

Official Title: LCI-PCD-RRMM-NIVO-001: Nivolumab As An Adjunctive Therapy In Relapsed Refractory Multiple Myeloma Patients With Sub-Optimal Response To Idecabtagene Vicleucel NCT06523621

IRB-Approved Date: 03/18/2025

**ATRIUM HEALTH WAKE FOREST BAPTIST COMPREHENSIVE CANCER
CENTER (AHWFBCCC)
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**

Sponsor / Study Title: Atrium Health Wake Forest Baptist Comprehensive Cancer Center / “Nivolumab As An Adjunctive Therapy In Relapsed Refractory Multiple Myeloma Patients With Sub-Optimal Response To Idecabtagene Vicleucel”

Protocol Number: LCI-PCD-RRMM-NIVO-001

**Principal Investigator:
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[REDACTED]

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see if nivolumab is safe and useful to treat participants with relapsed refractory multiple myeloma who have received idecabtagene vicleucel (commonly known as ide-cel or Abecma). Relapsed or refractory means that your multiple myeloma has been previously treated and returned requiring new anti-cancer treatment. You are invited to be in this study because you have been diagnosed with multiple myeloma, have received CAR-T therapy with ide-cel and have had less than a complete response after your first treatment. Your participation in this research will involve study treatment with nivolumab, an immunotherapy drug which works with your own immune system to attack cancer cells. Nivolumab will be given through your vein every 4 weeks for a total of 2 doses.

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This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. Accordingly, when the participant cannot legally consent to take part, pronouns “you” and “your” should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant’s representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant will be offered the ability to leave the study if desired.

All research studies involve some risks. Additional information regarding the risks associated with this research study will be included in the “WHAT ARE THE RISKS OF THE STUDY?” section below. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Current standard of care after ide-cel treatment is supportive care and to monitor for relapse. At time of relapse, there may be additional treatments available. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact the study doctor using the contact information listed on the first page of this consent form.

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

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the research team to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to monitor for improvement in response after being treated with nivolumab. We are also monitoring any side effects and how well this study treatment is tolerated (how well your body handles this study treatment).

Nivolumab is an immunotherapy agent that helps your own immune system fight cancer. Nivolumab has been approved by the US Food and Drug Administration (FDA) to treat cancer found in the lungs, head, neck, colon, rectum, stomach, esophagus, bladder, urinary tract, melanoma

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and Hodgkin lymphoma, but it has not been approved in multiple myeloma at this time. Treating multiple myeloma with nivolumab after CAR-T therapy is investigational.

This study is being carried out under the sponsorship of Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC). Bristol Myers Squibb is providing nivolumab that will be used in this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

People who are at least 18 years of age and have responded to ide-cel, but had less than a complete response will be considered for consent and enrollment in this study.

There will be approximately 50 participants enrolled into the study over about 24 months.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will have the opportunity to review this consent form and discuss any questions you may have with your study doctor and research team. Enrollment in this study will not affect any of your medical care in any way. After you sign consent (which may be completed in person or electronically), the research team will confirm that you qualify for the study.

Before you begin the study (Screening):

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

- Provide your date of birth, gender at birth, race, ethnicity, insurance status and zip code
- Documentation of your medical and cancer related history to include previous anti-cancer treatments and side effects or symptoms you may be experiencing
- Physical examination including vital signs (heart rate, blood pressure, breathing rate, and temperature) as well as height and weight measurements
- Performance status- how well you are able to perform daily activities
- Blood work for blood counts, blood chemistry, c-reactive protein, thyroid function, serum protein electrophoresis (SPEP), serum immunofixation (IFE), and serum free light chains (SFLC).
- Additional blood work (2 tablespoons) will be collected for research
- Collection of a 24 hour urine for urine protein electrophoresis (UPEP) and immunofixation (IFE)
- Serum (blood) or urine pregnancy test for women of childbearing potential
- Documentation of any medicines you are taking
- Positron Emission Tomography/Computed Tomography (PET/CT) scan to look at the cancer in your body
- Bone marrow biopsy after CAR-T as part of standard of care to determine how effective CAR-T was on your cancer.
- Samples from bone marrow biopsy obtained no more than 12 months before receiving CAR-T to be tested

During the Study (On Treatment):

After signing consent and once the tests and procedures show that you are eligible to participate in the study, and you choose to take part, you will begin study treatment as described below:

Your study treatment cycles will be 28 days in length.

You will receive nivolumab on Day 1 of each cycle for 2 cycles.

Nivolumab will be given to you intravenously (IV), which means through a vein. It takes approximately 30 minutes to infuse nivolumab. There may also be other medications given to you before or after nivolumab to prevent side effects, which will add to your time in the infusion center.

If you are having unfavorable side effects, nivolumab may be held for up to a week and will resume when your provider feels it is safe to resume study treatment.

You will have the following tests and exams prior to each infusion of nivolumab:

Day 1 of each cycle:

- Physical exam including vital signs (heart rate, blood pressure, breathing rate, and temperature) and weight
- Performance status
- Blood work for blood counts, blood chemistry, c-reactive protein, thyroid function, SPEP, serum immunofixation and serum FLC if not completed within 7 days of start of study treatment
- Collection of a 24 hour urine for UPEP and IFE (if positive at screening)
- Blood work for CD4 count (to be repeated every 4 weeks from ide-cel until greater than 200 on two consecutive tests)
- Blood work thyroid function
- Blood or urine pregnancy test if not done within 72 hours of start of study treatment
- Provide any side effects or symptoms you are experiencing
- Documentation of any medicines you are taking
- Additional blood work (approximately 2 tablespoons) to be collected for research if not collected at screening (Cycle 1 Day 1 only)

Day 15:

- Physical exam including vital signs (heart rate, blood pressure, breathing rate, and temperature) and weight
- Performance status
- Blood work for blood counts, blood chemistry, c-reactive protein, thyroid function
- Provide any side effects or symptoms you are experiencing
- Documentation of any medicines you are taking

End of Study Treatment (Safety Visit):

This visit will occur approximately 30 days after your last dose of nivolumab and will include the following tests and procedures:

- Physical exam including vital signs (heart rate, blood pressure, breathing rate, and temperature) and weight
- Performance status
- Blood work for blood counts, blood chemistry, c-reactive protein, SPEP, serum immunofixation and serum FLC
- Blood work for thyroid function to be repeated every 28 days from Cycle 2 Day 1 for 4 cycles
- Collection of a 24 hour urine for UPEP and immunofixation (if positive at screening)
- Provide any side effects or symptoms you are experiencing
- Documentation of any medicines you are taking

Active Follow-up:

If your cancer is still stable and you have not started a new anti-cancer therapy, you will be followed approximately every 4 weeks from your last nivolumab treatment with the following being collected at various times:

- PET/CT scan if determined to be part of standard of care by your provider to monitor your cancer
- Collection of current health status (survival status)
- Collection of any new anti-cancer therapy
- Blood work for SPEP, serum immunofixation and serum FLC
- Collection of a 24 hour urine for UPEP and immunofixation (if positive at screening)
- Bone marrow biopsy (per your provider's discretion) to be collected at 2 months and 5 months (or disease progression, whichever occurs first) from Cycle 1 Day 1
- Additional blood work to evaluate cancer status (approximately 2 tablespoons) and bone marrow aspirate to be collected for research at 2 months and 5 months (or disease progression, whichever occurs first) from Cycle 1 Day 1

You will remain in active follow-up until your cancer progresses, you start new anti-cancer therapy, or you withdraw your consent to participate.

Disease Progression:

If it is suspected that your cancer has progressed, you may have a bone marrow biopsy to confirm that your cancer has progressed. You will also have additional blood work for research (approximately 2 tablespoons) at time of progression.

Long Term Follow-up:

If your cancer has progressed, you will move into long term follow-up and be followed approximately every 3 months from the date of progression or start of new anti-cancer therapy and be followed until you withdraw your consent to participate or the study ends. During this period, your current health status will be collected.

STORAGE OF BIOLOGICAL SPECIMENS

The research that may be performed with your blood and tissue samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. The results of the research performed with your blood and tissue samples will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood and tissue samples will not affect your care.

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

Your blood and tissue samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, or social security number. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. If you withdraw from study participation for any reason, any specimens that have already been collected but not yet processed may be destroyed upon your written request. Any data that has already been collected from your samples will be kept.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study until the study is completed or ended early, if you/your LAR withdraw consent for study participation, you are no longer able to be contacted, or death. If you come off the study for any of these reasons, you will not have any additional blood or tissue samples collected.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the study doctor or research team first.

WHAT ARE THE RISKS OF THE STUDY?

Taking part in this research study may involve providing information that you consider confidential or private which could lead to accidental disclosure of your protected health information (PHI). If this information were released, it could be misused. Your privacy is very important to us, and we will use many safety measures to protect your privacy. However, despite all the safety measures that we will use, we cannot guarantee that your identity will never become known. You may be asked to submit your information using electronic systems to sign consent. Efforts, such as using a code instead of your name when possible, keeping paper and electronic research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. However, there is some risk of loss of confidentiality and privacy.

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

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Biopsy: During your bone marrow biopsy, you may experience pain and/or discomfort at the site where the needle is inserted. The amount of pain and/or discomfort will depend on your pain tolerance, which is different for each person. Some people describe a sharp pain in the bone where the needle is inserted. Other people describe it as a long, hard punch or kick. This pain and/or discomfort only lasts a few seconds during the procedure. Tenderness over the area may last for a few days. Bleeding from the site or infection may occur but is rare.

PET/CT Scan: PET/CT scan risks can be associated with contrast dye injected through your vein. This contrast dye may cause pain or burning at the injection site. Another risk is the possibility of having an allergic reaction which could be severe or life-threatening.

Radiation Exposure: This research study involves exposure to radiation from PET/CT scans. The amount of radiation exposure you will receive from these scans is equivalent to a uniform whole body dose of 5.5 rem. The parts of your body that will get the most radiation is where your cancer is at. This is equal to 1.1 times the annual radiation exposure limit allowed for a radiation worker (5 rem) and is greater than the amount of radiation that you would get if you were having any of the usual x-rays or scans done on sick patients. There may be a very small chance that the radiation could cause a cancer. The excess cancer risk from the radiation is estimated to be about 0.22% where the lifetime cancer risk is about 20%.

To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

There also may be other risks that we cannot predict. You should tell the research team about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study to identify possible safety issues to participants and to provide advice and recommendations on possible changes to the research study for the protection of participants.

REPRODUCTIVE RISKS AND OTHER ISSUES RELATED TO PARTICIPATING IN RESEARCH

Pregnant or breastfeeding women are excluded from participation in this study. If you are a woman of childbearing potential, you must have a negative serum pregnancy test within 72 hours before enrolling into the study.

You must agree to use a highly reliable method of birth control, from time of signing this consent until 5 months after the last nivolumab infusion.

Highly reliable methods of birth control:

- Progestogen-only hormonal contraception associated with inhibition of ovulation
- Hormonal methods of contraception including combined oral contraceptive pills (contain both estrogen and progestogen), vaginal ring, injectables, implants, transdermal, and intrauterine hormone releasing systems (IUS)
- Intrauterine devices (IUDs)
- Bilateral tubal occlusion
- Vasectomized partner
- Complete abstinence (refraining from all acts of vaginal sex)

It is important for you to tell the study doctor if:

- You have difficulty following the study doctor's birth control advice
- Your normal period is late or missed
- You think that you might be pregnant
- There is a change in your method(s) to avoid pregnancy

If you become pregnant during this study or within 5 months of your last dose of nivolumab, your study doctor will discuss with you what you should do. If you get pregnant, you will be asked to stop taking part in the study.

RISKS ASSOCIATED WITH NIVOLUMAB

Nivolumab is an immunotherapy which works by encouraging the body's own immune system to attack cancer cells.

All drugs may have side effects. Most side effects are mild to moderate, but some may be serious and require additional treatment. Each person's reaction to a drug may be different. If any side effect occurs, please inform your provider immediately.

Very common (may affect more than 1 in 10 people):

- Infections of the upper respiratory tract
- A decreased number of red blood cells (which carry oxygen), white blood cells (which are important in fighting infection) or platelets (cells which help the blood to clot)
- High (hyperglycemia) or low (hypoglycemia) sugar levels in the blood
- Diarrhea (watery, loose or soft stools), vomiting, nausea, constipation, stomach pain
- Skin rash sometimes with blisters, itching
- Feeling tired or weak, fever, edema (swelling)
- Decreased appetite
- Headache
- Shortness of breath (dyspnea), cough
- Pain in the muscles, bones (musculoskeletal pain) and joints (arthralgia)

Common (may affect up to 1 in 10 people):

- Serious lung infection (pneumonia), bronchitis
- Allergic reaction, reactions related to the infusion of the study drug including life-threatening allergic reaction
- Underactive thyroid gland (which can cause tiredness or weight gain), overactive thyroid gland (which can cause rapid heart rate, sweating and weight loss), swelling of the thyroid gland
- Inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs), dizziness
- High blood pressure (hypertension)
- Inflammation of the lungs (pneumonitis, characterized by coughing and difficulty breathing), fluid around the lungs
- Inflammation of the intestines (colitis), mouth ulcers and cold sores (stomatitis), dry mouth
- Skin color change in patches (vitiligo), dry skin, redness of the skin, unusual hair loss or thinning, hives (itchy, bumpy rash)
- Inflammation of the joints (arthritis)
- Pain, chest pain
- Blurred vision, dry eyes
- Dehydration, decrease in body weight
- Fast heart rate
- Kidney failure (including abrupt loss of kidney function)

Uncommon (may affect up to 1 in 100 people):

- Increase in some white blood cells
- Decreased secretion of hormones produced by adrenal glands (glands situated above the kidneys), underactive function (hypopituitarism) or inflammation (hypophysitis) of the pituitary gland situated at the base of the brain, diabetes
- Increased acid levels in the blood
- Damage to nerves causing numbness and weakness (polyneuropathy), inflammation of the nerves caused by the body attacking itself, causing numbness, weakness, tingling or burning pain (autoimmune neuropathy)
- Inflammation of the heart muscle
- Inflammation of the eye (which causes pain and redness)
- Inflammation of the covering of the heart and accumulation of fluid around the heart (pericardial disorders), abnormal heart rhythm, changes in the rhythm or rate of the heartbeat
- Fluid in the lungs
- Inflammation of the pancreas (pancreatitis), inflammation of the stomach (gastritis)
- Inflammation of the liver (hepatitis), blockage of bile ducts
- Skin disease with thickened patches of red skin, often with silvery scales (psoriasis), skin condition of the face where the nose and cheeks are unusually red (rosacea), severe condition of the skin that causes red, often itchy spots, similar to the rash of measles, which

starts on the limbs and sometimes on the face and the rest of the body (erythema multiforme)

- Inflammation of the muscles causing pain or stiffness (polymyalgia rheumatica)
- Chronic diseases associated with a build-up of inflammatory cells in various organs and tissues, most commonly the lungs (sarcoidosis)

Rare (may affect up to 1 in 1000 people):

- A disease causing the inflammation or enlargement of a lymph node (Kikuchi lymphadenitis)
- Acid in the blood produced from diabetes (diabetic ketoacidosis)
- A temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome), loss of the protective sheath around nerves (demyelination), a condition in which the muscles become weak and tire easily (myasthenic syndrome)
- Inflammation of the brain
- A temporary and reversible non-infectious inflammation of the protective membranes surrounding the brain and spinal cord (aseptic meningitis)
- Decreased function of the parathyroid gland
- Inflammatory disease of blood vessels
- Ulcer of the small intestines
- Severe and possibly fatal peeling of the skin (toxic epidermal necrolysis or Stevens-Johnson syndrome)
- Disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome), aching muscles, muscle tenderness or weakness, not caused by exercise (myopathy), inflammation of the muscles (myositis), stiffness in muscles and joints, muscle spasm (rhabdomyolysis)
- Inflammation of the kidney
- Inflammation of the bladder, signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen

Other side effects that have been reported with frequency not known (cannot be estimated from the available data):

- Solid organ transplant rejection
- A group of metabolic complications occurring after cancer treatment characterized by high blood levels of potassium and phosphate, and low blood levels of calcium (tumor lysis syndrome)
- An inflammatory disorder (most likely of autoimmune origin) affecting the eyes, skin and the membranes of the ears, brain and spinal cord (Vogt-Koyanagi-Harada syndrome)
- Changes in any area of the skin and/or genital area that are associated with drying out, thinning, itching and pain (lichen sclerosis or other lichen disorders)
- A condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (called hemophagocytic lymphohistiocytosis)

Nivolumab is a cancer drug, known as immune checkpoint inhibitor. Other similar immune checkpoint inhibitors have shown an increased risk of death, when used in combination and until disease progression with lenalidomide and dexamethasone or pomalidomide and dexamethasone in patients with multiple myeloma. The reported causes of death include cardiac and respiratory problems, and other causes of death. The impact of giving two doses of nivolumab after CAR-T therapy is not known and determining the safety of this is an objective in this study. There may be side effects that are not yet known that may occur and may be life threatening or lead to death.

Additional information on pneumonitis:

Your provider and research team will watch you closely for changes in your ability to breathe and for other signs or symptoms that might show you are developing lung inflammation and will perform regular tests including physical exams, blood tests and monitoring your oxygen levels.

Please inform your provider or research team AT ONCE if you experience any of the following:

- Any new shortness of breath
- Any new or increased chest pain
- Any new or increased pain/difficulty while breathing
- Any new or increased cough or any significant change in your type of cough; for example, any new or increased mucous or blood in your cough
- Any change in the amount of oxygen you require
- Any fever, fatigue, or other symptoms that occur at the same time as any changes to your breathing or other lung symptoms

As with all drugs, side effects may include allergic reaction. Allergic reactions may range from minor itching or rash to major reactions which can result in death.

Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be reduction in the side effects of immunotherapy, reduction in the symptoms from immunotherapy, or slower progression of your cancer.

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Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

- You do not have to be in this study. Standard of care after ide-cel therapy is supportive care and to monitor for relapse. At time of relapse, there may be additional treatments available, including other FDA-approved therapies. Treatment options outside this clinical trial are dependent on your previous treatment and prognosis. You should talk to the researchers about all the choices you have.

WHAT ARE THE COSTS?

Study drug or procedures related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. Rarely, medical insurance companies will not pay for regular medical care once they become aware that a participant is participating in a research study. Since we do not know what each individual research company will cover, you may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SUPPORTING THIS STUDY?

This study is being supported by Bristol Myers Squibb (BMS). BMS is providing money to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest with BMS or the study drug being studied.

The decision whether to enroll in the study is yours alone. You should have all the information you need to be comfortable with your decision.

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

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

Atrium Health - Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for treatment of injuries or illnesses. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of \$25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury, contact the study doctor using the contact information listed on the first page of this consent form.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or research team first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because the study is terminated or completed, you are lost to follow up (you are no longer able to be contacted), or death. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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

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AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you

Printed Name of Research Participant

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:

Atrium Health Wake Forest Baptist Comprehensive Cancer Center - LCI-PCD-RRMM-NIVO-001: Nivolumab As An Adjunctive Therapy In Relapsed Refractory Multiple Myeloma Patients Who Respond To Idecabtagene Vicleucel.

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 doctor 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), Wake Forest University Health Sciences 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. You may change your mind and withdraw (take back) this Authorization at any time, except to the

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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 Participant or Research Participant's Legally Authorized Representative

Printed name of Research Participant or Research Participant's Legally Authorized Representative

Authority of Research Participant's Legally Authorized Representative to act on behalf of Participant (specify health care power of attorney, spouse, etc)

Date

WHOM TO CONTACT ABOUT THIS STUDY

Barry Paul, MD

Advarra IRB Approved Version 18 Mar 2025

Revised 18 Mar 2025

Affix Participant Barcode Label Here

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

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.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:

Study Subject Adviser

[REDACTED]
[REDACTED]
[REDACTED]

- or call **toll free**:

[REDACTED]

- or by **email**:

[REDACTED]

Please reference the following number when contacting the Study Subject Adviser: Pro00081644.

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.

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 Participant

____/____/____
Date Time

Printed Name of Research Participant

Signature of Legally Authorized Representative (if applicable)

____/____/____
Date Time

Printed Name of Legally Authorized Representative (if applicable)

Authority of Legally Authorized Representative to act on behalf of Participant (specify health care power of attorney, spouse, etc.)**STATEMENT OF PERSON EXPLAINING CONSENT**

I have carefully explained to the participant or the participant's legally authorized representative the nature and purpose of the above study. There has been an opportunity for the participant or the participant's legally authorized representative to ask questions about this research study. I have been available to answer any questions that the participant or the participant's legally authorized representative has about this study.

Signature of Person Explaining Consent

____/____/____
Date Time

Printed Name of Person Explaining Consent

Affix Participant Barcode Label Here