Official Title: LCI-LUN-IMM-BIO-001: A Prospective Study Of Immune Signatures In Metastatic Non-Small Cell Lung Cancer (mNSCLC) Patients At Completion Of Immune Checkpoint Inhibitor Treatment Either As Monotherapy Or In Combination With Chemotherapy In The First Line Setting
NCT05415358
IRB-Approved Date: 1/3/2025

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Atrium Health Wake Forest Baptist Comprehensive Cancer Center / "A Prospective Study Of Immune Signatures In Metastatic Non-Small Cell Lung Cancer (mNSCLC) Patients At Completion Of Immune Checkpoint Inhibitor Treatment Either As Monotherapy Or In Combination With Chemotherapy In The First Line Setting"**
Protocol Number:	**LCI-LUN-IMM-BIO-001**
Principal Investigator: (Study Doctor)	**Kathryn Mileham, MD**
Telephone:	**[redacted] (24 Hours)** **[redacted] (24 Hours)**
Address:	**Levine Cancer Institute** **[redacted]**

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. You will discuss the Informed Consent Form with the study staff and the study investigator in person, during a telephone call or via a secure video conference call.

If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form. If you agree to take part in the study, you will sign and date the Informed Consent Form either by signing and dating a copy of the printed paper form or by signing and dating electronically using the Florence eConsent platform. Written consent can be done in person or remotely using electronic consent.

After you have signed and dated this paper or electronic Informed Consent Form, you will be given a paper copy or be able to save a copy for your records and/or email a copy to yourself.

INTRODUCTION

The Study Doctor (Principal Investigator) listed on the first page of this form is asking you to participate in this research study at Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC). The purpose of this study is to examine your blood and understand recurrence or the chance of your cancer coming back. You are being asked to take part in this study because you have metastatic non-small cell lung cancer (mNSCLC) that has been treated with an immune checkpoint inhibitor either alone or together with chemotherapy as the first line of treatment. It is already understood which patients are most likely to benefit from being treated with immunotherapy such as immune checkpoint inhibitors and we hope to gain knowledge about risk factors of cancer worsening in patients who have been treated with immune checkpoint inhibitors. Additionally, information is being reviewed like age, gender and smoking status to identify any factors that might affect how long the treatment keeps working.

In this observational research study, your blood will be studied by looking at markers at the time of treatment completion. These markers will help us to see if there are any factors that make progression of your cancer more likely at the completion if immune checkpoint inhibitor treatment.

If you agree to take part in this study, you will have a blood sample collected up to 3 time-points over the length of your study participation. These collections will occur during a standard of care visit you already have scheduled. If you do not have a standard of care visit scheduled during any of the three time-points, an appointment will be made for you to come in to have blood drawn for research purposes. You will also be given the option to allow permission for any remaining collected blood to be kept for future unplanned research. Your blood samples collected for research will not be labeled with any information to identify you, only a unique ID number. You will not receive any results from your blood samples.

You may also have a biopsy performed as directed by your doctor as a part of routine care at time of progression. During the biopsy, a small portion of tumor tissue will be removed. We would like to keep a portion of leftover tissue. The leftover tumor tissue from your biopsy will be collected for research purposes. We will also obtain previously biopsied tissue that was collected before you started anti-cancer therapy, if available, to use for research purposes.

Information will be collected throughout study participation from imaging scans completed as part of routine care throughout study participation. This information will show if your cancer is the same, better or worse.

Samples collected on subjects during screening who decide not to participate or are considered not eligible for this study, will be destroyed.

There will be approximately 23 subjects who participate in this study at Atrium Health Wake Forest Baptist Comprehensive Cancer Center. Subjects will remain on study for approximately 6 months or until progression, whichever comes first.

Affix Participant Barcode Label Here

WHAT WILL HAPPEN DURING THE STUDY

To participate in this study, you will need to review, sign, and date this consent form and provide authorization (permission) for the release of your medical records for research purposes. By doing so, you are giving us permission to determine if you are eligible to participate in the study.

Screening:

- You will be asked questions about your demographics including smoking status
- Information about your medical history will be collected to include cancer type, cancer treatment, best response from treatment, history of prior malignancies, race, ethnicity, history of HIV, hepatitis B or C and history of autoimmune disease

Baseline:

- Blood collection for research
- Collect data from standard of care imaging
- Tissue that was collected before you started anti-cancer therapy, if available, will be collected for research purposes.

3 Months Visit (after immune checkpoint inhibitor **completion):**
Note: This visit will not occur if you have disease progression prior to this time-point

- Blood collection for research
- Collect data from standard of care imaging

Disease Progression:

- Blood collection for research prior to starting a new anti-cancer therapy only if progression occurs prior to 6 months after immune checkpoint inhibitor completion
- Collect data from standard of care imaging
- If you have a biopsy as part of routine care, some of the tissue will be collected for research purposes.

6 Months Visit (after immune checkpoint inhibitor **completion):**
Note: This visit will not occur if you have disease progression prior to this time-point

- Blood collection for research
- Collect data from standard of care imaging

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YOUR ROLE IN THE STUDY

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include telling the truth about your medical history and keeping scheduled lab appointments/visits for blood draws.

RISKS OF THE STUDY

Blood Draw Risks

Taking blood from a vein in your body may cause some pain, redness or bruising at the site where the blood is drawn. You may also feel faint or lightheaded. Although rare, an infection at the site of the blood draw is possible.

Unknown Risks

This research study has minimal physical risks to you because the only procedures involved are blood draws. There may be other risks that are unknown. Please tell the study doctor or study staff right away if you experience any new problems.

ALTERNATIVES TO BEING IN THE STUDY

You do not need to take part in this research study. There is no alternative to being in this study other than to not participate. The blood collection results will not change the management of your cancer by your treating physician.

POTENTIAL BENEFITS OF BEING IN THE STUDY

You will not receive any benefit from being in the study. Information in this study may help other people with your disease in the future.

COSTS OF BEING IN THE STUDY

The lab tests required by the study are done at no cost to you. You or your insurance carrier will be billed in the usual manner for all other standard of care procedures.

YOUR PAYMENT FOR BEING IN THE STUDY

You will not be paid to be in this study.

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STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use from the study sponsor.

COMPENSATION FOR INJURY

In the event that you are injured as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You will be responsible for deductibles, co-payments, and co-insurance. There are no plans to pay or give you other compensation for the injury. You do not waive any legal rights by signing this consent form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

For insurance or other payment reporting purposes, we may need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because we may have to check to see if you receive Medicare and if you do, report the payment we make to Medicare.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

CONFIDENTIALITY

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by the Sponsor, by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

Affix Participant Barcode Label Here

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you

_____

Printed Name of Research Subject

must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

LCI-LUN-IMM-BIO-001: A Prospective Study of Immune Signatures In Metastatic Non-Small Cell Lung Cancer (mNSCLC) Patients At Completion Of Immune Checkpoint Inhibitor Either As Monotherapy Or Combination With Chemotherapy In the First Line Setting

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Study sponsor and/or its associated companies
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Other persons or agents authorized by the study sponsor
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations
- Data coordinating centers that will receive and process PHI; and/or;
- Advarra Institutional Review Board (Advarra IRB) or Data Safety and Monitoring Boards.

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization.

Affix Participant Barcode Label Here

You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to the Study Doctor at the address listed on the first page of this form.

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by you in writing as described above.

_____

Signature of Research Subject

_____

Printed name of Research Subject

_____

Date

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

Affix Participant Barcode Label Here

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00058707.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

BEING A STUDY VOLUNTEER AND WITHDRAWING FROM THE STUDY

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons

NEW INFORMATION ABOUT THE STUDY

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Affix Participant Barcode Label Here

OPTIONAL AND FUTURE STUDIES-BIOSPECIMEN COLLECTION

The study doctor and her associates (the investigators) are asking you to allow your remaining blood from already collected study labs to be stored for future unplanned research. Regardless of your decision to participate in this blood storage, you may still participate in the study, if you choose to. However, you must agree to participate in the main study in order to be eligible for participation in this optional tissue storage.

If you agree to all your remaining blood from already collected study labs to be stored, it will be stored indefinitely at the Levine Cancer Institute Biospecimen Repository, a place where human samples are securely stored and where any of your remaining archived and/or freshly collected samples will be stored.

If you decide at a later date to withdraw your consent for any reason, you have the option not to allow Atrium Health Wake Forest Baptist Comprehensive Cancer Center to use your blood for testing by contacting the study doctor at the telephone number or address listed on the first page of this form. Blood samples will be destroyed only if they have not already been tested.

Participation in this blood storage is optional and refusing to participate will not affect your eligibility for the study.

Do you give permission to have remaining blood from already collected study labs to be stored for future unplanned research?

Yes_____ No_____ Initials_____

Affix Participant Barcode Label Here

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____

Signature of Research Subject Date Time

_____

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____

Signature of Person Explaining Consent Date Time

_____

Printed Name of Person Explaining Consent

Affix Participant Barcode Label Here