THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Phase I Study of Belantamab Mafodotin Maintenance Therapy After Salvage Autologous Hematopoietic Cell Transplantation in Patients with Relapse Refractory Multiple Myeloma
2020-1059

Subtitle: GSK2857916 – ICF Model Safety Language May 2023 – Protocol Version 12, 09 June 2025

Study Chair: Neeraj Saini

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by the MD Anderson Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to learn if belantamab mafodotin (Blenrep) can help to prevent multiple myeloma (MM) from coming back after patients have had an autologous stem cell transplant (AutoSCT). The safety of this drug when given after a transplant will also be studied.

This is an investigational study. Belantamab mafodotin is FDA approved and commercially available for the treatment of MM. It is considered investigational to study the effects of belantamab mafodotin in patients with MM who have had an autologous stem cell transplant. The study doctor can explain how the study drug is designed to work.

The study drug may help prevent MM from coming back. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may continue taking the study drug for as long as the study doctor thinks it is in your best interest.

Belantamab mafodotin will be provided at no cost to you while you are on study. You and/or your insurance provider will be responsible for the cost all tests and procedures in this study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard of care therapy. The study doctor will discuss with you which therapies are available outside of this study. You may choose to receive other investigational therapy, if available. The study doctor will discuss the possible risks and benefits of these treatments. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible. If you have had some of these tests recently, they may not need to be repeated:

- You will have a physical exam.
- You will have an eye exam by an eye doctor.
- Blood (about 3 tablespoons) and urine will be collected for routine tests.
- Blood (about 1-2 teaspoons) will be drawn to test for current and/or past viral infections such as hepatitis B or C and HIV (the AIDS virus).
- Urine will be collected over 24 hours to check the status of the disease. The study staff will give you a container and instructions on how to collect the urine.
- You will have an EKG and an echocardiogram (ECHO) to check your heart function.
- You will have a bone marrow biopsy to check the status of the disease and for cytogenetic testing. Cytogenetic testing looks at how genetic changes to cells may affect how the disease may react to the study drug. To collect a bone marrow biopsy, an area of the hip or other site is numbed with anesthetic, and a small amount of bone is withdrawn through a large needle.
- If the doctor thinks it is needed, you will have radiological studies, which may include a bone survey, an MRI, or a PET-CT scan to check the status of the disease. A bone survey is a series of x-rays of all or most of the bones in your body.
- If you can become pregnant, blood (about 1-2 teaspoons) will be drawn for a pregnancy test within 72 hours (3 days) before your first dose of study drug. To take part in this study, you must not be pregnant. This test will be repeated if it is believed that you may be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in this study, you will not be enrolled. Other treatment options will be discussed with you.

Up to 20 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration
Each study cycle is 84 days.

If you are found to be eligible to take part in this study, you will receive belantamab mafodotin by vein over 30 minutes (+/- 15 minutes) every 12 weeks. If the study doctor thinks it is needed, the dose level of belantamab mafodotin you receive may be changed.

You may continue to receive belantamab mafodotin until your disease returns or if you experience intolerable side effects.

You may be given standard drugs before or during the belantamab mafodotin infusion(s) to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

Since the study drug may cause eye irritation during the belantamab mafodotin infusion, you may apply cooling eye masks at the start of each infusion and continue to do so for up to 4 hours, as tolerated and needed.

Every day, starting with Day 1 of Cycle 1, you will use artificial tears (eye drops) in each eye at least 4 to 8 times daily until the end of treatment. Participants who have signs of any eye problems at the end of treatment will have an eye exam at least every 3 months for up to 1 year, or until your eye doctor thinks they are no longer needed.

Do not wear contact lenses while on study.

Study Visits

On **Day 1 of each cycle**:

- You will have a physical exam.
- You will have an eye exam within 5 days before each dose of belantamab mafodotin or on the day of dosing, before the infusion. This will be repeated about 1 month after your first dose.
- Blood (about 3 teaspoons) will be drawn for routine tests and to check the status of the disease. If it is more convenient for you, you may have some of these blood tests done at a local lab or doctor's office that is closer to your home. This will be discussed with you.
- Urine will be collected over 24 hours for routine tests and to check the status of the disease. The study staff will give you a container and instructions on how to collect the urine.
- If you can become pregnant, blood (about 1-2 teaspoons) will be drawn for a pregnancy test within 72 hours (3 days) before your first dose of study drug in Cycle

1. After Cycle 1, blood or urine may be collected for a pregnancy test within 72 hours of the first dose in each cycle.

At **6 months and then at 1, 2, and 3 years after starting treatment**:

- You will have a physical exam.
- Blood (about 3 teaspoons) will be drawn for routine tests and to check the status of the disease. If it is more convenient for you, you may have some of these blood tests done at a local lab or doctor's office that is closer to your home. This will be discussed with you.
- You will have a bone marrow biopsy to check the status of the disease and for cytogenetic testing. This may also be done at any time the study doctor thinks it is needed.
- If the study doctor thinks it is needed, you will have radiological studies to check the status of the disease.
- At Year 3, if you can become pregnant, blood (about 1-2 teaspoons) or urine will be collected for a pregnancy test

At least **70 days after the last dose of study drug**, if you can become pregnant, blood (about 1-2 teaspoons) or urine will be collected for a pregnancy test. One (1) time a month for up to 4 months after the last dose of study drug, research staff will contact you regarding pregnancy status. The call will last about 5-10 minutes.

If the disease gets worse during the study or if at any time the doctor thinks it is needed to check on your health, you will have some or all of the following tests/procedures:

- You will have a bone marrow biopsy to check the status of the disease.
- Blood (about 3 teaspoons) will be drawn for routine tests and to check the status of the disease.
- Urine will be collected over 24 hours for routine tests and to check the status of the disease.
- At 6 months and 1 year, and if the doctor thinks it is needed, you will have a skeletal survey, MRI, or PET-CT scan to check the status of the disease.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects that the drug is known to cause. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form.

Many side effects go away shortly after treatment is stopped either permanently or temporarily, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death. Some side effects, like infusion reactions, typically happen within 24 hours after receiving the study drug.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug/procedures.

Belantamab Mafodotin Side Effects

Belantamab mafodotin has been studied as monotherapy and is an approved drug in combination with bortezomib and dexamethasone and pomalidomide and dexamethasone. Clinical development of belantamab mafododin is ongoing; therefore, not all of its side effects are known at this time. As of 27 February 2025, over 1700 people worldwide with multiple myeloma have received belantamab mafodotin across all ongoing and completed clinical studies.

Some common side effects reported with belantamab mafodotin are described below:

Eye Side Effects

Some people who have received belantamab mafodotin in clinical studies developed problems in the front part of the eye called the cornea. Sometimes the changes can only be observed by an eye care specialist during eye examination, and they do not result in any symptoms. Those changes might be more frequent in patients who had problems with dry eye before treatment with belantamab mafodotin. However, some patients develop symptoms related to belantamab mafodotin. The symptoms could range from a feeling of dryness in the eye to more severe symptoms, like blurry vision or changes in your eyesight that could affect your ability to see things clearly and may affect your reading ability or lead to difficulty in driving.

These effects typically go away if the study drug is paused and the dose reduced upon re-start, but please discuss with your study doctor if you have questions. In severe cases, sores can develop on the eye, possibly with infection. If untreated, or even in severe cases when treated, this condition could lead to scarring that may permanently affect your eyesight, including severe vision loss.

If you experience new eye symptoms (such as pain or irritation, blurry vision, or feeling like something is in your eye), you should urgently seek medical attention by an eye care specialist. Your eyes will be examined repeatedly during the study, as it is important to monitor the effects of belantamab mafodotin on your eyes.

If you develop problems with your eyesight or other problems with your eyes, do not drive or operate heavy machinery until you have had your eyes examined by an eye care specialist.

Abnormal bruising and bleeding

Belantamab mafodotin can decrease the number of blood cells called platelets, which help to clot your blood. Symptoms of low platelet counts (called thrombocytopenia) can include abnormal bruising of your skin, bleeding for longer than usual after your blood has been drawn, or bleeding from your nose or gums. In some cases, the bleeding can occur from other areas of your body. Bleeding may be serious or life-threatening and may require a transfusion. Your study doctor will closely monitor your platelets by checking your blood tests before you start your treatment and regularly during the study.

Infusion-related reactions

Some people may have allergic-like reactions when they receive an infusion of belantamab mafodotin. These usually develop within minutes or hours but can develop up to 24 hours after your dose is given. It is a reaction to the drug being a foreign protein,

and you may have flushing, chills, fever, problems with breathing, feeling like your heart is racing, or a drop in blood pressure (which may cause you to feel dizzy, light-headed, or like you're going to faint). You will usually spend an hour after your dose to check whether you will develop these symptoms but if you experience any of these symptoms at any time contact your study doctor immediately.

Inflammation of the lungs
Some people who have received belantamab mafodotin experienced inflammation of the lungs which can cause cough, shortness of breath, and difficulty breathing and in rare cases, death. It is not certain if belantamab mafodotin causes the inflammation or not. If you experience new or worsening breathing problems like cough or shortness of breath with an unknown cause, contact your study doctor immediately.

Excess protein in the urine
Some people receiving belantamab mafodotin have developed excess levels of protein (called albumin) in the urine, which can sometimes be a sign of a kidney disorder. Your study doctor will closely monitor protein levels in your urine regularly during the study. If your urine looks foamy or frothy or if you notice new swelling or more swelling than usual in your feet, legs, or other parts of your body, contact your study doctor immediately.

Side effects
The side effects described below are from 312 people with relapsed/refractory multiple myeloma who received at least 1 dose of belantamab mafodotin in 1 study, at a dose of 2.5 mg/kg.

The most common side effects occurring in more than 10% of participants (10 or more out of 100 participants) were:

- Eye side effects: blurred vision, dry eyes, eye pain, changes in vision, eye discomfort or irritation, feeling of something in your eye, abnormal sensitivity to light, difficulty seeing at night, swelling, or other changes to the front part of eye
- Low number of blood cells called platelets, which may cause bleeding and easy bruising; bleeding may be serious or life-threatening and may require a transfusion
- Anemia (when your body has fewer red blood cells than normal)
- Having fewer white blood cells than normal (leukopenia)
- Feeling sick to your stomach (nausea)
- Feeling tired (fatigue)
- Abnormal liver tests
- Fever (if you have a fever, please contact your study doctor), symptoms may include chills or flushing
- Low number of certain types of white blood cells called neutrophils (neutropenia) and lymphocytes (lymphopenia), which could increase the risk of infection; symptoms may include chills or flushing. If you have a fever, please contact your study doctor immediately
- Diarrhea

- Reactions from the infusion of belantamab mafodotin, usually happening within the first 24 hours after the infusion: symptoms may include: flushing, chills, fever, difficulty breathing, rapid heartbeat, or a drop in blood pressure (feeling light-headed)

Other common side effects seen in 1% to 10% of participants (between 1 to 10 out of 100 participants) were:

- Other eye side effects: eye irritation, sores on the eyes possibly with infection, double vision, itchy eyes, watering of the eyes, eye discomfort, problems with vision.
- Pneumonia, or other lung infections, which might cause shortness of breath, chest pain, a new or worsening cough
- Cold or cold-like symptoms (upper respiratory tract infection)
- Increased albumin, a type of protein, in the urine (albuminuria)
- An increase in an enzyme released into the blood when muscle is damaged (creatine phosphokinase)
- Vomiting

In studies which are testing belantamab mafodotin in combination with bortezomib + dexamethasone or pomalidomide + dexamethasone, disorder of the blood vessels in the liver (porto-sinusoidal vascular disorder) was observed. This can lead to: abnormal liver blood tests and long-term problems such as increased pressure of the blood vessels in the abdomen (portal hypertension); swelling of blood vessels (varices); or a build-up of fluid in the abdomen which can cause abdominal pain, weight gain or swelling of the abdomen (ascites).

In another study which is testing belantamab mafodotin in combination with 2 medicines already approved for the treatment of relapsed refractory multiple myeloma (called lenalidomide and dexamethasone), 2 patients who had low white blood cell (neutrophil) counts developed serious infections which led to death.

If you have fever at any point while you are in this study, contact your study doctor immediately.

Embryo-fetal toxicity: Belantamab mafodotin may harm an unborn baby. You must have negative pregnancy tests to continue in the study if you are a woman who can have children. See section called "**Pregnancy Related Risks**" below for further details.

Fertility: Belantamab mafodotin treatment may affect men and women's ability to have children. See section called "**Pregnancy Related Risks**" below for further details.

There may be other side effects that may happen that are not known now. For example, all drugs can cause an allergic reaction in some patients. Certain problems can become worse if not treated quickly. Call the study doctor right away if:

- You feel very tired or faint
- You feel pain or sick in your stomach and you do not want to eat
- You bruise easily or develop itching
- You have yellow eyes or skin, or dark urine
- You become confused

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein (blood vessel) at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **bone marrow aspirations/biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the aspiration/biopsy. An allergic reaction to the anesthetic may occur. A scar may form at the aspiration/biopsy site.

During the **eye exam**, your pupils will be dilated with eye drops to allow a good view of the back of the eye. This will result in some blurred vision lasting for a few hours. You will not be able to drive during this time.

EKGs and ECHOs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

X-rays send a small amount of radiation though the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Belantamab mafodotin may affect your ability to have children in the future. If you may want to have children in the future, you should consider storing eggs/sperm frozen and stored before beginning treatment in this study. Talk to your doctor if you have questions about this process.

Birth Control Specifications: Approved birth control methods include birth control pills, injections, or implants (such as an intrauterine device [IUD] or intrauterine system [IUS]); condom or diaphragm with spermicidal foam/gel/film/cream/ suppository; or sterilization of yourself or partner.

Males: Do not donate sperm during the study and for 6 months after your last dose of study drug. Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. If your partner/spouse becomes pregnant while you are on this study, the sponsor would like to collect information about the pregnancy. The study supporter, GlaxoSmithKline (GSK), will make their contact information available to you so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

Females: Women who can get pregnant will need to use 2 methods of birth control (1 method that is highly effective) while in this study and for 4 weeks after the last dose of lenalidomide. In addition, they will have to use 1 effective method of birth control for a total of 4 months after the last dose of belantamab mafodotin or daratumumab.

You must not donate eggs (ova, oocytes) during the study and for 4 months after the last dose of belantamab mafodotin or daratumumab, or 4 weeks from the last dose of

lenalidomide, whichever is longer. You must not breastfeed while on study and for at least 4 months after your last dose of the study drug.

If you become pregnant or suspect that you are pregnant, you must tell the study doctor immediately. GSK will ask for information about the pregnancy.

The study staff will follow up with you for up to 6-8 weeks after the estimated delivery date to check on how your delivery went and the health of your baby.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

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

Additional Information

4. You may ask the study chair (Dr. Neeraj Saini, at 713-792-8750) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can help you safely stop study treatment. It may be dangerous to suddenly stop study treatment. The study doctor will also decide if you need to have any visits or tests to check on your health. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you withdraw from the study but have a safety-related event (such as a side effect) that may be related to your participation in this study or study drug, information about the event and your routine medical care will be collected from your medical record for this study. If you have any questions about this, please talk to the study doctor or study staff.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, GlaxoSmithKline, Inc., the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

   Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is supported by: GlaxoSmithKline, Inc.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Samples
Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

A federal law called the Genetic Information Nondiscrimination Act (GINA) 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 deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Outside Care

Part of your care may be provided outside of MD Anderson by your home doctor(s).

Conflict of Interest

Outside relationships are disclosed to and approved by the Conflict of Interest Committee, which reviews these relationships for compliance with institutional policy. This review helps the IRB to assure that financial relationships do not have an impact on the conduct of this study. The following members of the study staff have disclosed compensation from the funding source(s) of this study:

- Nimisha Patel (Co-investigator)
- Dr. Hans Lee (Co-Investigator)

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- GlaxoSmithKline, Inc., who is a supporter of this study, and/or any future sponsors/supporters of the study or study technology
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT