic information obtained from any tests or from this research, be kept confidential. Our state law prohibits any insurer using this information in a discriminatory manner against you or any member of your family in issuing or renewing insurance coverage for you or your family. Our state law further prohibits our sharing your genetic information with anyone except in a few narrow circumstances, one of these being a research project of this type, approved by the Institutional Review Board and then we must take all steps to protect your identity. You will still be responsible for paying for health care, however. The Medical University of South Carolina will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

6. Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people feel anxious about the possibility of having a defective gene that would place them or their children at risk. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress. The risks of not knowing what is found include not being aware if there is treatment for the problem being studied. But these risks can change depending on whether there is a treatment or cure for a particular disease, and on how clear the results are. If there is a medical reason to seek specific information from you, your doctor will tell you this. A process called "genetic counseling" is often appropriate in such cases; you should ask your doctor or nurse about this if you have any questions.

Investigators in this study may try to recontact you in the future to find out about your health. If you are recontacted and want to know what the investigators have learned about your samples, you should understand that the following are the kinds of things the investigators or your health team might tell you:

a) Information is too sketchy to give you particular details, but you will receive a newsletter informing you about the results of the project.

b) You carry a gene for a particular disease that can be treated.

c) You can carry a gene for a particular disease for which there is no current treatment. This news might cause severe anxiety or other psychological distress, depending on the severity of the disease.

d) You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene. It can be very difficult to decide whether to share such information with relatives. Genetic counselors can help sort out the various options in such a case.
Also, for any future research, we may contact you with a new consent form giving you additional information.

7. If you are concerned about a potential genetic disorder, you and your doctor might choose to test specifically for it. This would require additional blood or tissue samples and would not be part of this research project. You should discuss this option with your doctor or genetic counselor.

8. The presence of a genetic marker does not necessarily mean that an individual will develop a disease. Informing people of all such markers independently of medical need can cause unnecessary anxiety. On the other hand, the absence of a marker does not mean that someone will not get the disease. Genetic diseases appear as a result of a complex mixture of hereditary, environmental, behavioral and other factors.

These are the best-known risks and challenges of genetic research. There might be other risks we do not know about yet.

It is important that you talk to your doctor, nurse or genetic counselor if you have questions or concerns about the research study.

As a study participant, you may be asked for additional blood samples. This would be collected during regular scheduled office appointments related to your lung cancer care and treatment.

**Risks of having your blood drawn:**

- ✓ pain (common)
- ✓ a bruise (sometimes)
- ✓ fainting or passing out (not very often)
- ✓ infection (rare)

**Other unexpected risks:**

There are no perceived risks associated with collection of sputum or saliva for this study. When you have regularly scheduled doctor and clinic appointments, saliva will be collected in clinic with an oral swab. Sputum will either be collected by asking you to expectorate (cough up and spit) while at clinic, at the time of a routine bronchoscopy or even at the time of a surgical procedure.

You may have side effects that we do not expect or know to watch for now. Call your study doctor if you have any symptoms or problems.

## E. POSSIBLE BENEFITS

Information learned in this study may give useful information about the causes, risks, treatments and prevention of lung cancer which might help people in the future. There is no direct benefit to you for participating in this study.

## F. ALTERNATIVE

You may choose not to participate in this research and not to donate your specimens. You can still receive care and treatment at MUSC for your condition even if you do not participate in this research.

## G. COSTS

Being in this study will not cost you any money. Your insurance company will also not be billed for donating your specimens.

## H. COMPENSATION

You will not be paid for participation in this study.

## I. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance nor will it be part of your academic record at this Institution.

## J. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be part of your personnel record at this Institution.

## K. PATIENT WITHDRAWAL

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at MUSC.

Even if you do not change your mind, the study leader or the sponsor of this study can take you out of the study. Some of the reasons for doing so may include:

a) The study sponsor closes the study
b) You are unable to donate a specimen

Unless you notify us, this permission to use your specimen and the information does not expire. If you decide that you do not want us to use your specimens or information after you sign this form, please contact the study physician in writing to let us know that you are withdrawing your permission. The mailing address is:

Dr. Chad Denlinger
Ashley River Tower (ART)
25 Courtenay Drive
Charleston SC, 29452

At this time, we will stop using your specimens and information.

## L. NEW INFORMATION

Because the research will not have any effect on your care, you will not be given the results of any research performed with your specimen. In addition, no results will be placed in your chart. If information is learned that is believed to be important for your clinical condition, the study doctor at your hospital will be notified. He/she will determine if this information will change the care which you may already be receiving.

## M. SPONSOR COMMITMENT

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at MUSC.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) or other authorities will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that your are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

## Volunteers Statement

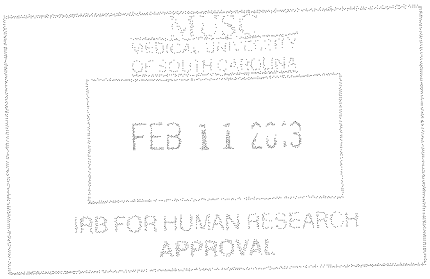
I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Chad Denlinger, MD at (843) 876-4844. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below

| | | | |
|---|---|---|---|
| Signature of Person Obtaining Consent | Date | Signature of Participant | Date |
| Signature of Legal Guardian (if applicable) | Date | | |



# WUSTL Informed Consent

# INFORMED CONSENT DOCUMENT

## Project Title: Lung Cancer Biospecimen Resource Network - Biospecimen Collection

**Principal Investigator:** **Bryan Meyers, MD, MPH**

**Research Team Contact:** **Jo Musick, RN: (314) 747-0707**
**Christine Frederiksen, MS: (314) 362-2412**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form you are agreeing to participate in this study.

- If you have any questions about anything in this form, you should ask the research team for more information.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

**WHAT IS THE PURPOSE OF THIS STUDY?**

This is a research study. You are being asked to be in this study, because you have been diagnosed with a known or suspected lung cancer.

The purpose of this project is to *collect* and *store* biologic specimens from people who have lung cancer for use in *future research studies* to help better diagnose and treat this disease.

Lung cancer is the leading cause of cancer related death in men and women today. Doctors and scientists need samples from patients with lung cancer in order to do research to help better understand and treat this problem. Often samples from lung cancer patients are not saved for research, and this has made it difficult to do some types of research. We are working to make a "bank" of specimens from patients with lung cancer to make this available to doctors and scientists to study. The types of specimens we want to collect include tissue samples (from the cancer and surrounding lung tissue), blood, saliva, urine, sputum, and/or bronchial washings (fluid which is collected during a procedure to "wash" or irrigate the lung and/or breathing passages).

Specimens that are collected for this bank called the "**Lung Cancer Biospecimen Resource Network (LCBRN)"** will be stored in a secure facility located at the University of Virginia (UVA). The specimens will then be made available to researchers throughout the United States as they seek to improve the understanding, diagnosis, and/or treatment of lung cancer. There are methods in place to protect your privacy and confidentiality.

**WHAT WILL HAPPEN DURING THIS STUDY?**

If you agree to participate in this research, we may collect the following specimens from you which would be "left-over" after certain clinical procedures/surgeries which you might have:

- **Tissue** – if you are having surgery for your lung cancer, we will collect tissue that is left over after all the clinical tests have been done. No additional tissue would be taken at the time of your surgery only for this specimen bank.
- **Bronchial Washings** – if you are having surgery or a procedure where you will have your lungs flushed/ "washed" with water (such as a bronchoscopy or surgery to remove a portion of your lung), we would also like to save the fluid used after the washing as it may contain cells that would be beneficial for research.

The following specimens may be collected only for the purpose of this specimen bank ("extra" specimens that would not routinely be collected from you for your regular care):

- **Blood** – We would like to draw up to 4 tablespoons of blood from you during your first year of study participation and then up to 1 tablespoon of blood every 6 months for a maximum of 5 years at times when you are returning to Washington University Medical Center (WUMC) for your regular care. This would be a maximum of about 12 tablespoons of blood over the entire 5 years.
- **Urine** – we would like to collect 8 tablespoons of urine from you during your first year of study participation and then up to 2 tablespoons of urine every 6 months for a maximum of 5 years at times when you are returning to WUMC for your regular care. This would be a maximum of about 24 tablespoons of urine over the entire 5 years.
- **Sputum** – you will be asked to take a deep breath and cough hard until some sputum comes up into your mouth. You will be given a cup to spit the sputum in for donating this type of specimen. If you are not able to cough up any sputum, that is okay.
- **Saliva** – we will give you a cotton swab to chew to help make saliva in your mouth. We will collect the swab with your saliva in a plastic tube.

Not all people will donate all kinds of specimens, and you do not have to donate all types of specimens in order to participate in this research. Your specimens will be identified using a special code. Neither your name nor any other personal identifying information (like your initials or birthdate) will be kept with your specimen. The research team here at WUMC will keep records that "link" you to your specimens; however this link will not be shared with researchers who receive specimens from the bank.

In addition to your specimens, you are also being asked to give your permission for the people in the specimen bank to record information about your medical history and your condition. We will review your medical record and record information about your medical history such as exposures to substances that may increase your risk for cancer, smoking history, previous medications, and environmental factors. This information helps the researchers to understand more about your specimen, and may be even more useful over time. Again, we will keep your identity private here at WUMC, and will not release that to researchers who use specimens from the bank.

Your specimens and information will be stored for an unknown period of time (perhaps years) for future studies. The specimens and information will be destroyed when they are no longer needed.

**Will you save my samples or research data to use in future research studies?**

As part of this study, we are obtaining blood samples, tumor tissue, and health data as described above from you, which will be stored in the LCBRN data and specimen repository to be used for other research projects in the future. A data and specimen repository is formed with the purpose of broad sharing with others in the research community.

With your participation in this study, you are providing permission to share your tissue/blood/data with other investigators doing research in lung cancer. These investigators may be here at WUMC or at other research centers. Only qualified researchers, who have received prior approval from individuals that monitor the use of the data and specimens, will be able to look at your information.

These future studies may provide additional information that will be helpful in better understanding lung cancer, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your tissue/blood/data might be used to develop tests, treatments or cures. There are no plans to provide financial compensation to you should this occur. If you agree to participate in this study, this means we will store your tissue/blood/data and may use it for studies going on right now as well as studies that are conducted in the future.

If you agree to participate in this study and therefore let us store and use your tissue/blood/data for future research, but later change your mind, you should contact Dr. Bryan Meyers at (314) 362-8598. The tissue/blood/data will no longer be used for research purposes. However, if some research with your tissue/blood/data has already been completed, the information from that research may still be used. Also, if the tissue/blood/data has been shared with other researchers it might not be possible withdraw the tissue/blood/data to the extent it has been shared.

**HOW MANY PEOPLE WILL PARTICIPATE?**

Up to 500 people will be in this study at WUMC. Up to 1,500 people will be in this study at all places.

**HOW LONG WILL I BE IN THIS STUDY?**

If you agree to be a part of this research, we would like to follow up with you either in the hospital after your surgery or at your regularly scheduled clinic visits during the first year and then every 6 months for up to 5 years to see how you are doing, and obtain follow up specimens as possible. It is considered routine practice for you to continue your follow-up for 5 years after a cancer diagnosis. You will not be asked to return to WUMC specifically for the purpose of this research, however, we would like to obtain additional specimens from you during this time if you are returning to WUMC for your care and treatment during the next 5 years.

**WHAT ARE THE RISKS OF THIS STUDY?**

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The main risks to providing specimens for genetic testing and/or for future research may be the accidental release of information. An example of this would be if your name was released accidently with the stored specimens and/or the results of the tests run on your specimens.

**Risks of having your blood drawn:**

**Likely / Common**

- pain
- a bruise

**Less Likely / Less Common**

- fainting or passing out

**Rare**

- infection

**WHAT ARE THE BENEFITS OF THIS STUDY?**

Information learned in this study may give useful information about the causes, risks, treatments and prevention of lung cancer which might help people in the future. There is no direct benefit to you for participating in this study.

**WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

Being in this study will not cost you any money. Your insurance company will also not be billed for donating your specimens.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

**WILL I BE PAID FOR PARTICIPATING?**

You will not be paid for being in this research study.

**WHO IS FUNDING THIS STUDY?**

This study is funded through a grant from the United States Department of Defense Congressionally Directed Medical Research Program (CDMRP). This means that Washington University is receiving payments from the United States Department of Defense (CDMRP) to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from CDMRP for conducting this study.

**WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?**

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator Dr. Bryan Meyers at (314) 362-8598 and/or the Human Research Protection Office at (314) 633-7400 or 1-(800)-438-0445.

Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related injury,

please notify the investigator as soon as possible.

**HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?**

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- People who pay for the study (Department of Defense)
- People who use the registry
- Hospital or University representatives, to complete Hospital or University responsibilities
- Washington University's Institutional Review Board (a committee that reviews and approves research studies)
- The LCBRN coordinating center located at University of Virginia
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.

Your primary care physician if a medical condition that needs urgent attention is discovered

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your PHI, including your social security number, relating to your participation in this study will be stored in a secure database at the Siteman Cancer Center. This database and also your treatment records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, we will

This consent form or similar documentation that you are participating in a research study may be included in your clinical medical record. Anyone with access to your medical record, including your health insurance company will be able to see that you are participating in a research study.

- Paper forms and hard copy reports will be stored in a secure area with limited access, under double lock protection within the designated area of the clinical research team here at WUMC. Hard copy records will not be allowed to be transported or transferred outside this storage area. Only investigators for this study and clinicians caring for you will have access to the data.
- Electronic data will be stored in a server that is configured to store data regulated by HIPAA (the Health Insurance Portability and Accountability Act). Only investigators for this study and clinicians caring for the patient will have access to the data. They will each use a unique log-in ID and password that will keep confidential.
- All tissue/blood/data will be stored labeled only with a LCBRN code number and no identifying information (name, medical record number, etc.). The link between the LCBRN code and your identity will be two tiered. The secure LCBRN database will contain the link between the LCBRN code and your local medical record number (MRN), with only LCBRN personnel having access to this database.

- The following security precautions will be implemented for specimens stored in the LCBRN:
  - Specimens will be stored in a locked freezer/ or locked room
  - Specimens will be stored with a LCBRN code number and no HIPAA identifiers

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

**If you decide not to sign this form, it will not affect**

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

**If you sign this form:**

- You authorize the use of your PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use the direct link: http://hrpohome.wustl.edu/participants/WithdrawalTemplate.rtf) or you may request that the Investigator send you a copy of the letter.
    - **If you revoke your authorization:**

- The research team may only use and share information already collected for the study.
- Your information may still be used and shared if necessary for safety reasons.
- You will not be allowed to continue to participate in the study.

**IS BEING IN THIS STUDY VOLUNTARY?**

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

**What if I decide to withdraw from the study?**

You can change your mind at any time. Your permission does not end unless you cancel it. You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu under Information for Research Participants. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

**Will I receive new information about the study while participating?**

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Because the research will not likely have any effect on your care, you will not be given the results of any research performed with your specimen.

**WHAT IF I HAVE QUESTIONS?**

We encourage you to ask questions. If you have any questions about the research study itself, please contact Dr. Bryan Meyers at (314) 362-8598 or one of the nurses listed on the first page of this consent form.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, (314) 633-7400, or 1-(800)-438-0445 or email hrpo@wusm.wustl.edu. General information about being a research participant can be found by clicking "Participants" on the Human Research Protection Office web site, http://hrpohome.wustl.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

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This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

**Do not sign this form if today's date is after EXPIRATION DATE: 06/21/16.**

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

**Statement of Person Who Obtained Consent**

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)