Informed Consent Form

A Phase 2 Study of Defactinib and Avutometinib, in Combination with Nivolumab for patients with anti-PD1 refractory LKB1-Mutant Advanced Lung Adenocarcinoma

NCT Number: NCT06495125

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 50 people who are being studied, at Emory, and Saint Joseph's Hospital.

Why is this study being done?

This study is being done to answer the question: Will treatment with the oral drugs Defactinib and Avutometinib along with Nivolumab be effective against your cancer. You are being asked to take part in this study because you have advanced stage non-small cell lung cancer. Your cancer has been treated with standard immunotherapy and chemotherapy; your scans show that the cancer is beginning to get worse again and a new treatment approach is needed.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will remain on study treatment as long as you are getting a benefit from it. If you come off study treatment, you will be contacted every 3 months for up to 5 years and asked how you are doing and to see if you started any new drugs for your cancer. The researchers will ask you to do the following: You will be asked to take medicines called Defactinib and Avutometinib by mouth and receive nivolumab through IV. Blood will be taken during the study and processed by the local laboratory to monitor your health. You will participate in other clinical assessments as detailed below. Your temperature, weight, blood pressure and pulse rate will be taken at each study visit. You must also keep track of the pills you take in the study diary. Some of these procedures will be paid for by the study. If your disease harbors a protein mutation, you may forego the potential clinical benefit of oral protein inhibitors by choosing to enroll in the trial without prior therapy with an oral protein inhibitor.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. This study is not intended to benefit you directly. It is possible that the combination of Defactinib

and Avutometinib with Nivolumab has greater effect on your cancer than treatment with immunotherapy alone.

What are the risks or discomforts you should know about before deciding?
The study will take time. The drug combination that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Diarrhea, nausea, vomiting fatigue loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
If you choose not to part in this study, you can still receive care. This may include other chemotherapies such as docetaxel with or without ramucirumab, participation in another clinical trial, or supportive care.

Costs
The study sponsor, Emory, and Saint Joseph's Hospital will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: A Phase 2 Study of Defactinib and Avutometinib, in Combination with Nivolumab for patients with anti-PD1 refractory LKB1-Mutant Advanced Lung Adenocarcinoma

IRB #: STUDY0006144

Sponsor Investigator: Conor Steuer, MD

Co-Principal Investigator: Suresh S. Ramalingam, MD

Study Supporter: Verastem

Study Funder: NCI Lung Cancer P01 CA257906

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to learn if treatment with oral drugs defactinib and avutometinib along with nivolumab lead to better outcomes in patients that have lung cancer.

What will you be asked to do?

You will participate in the pre-study activities which include a physical, a medical history, EKG, scans (PET or scan of chest and abdomen), an ophthalmologic test, and blood draws. You will be asked to take 200 mg of defactinib (by mouth) twice daily for 21 days, and 3.2 mg of Avutometinib (by mouth) twice weekly for 21 days in combination with 480 mg of nivolumab (intravenously) on day 1 of each cycle. Treatment cycles will be repeated every 4 weeks. The time between screening and the start of treatment is typically 28 days.

You must avoid grapefruit, grapefruit juice, St. John's Wort and other medications (with or without prescriptions), supplements, herbal products or foods that influence liver enzymes.

You must also keep track of the pills you take in the study diary.

If your cancer harbors a protein mutation, you may forego the potential clinical benefit of oral protein inhibitors by choosing to enroll in the trial without prior therapy with an oral protein inhibitor.

How will your study drug be provided?

The study drugs (avutometinib and defactinib) that you will take will be dispensed by Investigational Drug Services and delivered to the principal investigator or study team member. Nivolumab will be supplied commercially. The principal investigator or health care providers on his/her research team will provide the study drugs to you. If you have questions about the study drug, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the study drugs. The number for the pharmacy is included on your study drug packages, if given one.

Note: The research team for this study includes non-licensed team members who may obtain your consent or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

Defactinib and Avutometinib are relatively new investigational therapies, there may be unexpected side effects in addition to those listed in the table below.

ORAL MEDICATION RISKS

Defactinib	Avutometinib (VS-6766)
Side effects seen in greater than 75% of participants:	
• None	Skin disorders, such as rash, are a common side effect. Your study doctor may need to give you medicine to treat the rash. More specific skin reactions include:

	• A skin condition that causes acne-like bumps or large patches, sometimes on the face, scalp, chest, and upper back. The bumps on the affected skin are usually red, filled with pus and may crust over.
Side effects seen in 50% to 74% of participants:	
• None	Issues related to digestion, including stomach and bowel, such as: • Diarrhea (loose stools) • Nausea (feeling sick)
Side effects seen in 25% to 49% of participants:	
• Generalized stomach issues: • Diarrhea (loose stools) • Nausea (feeling sick) • Feeling more tired than usual	Generalized stomach issues such as: • Vomiting (throwing up) Eye disorder such as: • Decreased ability to see. As a precaution, your eyes will be tested periodically during this study. However, <u>you must immediately report to your study doctor if you observe any problems with your eyes.</u> Some laboratory values changes such as: • Increase in value that measures injury or stress to the muscle tissue or the heart. Symptoms may include muscle weakness, or pain and cramps. • Swelling in the feet and ankles • Feeling more tired than usual.
Side effects seen in 10% to 24% of participants	
Generalized stomach issues such as: • Vomiting (throwing up) • Constipation • Decreased appetite Some laboratory values may increase such as: • Increased levels of bilirubin, a break down product of red blood cells. This could include jaundice, a yellowing of your skin or whites of your eyes or	Some laboratory values changes such as: • Increase in an enzyme, aspartate aminotransferase or AST, found in the blood that may indicate damage to the liver. • Low levels of a blood protein called albumin, which can cause generalized swelling and may suggest a problem with your liver. • Decrease of appetite • Constipation • Stomatitis, which is a swelling of the mouth and/or lips. Symptoms include

darkening of the urine. Blood chemistry will be tested during this study. However, you must immediately report to your study doctor if you observe either of these symptoms. • Shortness of breath • Cough • Swelling in the feet and ankles • Pain in the joints • Headache	redness inside the mouth or individual painful sores that can make it uncomfortable to eat. • Redness, hot, and often painful swelling of the tissues next to the nail of a finger or toe usually with infection and pus formation.
Rare cases (less than 10% of participants) or seen at higher doses than will be given in this study or as seen with other similar drugs:	

• None	• Eye Disorders:
	  • Damage to the inside of the eye causing tiny specks that seem to drift through your field of vision, sometimes called floaters, flashes of light in one or both eyes, and blurred vision.
	  • Loss of blood flow to the inside of the eye causing blurry vision or partial or complete loss of vision (blindness) which could be permanent.
	  • Some laboratory values changes such as: Increase in an enzyme, alanine aminotransferase or ALT, that measures damage to the liver.
	• Swelling of the inner lining of the gut, with symptom of burning or tingling sensation.

All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters.

As avutometinib and defactinib are relatively new investigational therapies, there may be unexpected side effects in addition to those listed above.

Intravenous Medication Risks

Nivolumab
More Common Risks (seen in approximately 50% of patients)
• Back pain • blistering, peeling, or loosening of the skin • blurred vision • bone, joint, or muscle pain • burning, numbness, tingling, or painful sensations • change or loss of taste • chest tightness • chills • constipation • cough • depressed mood • diarrhea • difficulty in moving • dizziness • dry skin and hair
Less Common Risks (Seen in approximately 40% of patients)
• Chest pain • dark urine • general feeling of discomfort or illness • light-colored stools • pain • sensitivity to heat • stomach cramps • sweating • tenderness • thickening of bronchial secretions
Rare Risks (Seen in approximately 10% of patients)
• Bloating • bloody or cloudy urine • change in vision • darkening of the skin • drowsiness • eye pain • fruity breath odor • increased hunger, thirst, and urination • indigestion

- mental depression
- pains in the stomach, side, or abdomen, possibly radiating to the back
- redness of the eye

You should use prophylactic (preventative) medications during the first 2 cycles of avutometinib and defactinib dosing (optional starting with Cycle 3) to help fight skin toxicities. Hydrocortisone 1% cream, moisturizer and sunscreen (sun protection factor [SPF] ≥30) or higher should be applied topically twice daily, along with a systemic antibiotic (minocycline 100 mg daily or doxycycline 100 mg twice daily). Application of topical agents should include the most commonly affected skin areas such as face, scalp, neck, upper chest, and upper back. In addition, you should avoid unnecessary exposure to sunlight.

You will be exposed to radiation from nuclear medicine and CT scans. These procedures are necessary for your medical care and will occur even if you do not participate in this study. The radiation dose estimate that you will receive is equal to or less than the radiation exposure allowed to be received by a radiation worker for 5 years. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. Although the risk from radiation is cumulative it is not expected to adversely affect your condition or treatment. The Emory University Radiation Safety Committee has reviewed and approved the use of radiation in this research study.

If it is biologically possible for you to become pregnant: to protect against possible side effects of the study drug, people who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a person of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study and for 1 month after study completion. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant people will be taken out of the study and monitored for any possible effects until the time of birth). Female patients should not breastfeed during the study and for at least 3 weeks after the last dose of avutometinib (VS-6766).

If it is biologically possible for you to make someone pregnant: the effect of the study drug on sperm is not known. To protect against possible side effects, you should not get a sexual partner pregnant while taking the study drug and for 3 months after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study. Male patients must also refrain from donating sperm during their participation in the study and for at least 3 months after the last dose of avutometinib (VS-6766).

If you will take the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may not benefit from joining the study. Your condition may improve while you are in this study or it may get worse. This study is designed to learn more about advanced stage lung adenocarcinoma. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will not be compensated for being in this study.

What are your other options?

If you choose not to join this study, you can get care outside of this study. Other standard of care medications and therapies that are used to treat NSCLC, including chemotherapy, with or without immune therapies, or bevacizumab.

- Treatment with medications that will make you feel more comfortable but have no effect on your cancer
- Other experimental treatments
- Palliative care: If you decide that you don't want any more active treatment, one of your options is called "comfort care", also called palliative care.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory, Saint Joseph's Hospital will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory, or Saint Joseph's Hospital received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory, and Saint Joseph's Hospital from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study drug manufacturers or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data and specimens that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data and specimens may be useful for other research being done by investigators at Emory, Saint Joseph's Hospital or elsewhere. We may share the data or specimens, linked by the study code, with other researchers at Emory, Saint Joseph's Hospital or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory, Saint Joseph's Hospital. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

How is my Genetic Information Protected? What are the Risks?

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement

policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege

In the State of Georgia, in some circumstances your genetic information may have special legal protections called "privilege." This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law.

Medical Record

If you have been an Emory, or Saint Joseph's Hospital patient before, then you already have an Emory or Saint Joseph's Hospital medical record. If you have never been an Emory or Saint Joseph's Hospital patient, you do not have one. An Emory or Saint Joseph's Hospital medical record will be made for you if an Emory Atlanta, or Saint Joseph's Hospital provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory, Saint Joseph's Hospital medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include:

- Study drug administration procedures
- Tumor Measurements
- Tumor Genomic Testing

Tests and procedures done at non-Emory, or Saint Joseph's Hospital places may not become part of your Emory, or Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory, Saint Joseph's Hospital will help you get immediate medical care. However, Emory, Saint Joseph's Hospital, and the Federal Government (including but not limited to the National Institutes of Health as applicable) do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory, Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover. Emory, Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory, Saint Joseph's Hospital and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory, Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- Pregnancy
- Significant study intervention non-compliance or if any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- Participant unable to receive study drug for a continuous duration beyond 4 weeks

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as the drug manufacturer, laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory, Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Verastem, Inc. is the manufacturer of the study drugs. The manufacturer may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the drug manufacturer may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:

  - Emory, Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory, Saint Joseph's Hospital Research and Healthcare Compliance Offices, and the Emory, Saint Joseph's Hospital Office for Clinical Research.
  - Other researchers and centers that are a part of this study.
  - Government agencies that regulate the research as applicable to this study (e.g. regulatory agencies within and outside the United States such as the Office for Human Research Protections, Food and Drug Administration, and public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Conor Steuer, MD
Winship Cancer Institute of Emory University 1365-C Clifton Road NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly, and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your PHI to people who are not covered by the Privacy Rules, then your PHI won't be protected by the Privacy Rules. People who do not have to follow the Privacy Rules can use or disclose your PHI to others without your permission if they are not required by law to protect the privacy of your PHI.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove specific identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without those specific identifiers may be used or disclosed to other people or organizations for purposes besides this study without your further consent.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Conor Steuer, MD at 404-778-5378

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke**. 

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**

Optional Study Information

What is the purpose of this study?
To identify biomarkers (measurable substance) in tumor tissue that predict for a favorable or unfavorable outcome related to disease processes.
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What will I be asked to do?
If participating in this substudy, a biopsy will be taken. This is where a needle will be placed into the tumor and a small amount of tissue removed for laboratory testing.

Risks for Biopsy Include:

- Excessive bleeding (rare)
- Infection
- Puncture damage to nearby tissue or organs
- Skin numbness around the biopsy site

Will I benefit directly from the study?
This sub-study is not designed to benefit you directly. Your lung cancer may improve while you are in this study but it may not, and it may even get worse. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will not be offered compensation for being in this sub-study.

What are my other options?
You can participate in the main study and not take part in this sub-study.

Withdrawal from the Sub-study
You have the right to leave this sub-study at any time without penalty. You may stay in the main study even if you leave this sub-study.

The researchers also have the right to stop your participation in this sub-study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- Pregnancy
- Significant study intervention non-compliance or if any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

- Participant unable to receive study drug for a continuous duration beyond 4 weeks

Contact Information
See contact information for the main study, above.

HIPAA Authorization for Optional Sub-study

You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not, you can still be in the main research study.

Your PHI will be used in the Optional Sub-study the same way it will be used and disclosed for the main study.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY
Please **print** your name, **sign**, and **date** below if you agree to be in the optional study(ies) described above. By signing this form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____
Signature of Subject (18 or older and able to consent) Date Time

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time