# Informed Consent Form

WINSHIP4400-18: Pilot Integrated Biomarker Trial of VX15/2503 in Combination with Ipilimumab or Nivolumab in Patients with Resectable Metastatic Melanoma

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EMORY UNIVERSITY | Institutional Review Board
Research Administration

EMORY | WINSHIP CANCER INSTITUTE
A Cancer Center Designated by the National Cancer Institute

**You Are Being Asked to Be in a Research Study**

**What Is a Research Study?**

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

**Do I Have to Do This?**

**No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.**

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

**What Is This Document?**

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

**What Should I Do Next?**

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this and talk about it with your family and friends.

**Emory University**
**Consent to be a Research Subject / HIPAA Authorization**

**Title**: Pilot integrated biomarker study of VX15/2503 in combination with ipilimumab or nivolumab in patients with resectable metastatic melanoma

**Principal Investigator:** Michael Lowe, MD, MA

**Investigator-Sponsor:** Michael Lowe, MD, MA

**Study-Supporter**: Vaccinex, Bristol-Myers Squibb

## Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that 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.

Vaccinex and Bristol-Myers Squibb, as a study-supporters, have agreed to manufacture and provide the study drug, VX15/2503, and to provide certain other financial support to conduct the study. Vaccinex and Bristol-Myers Squibb are not the sponsors of this study.

## What is the purpose of this study?

The purpose of this study is to find out what effects, good and/or bad, VX15/2503 (the "study drug") in combination with nivolumab and/or ipilimumab (immunotherapy agents) have on you and your cancer. The study drug and immunotherapy agents kill cancer cells in different ways. Giving these treatments may make your cancer shrink or slow down its growth before your surgery.

This is a pilot study of VX15/2503 in combination with nivolumab and/or ipilimumab. VX15/2503 is an experimental drug; it is not approved by the Food and Drug Administration (FDA). Nivolumab and ipilimumab are FDA approved for melanoma, but not for use before surgery.

The study drug and its combination with nivolumab and/or ipilimumab is considered "investigational" because the combination is not approved by the FDA for use. The study drug has been previously tested in humans. This study will help researchers determine what the side effects and drug interactions might be.

**What will I be asked to do?**

**Screening Visit**
Your first visit will make sure that you are able to participate in this study. The visit will take place within 14 days before you have your first treatment with the study drug. The following tests and procedures must be done. Most of the tests are part of your routine medical care. Your doctor, with the help of study staff, will:

- Obtain your complete medical history
- Review any medications you have taken or are currently taking
- Do a complete physical examination (including height and weight)
- Record your vital signs (body temperature, heart rate, blood pressure and breathing rate)
- Record your performance status (how well you are able to perform your everyday activities)
- Do tests to monitor your heart functions. One is called an electrocardiogram (ECG). This test measures the electrical activity of the heart. The other is called an echocardiogram, which is an ultrasound of the heart
- Collect blood samples (about 3 ¼ teaspoons [16 mL]) and a urine sample to check blood cell counts, organ function, the clotting of your blood and baseline levels of other chemicals. If you are a woman who is able to have children, a pregnancy test will be performed in this blood to see if you are pregnant.
- A computed tomography (CT) or positron emission tomopgraphy (PET) scan and brain magnetic resonance imaging (MRI) to find out the size and location of your tumor(s) at the beginning of the study.
- We will also collect any tumor tissue you may have available from previous biopsies or surgeries. A new biopsy will be obtained at the time of diagnosis/enrollment.

**PET and CT Scan:** A PET or CT scan allows your doctor to see inside your body to look at the size of your tumor(s). For the PET and CT scan an IV (intravenous) line may be started by a needle stick in the arm so a contrast liquid can be injected through the line. The IV contrast liquid is a special dye used to get clearer pictures of your body. You will lie flat on a table that will move you into the CT scanner, which is a large, tunnel-shaped machine. You will be asked to lie still and may be asked to hold your breath for a few seconds. The CT scan takes about 30 to 60 minutes and is considered a part of your standard medical care.

**MRI Scan:** An MRI scan also allows your doctor to see inside your body to see the size of your tumor(s). You may be given gadolinium (a contrast liquid) through a vein in your arm. Gadolinium is a liquid that causes some tumors to appear much brighter than normal tissue on MRI scans. Before gadolinium is injected, the tumor may not be visible. An intravenous (IV) catheter (a tiny tube) may be placed in your arm to inject the

contrast liquid. You will then lie on a table that will move into a large tunnel-shaped machine (similar to a CT scan). The MRI scan uses radio frequency waves (like those in an AM/FM radio) and a strong magnet to create a picture of your tumor(s). The MRI scan takes about 30 minutes and is considered a part of your standard medical care.

The results of the screening tests will show whether you are able to take part in this study. If you are able to take part and still want to participate, you will plan another visit to start your treatment.

**Treatment:**
If you chose to undergo treatment, you will get your first dose of drug within the 14 days after your screening visit. You will be enrolled into 1 of 4 possible treatment arms: a) VX15/2503 and nivolumab, b) VX15/2503 and ipilimumab, c) VX15/2503, nivolumab and ipilimumab, or d) nivolumab alone. Patients that choose to receive treatment will be assigned to treatment groups in order. If you are receiving drug treatment, you will receive the drugs on day 1 and 21, and then proceed to surgery 2-4 weeks following that. If you are not receiving drug treatment, you will proceed to surgery immediately and will not complete an End of Treatment visit.

45 patients will be enrolled at Emory.

**Study procedures:**

**Day 1:** The following procedures will take place:
- Record your vital signs (body temperature, heart rate, blood pressure and breathing rate)
- Collect blood samples (about 7.5 teaspoons [37.5 mL]) to check blood cell counts, organ function, and collect blood for research testing.
- The study drug will be given to you through a vein and it will take about one hour (if given alone), and up to 2.5 hours if study drug is given in combination with nivolumab or ipilimumab.
- We will ask you questions about any side effects you had since your last visit and about any changes in your medications
- After your treatment, we will collect blood samples (about 3.5 teaspoons [17.5ml]) to test the level of the drug in your bloodstream, and for research testing.

**Day 21:**
- Record your vital signs (body temperature, heart rate, blood pressure and breathing rate)
- Collect blood samples (about 7.5 teaspoons [37.5 ml]) to check for changes in chemicals caused by the study drug and drug level.
- The study drug will be given to you through a vein and it will take about one hour (if given alone), and up to 2.5 hours if study drug is given in combination with nivolumab or ipilimumab.
- We will ask you questions about any side effects you had since your last visit and about any changes in your medications
- After your treatment, we will collect blood samples (about 3.5 teaspoons [17.5ml]) to test the level of the drug in your bloodstream, and for research testing.

**Within 24 hours before your surgery:**

- Collect blood samples (about 7.5 teaspoons [37.5 ml]) to check for changes in chemicals caused by the study drug and drug level.

**Day of surgery:**

- Tissue from your tumor will be collected and banked for research purposes. Leftover samples may be used for future analysis.

**End of Treatment Visit*:***
It will take place approximately 4-8 weeks after your surgery for patients receiving study drugs. During this visit following procedures will take place:

- Review any medications you have taken or are currently taking
- Do a complete physical examination (including height and weight)
- Record your vital signs (body temperature, heart rate, blood pressure and breathing rate)
- Record your performance status (how well you are able to perform your everyday activities)
- We will ask you questions about any side effects you had since your last visit and about any changes in your medications
- Collect blood samples (about 7.5 teaspoons [37.5 ml]) to check for changes in chemicals caused by the study drug and drug level.

**How will my medicine be provided**?
The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

**Who owns my study information and samples?**
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

**What are the possible risks and discomforts?**

**VX15/2503**
Like all medicines, VX15/2503 may cause side effects, although not everybody gets them. Not all the side effects of VX15/2503 when given alone or with other drugs are known. Listed below are possible side effects of VX15/2503. This information is based on data from patients in other clinical trials with VX15/2503. Patients have not been treated with the combination of VS15/2503 and ipilimumab or nivolumab, thus we do not know what side effects the combination may have. You should tell your doctor or nurse right away about any possible side effects you experience.

The most common side effects are:

- Urinary tract infection

- Muscle weakness
- Contusion or skin bruising
- Insomnia
- Fatigue
- Decreased appetite
- Change in liver tests
- Arthralgia or joint pains
- Antibody response, a response that occurs when a substance enters the body resulting in a reaction by the immune system

Infusion reactions can occur when you are receiving the drug, with symptoms that include:

- Abdominal pain
- Decreased appetite
- Nausea/vomiting
- Low red blood cells
- Fever or chills
- Joint pain or stiffness
- Dizziness
- Headache
- Cough
- Shortness of breath
- Increase or decrease in blood pressure
- Irregular heartbeat
- Fatigue
- Skin reactions: including rash, itching, hives, redness, and dry skin

**Nivolumab**

Nivolumab may cause one or more of the side effects listed below. This information is based on data from cancer subjects in other clinical trials with nivolumab. In addition, there may be side effects that are not yet known that may occur when given in combination with VX15/2503. You should tell your doctor or nurse right away about any possible side effects you experience.

The most common side effects of nivolumab (more than 5%, up to 30%) include the following:

- Fatigue
- Skin reactions: including rash, itching, hives, redness, and dry skin.
- Diarrhea
- Nausea
- Abdominal pain
- Decreased appetite
- Low red blood cells
- Fever
- Joint pain or stiffness

Less common side effects of nivolumab (2-5%) include the following:

- Bowel inflammation
- Loss of color (pigment) from areas of skin
- Dry mouth
- Vomiting
- Weight loss
- Thyroid gland abnormalities
- Blood chemistry and/or liver function abnormalities
- Lung inflammation (pneumonitis - see details below)
- Cough
- Dizziness
- Headache
- Low white blood cells
- Muscle soreness, weakness, stiffness, spasms or paralysis
- Pain in arms or legs
- Tingling, burning, or numbness in hands and feet
- Shortness of breath
- High or low blood pressure
- Increased sensitivity of skin to sunlight
- Constipation
- Difficulty swallowing
- Low blood platelets (may increase risk of bleeding)

Rare but potentially serious side effects of nivolumab (less than 2%) include:

- Inflammation of the appendix
- Pituitary gland inflammation
- Inflammation of the eye
- Liver inflammation
- Acute kidney injury or failure
- Abnormal blood cell production
- Inflammation of the mouth and lining of the digestive tract
- Swelling of the face, arms, or legs
- Inflammation of the pancreas
- Autoimmune disorders, including Guillain-Barre syndrome
- Inflammation of the heart or its lining
- Increased blood sugar
- Decreased movement of the intestines
- Disorientation
- Inflammation of the membrane surrounding the spinal cord and brain
- Drug reaction with rash, blood cell abnormalities, enlarged lymph nodes, and internal organ involvement (including liver, kidney, and lung); known as Drug Reaction with Eosinophilia and

Systemic Symptoms (DRESS)

- Myasthenia gravis, a nerve disease that may cause weakness of eye, face, breathing, and swallowing muscles.
- Encephalitis
- Toxic epidermal necrolysis, a potentially fatal disease characterized by blistering and peeling of the top layer of skin resembling a severe burn, has occurred in patients who received nivolumab treatment. Rhabdomyolysis (muscle fiber released into the blood stream which could damage your kidneys) and polymyositis (chronic muscle inflammation with muscle weakness) has been reported in one patient.
- Cranial nerve paralysis involving one or more of the cranial nerves. Palsy occurs when a muscle becomes paralyzed or someone loses control of it. A patient may find it difficult to smile, to control eye movements, and to engage in other facial expressions.
- Lung inflammation (pneumonitis): Nivolumab might cause inflammation of the tissues of the lung. While many patients with x-ray or CT scan abnormalities have not developed any symptoms, some patients have developed mild to severe symptoms and, in rare cases, death has occurred as a result of lung inflammation. Signs and symptoms of lung inflammation may include the following: difficulty breathing, pain or discomfort while breathing, chest pain, cough, shortness of breath, rapid breathing, fever, low blood oxygen levels, or fatigue. During the study, your study doctor, nurse, and study team are trained to routinely ask about and check for signs and symptoms of lung inflammation mentioned above. They do this by talking with you about your symptoms and by performing regular tests.
- Complications, including fatal events, have occurred in patients who received allogeneic hematopoietic stem cell transplant (HSCT) before or after nivolumab. Complications, including rejection, have also been reported in patients who have received an organ or tissue transplant.

**Ipilimumab**

Ipilimumab may cause one or more of the side effects listed below. This information is based on data from other participants with cancer in other clinical trials of ipilimumab. In addition, side effects that are not yet known may occur when given in combination with VX15/250. You should tell your doctor or nurse right away about any possible side effects you may experience.

The most common side effects (more than 5% chance of occurring) of ipilimumab are as follows:

- Diarrhea
- Inflammation of the colon
- Increased liver enzyme levels
- Fatigue
- Itchy skin
- Rash
- Nausea
- Fever
- Decreased appetite
- Vomiting
- Colitis

- Abdominal pain
- Headache
- Constipation
- Adrenal gland abnormalities
- Pituitary gland abnormalities

Less common side effects (2–5% chance of occurring) of ipilimumab are as follows:

- Chills
- Weakness
- Muscle pain
- Redness of the skin

Rare side effects (less than 2% chance of occurring but potentially serious) of ipilimumab are as follows:

- Drop in pituitary hormone levels
- Allergic reactions
- Liver inflammation
- Pituitary gland inflammation
- Decreased red blood cell count
- Loss of color (pigmentation) from certain areas of the skin
- Decreased or blurred vision, or inflammation of the eye
- Numbness or tingling
- Inflammation of the membrane surrounding the spinal cord and brain
- Inflammation of the kidneys
- Joint pain

**Drug Interactions and Allergies:** For your safety, please tell your study doctor about all of your present and past diseases and allergies that you are aware of. Because the study drug is new, its interactions with other drugs may still be unknown. The study drug may increase your risk of side effects from other medications. It is important that you tell your study doctor of all prescriptions and/or over-the-counter drugs, herbal preparations, and nutritional supplements you are taking. The study treatment may have the potential to interact with certain types of tranquilizers, seizure medications, blood pressure medications, antibiotics, cancer therapies, antiviral medications, gastric acid medications and antidepressants. Your doctor will be watching you closely to check for problems related to taking multiple medications at the same time.

**Reproductive Risks and Side Effects**: Women who are pregnant or breastfeeding cannot take part in this study. This is because the drugs in this study may affect an unborn baby or be passed to a baby through mother's milk. If applicable, breastfeeding must be discontinued if you are getting the study drugs. The effect of the study drug on the fertility of males and females is unknown. If you are a woman capable of having children, you will be given a pregnancy test before you begin the study. To avoid risk to the fetus, it is important that you not become pregnant or father a baby while on this study or for 3 months after discontinuing the study drugs. Avoiding sexual activity is the only certain method to prevent pregnancy. However, if you choose to be sexually active, you should use an appropriate "double barrier" method of birth control (such as female use of a diaphragm, intrauterine device (IUD), or contraceptive sponge, in addition to

male use of a condom) or the female should be using prescribed "birth control" pills, injections, or implants. You should continue to use contraception for a period of at least 5 months after receiving the study medications. If you choose to be sexually active during this study, you understand that even with use of these birth control measures pregnancy could still result. The risks of getting the study drug while pregnant include potential loss of pregnancy or possible birth defects. If you become pregnant while you are taking part in this study, you must notify one of the doctors listed on this form right away so that management of the pregnancy and the possibility of stopping the study drugs can be discussed. The research team will also document and track the condition of the newborn to assess negative drug effects.

**If you are a man,** the effect of the study treatment 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 seven months after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study. If your partner becomes pregnant the pregnancy will be followed to its conclusion. If a child is born from the pregnancy the study team will assess the condition of the newborn to document any possible negative drug effects.

**Risks from Other Procedures**

**Risk of Blood Drawing and IV Access:** Putting a tube or needle in your vein to draw blood or give you drugs may hurt when the needle is put in. There is a risk of continued pain, bruising, dizziness, fainting or infection, which although rare, can occur.

**ECG:** For the ECG we attach small pads to your skin to record the electrical activity of your heart. The ECG itself is painless and does not involve risks. However, the places where the pads are placed could become red and slightly irritated. Sometimes it may be necessary to shave small areas of the chest (males) to attach the electrodes.

**CT Scan:** Your CT procedure will require the use of a "contrast agent." The contrast agent is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little causing swelling and discomfort, that is typically treated with ice packs.

**MRI Scan:** MRI exams use powerful magnets to create images of the body. In addition to the possible reactions to contrast materials, you may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

**Radiation-Related Risks:** 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 3 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.

**Other Risks**

The study drug may have side effects that no one knows about yet. Many side effects go away when the treatment is stopped. However, in some cases, the side effects could be serious, long lasting, permanent, or even fatal. It is possible that due to side effects there may be delay or inability to proceed with your surgery. Your doctor will let you know if he or she learns anything that might make you change your mind about being in this study.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

**Will I benefit directly from the study?**

This study is designed to learn more about the treatment of melanoma that this is treatable with surgery. You may benefit from the drugs offered in this study but may not benefit directly from participating in the study. 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 study.

**What are my other options?**

If you decide not to enter this study, there is care available to you outside of this research study. You have an option to proceed to surgery, which would be the standard of care treatment option. The study doctor will discuss these with you. You do not have to be in this study to be treated for your cancer.

Treatment on this protocol may affect your ability to participate in future clinical trials but will not prevent you from receiving standard of care treatments. Please ask you physician if you have any questions about this.

**How will you protect my private information that you collect in this study?**

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.

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Food and Drug Administration, Emory 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 Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research. The study-supporter, Vaccinex, Inc. and their authorized agents, may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by

law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

**Storing and Sharing your Information**

De-identified data from this study, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Medical Record**

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory 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 Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory places may not become part of your Emory 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 being in the study, Emory will help you get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Michael Lowe at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

**Costs**

Vaccinex and Bristol-Myers Squibb, the study-supporters, will provide the study drug VX15/2503, nivolumab, and ipilimumab. The study-supporter does not plan to pay you for any other items or 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 will submit claims to your insurance for items and services that the sponsor does not cover. Emory 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 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 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 final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this 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.

**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.

**Main Study**

**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 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. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

**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 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.
- Dr. Kudchakar is the Sponsor of the study. The Sponsor 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 Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- Vaccinex and BMS are the study supporters.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory 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 Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Food and Drug Administration.
    - 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.

**Optional Study: Storage of Samples for Future Research:**

**PHI That Will be Used/Disclosed for Optional Study:**
The PHI that we will use and/or disclose (share) for the optional storage and future research use of your PHI"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 for Optional Study:**
We will use and disclose your PHI for the conduct and oversight of the optional storage and future research use of your PHI including the administration and payment of any costs relating to subject injury.

**Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study**:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

**People Who Will Use/Disclose Your PHI for Optional Study:**
The following people and groups will use and disclose your PHI in connection with the optional storage and future research use of your PHI

- The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional storage of PHI for future research

**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:

Michael Lowe, MD
Winship Cancer Institute, 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 information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

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

**<u>Contact Information</u>**
Contact Dr. Michael Lowe, MD at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

## Consent and Authorization

**Consent and HIPAA Authorization for Optional Study/Studies:**
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study previously described:

**[Storage of Samples for Future Research] _____Initials**

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***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization 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**

_____ _____ ____:____ **am / pm**
**Signature of Subject (18 or older and able to consent)** **Date** **Time (please circle)**

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***TO BE FILLED OUT BY STUDY TEAM ONLY***

_____
**Name of Person Conducting Informed Consent Discussion**

_____ _____ ____:____ **am / pm**
**Signature of Person Conducting Informed Consent Discussion** **Date** **Time (please circle)**