Wake Forest®
School of Medicine

Department/Section of Internal Medicine/Molecular Medicine

PILOT STUDY: METABOLIC AND MICROBIAL PROFILING OF LUNG CANCER

Informed Consent Form to Participate in Research
Andrew Bishop, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to collect exhaled breath, saliva, blood, and urine samples before and after your suspected non-small cell lung cancer surgery to see what your samples can tell researchers about your cancer. You are invited to be in this study because you have suspected non-small cell lung cancer and are having surgery to remove your cancer. Your participation in this research will involve 2 visits and last about 5 weeks. These visits will coincide with your pre-surgery and post-surgery follow up appointments.

Participation in this study will involve non-invasive sample collections (breath, saliva, and urine with an optional blood collection), pre-surgery collection, and post-surgery follow-up collection. All research studies involve some risks. The risks to this study that you should be aware of is bruising, discomfort, bleeding, and infection of blood draws. The risks of this study beyond the surgical procedures are minimal. This study will require 1 additional blood draw at your postsurgical follow up appointment. There is not the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include not participating in the study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Andrew Bishop, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:Andrew Bishop, PhD.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board or the Research Subject Advocate at Wake Forest.

INTRODUCTION

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00059167
Meeting Date Approved 6/11/2020
Version Valid Until: 6/10/2021

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have suspected non-small cell lung cancer and you will have surgery to remove your tumor. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to look at your non-invasive samples (breath, saliva, blood, and urine) for any changes before and after your surgery. These samples will help researchers find out if there are specific compounds in your samples that may identify lung cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

90 people will take part in this study at Wake Forest Baptist Medical Center only.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will have the following tests and procedures:

Today, following your meeting, we will be asked of your smoking status. We will collect two breath samples, a saliva sample, a urine sample, and an optional blood sample. This will take place in an adjacent examination room where we will also ask you a few brief dietary and tobacco use questions. Before your follow-up appointment, a staff member will call you with a reminder for the study collections at your 1 month follow up appointment. Four weeks after your surgery (during your follow-up appointment), you will be asked the same dietary and tobacco use questions and we will collect two breath samples, a saliva sample, a urine sample, and an optional blood sample.

If you choose to provide a blood sample, you will have approximately two tablespoons of blood withdrawn from a vein today and after your surgery. The total amount of blood withdrawn during the study will be approximately four tablespoons.

Agree to provide blood (Please Initial): Yes _____
No _____

You will have two breath tests performed to collect exhaled breath today and after your surgery. The first test will collect approximately 6 minutes of exhaled breath. You will be asked to breathe into a collection device which will be placed over your nose and mouth. The second collection will require you to breathe into a collection tube for 10 minutes.

You will have approximately 5 teaspoons of urine collected today and after your surgery. The total amount of urine collected during the study will be approximately 10 teaspoons.

You will have about half a teaspoon of saliva collected today and after your surgery. The total amount of saliva collected during the study will be about 1 teaspoon.

STORAGE OF BIOLOGICAL SPECIMENS

In the future, research on your specimen may involve whole genome sequencing.

Your sample will be obtained in the Comprehensive Cancer Center at Wake Forest University Baptist Medical Center. The sample will be stored at the Wake Forest Biotech Place research laboratory in Winston-Salem, NC and it will be given only to researchers approved by Andrew Bishop, PhD. An Institutional Review Board (IRB) must also approve any future research study using your samples. In order to participate in this study, you must be willing to provide these samples for future research.

The research that may be performed with your blood, exhaled breath, urine, and saliva samples are not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood, tissue, exhaled breath, urine, and saliva samples will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood, tissue, exhaled breath, urine, and saliva samples will not affect your care.

Your blood, tissue, exhaled breath, urine, and saliva samples will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

Your blood, tissue, exhaled breath, urine, and saliva samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future.

____YES you many contact for future research studies

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00059167
Meeting Date Approved 6/11/2020
Version Valid Until: 6/10/2021

____NO I do not want to be contacted regarding future research studies.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 5 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

There are no additional costs to you by participating in this study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a prepaid cash card in the total of $50.00 for providing both pre- surgery and post-surgery collection time points.

Parking validation will be provided for all study-related visits.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Lung Cancer Initiative of North Carolina. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by

law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Andrew Bishop, PhD.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** medical history, smoking status, current medications, collection of your exhaled breath, saliva, blood, and urine, and the measurement of your tumor.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any

publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be deidentified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Andrew Bishop, PhD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Andrew Bishop, PhD, Assistant Professor
Internal Medicine/ Molecular Medicine
Wake Forest Baptist Health
Medical Center Blvd
Winston Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00059167
Meeting Date Approved 6/11/2020
Version Valid Until: 6/10/2021

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB or the Research Subject Advocate.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00059167
Meeting Date Approved 6/11/2020
Version Valid Until: 6/10/2021