**Informed Consent to Participate in Research**

**Your Name:** _____

**Study Title:** Multicenter Phase II, Double-Blind Placebo Controlled Trial of Maintenance Ixazomib after Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Multiple Myeloma

**Protocol:** BMT CTN 1302

**Principal Investigator:** *Insert local PI information*

**Sponsor:** The National Institutes of Health (NIH) is sponsoring this study by providing financial support for the coordination of this study through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

# 1. Introduction

We invite you to join this clinical trial, also known as a research study. You are being asked to join because:

- You are at least 18 and no older than 70 years of age.
- You have high risk **multiple myeloma (MM)**, a cancer of the plasma cells that begins in your bone marrow, OR your MM returned after an **autologous transplant.**
- You have a closely matched related or unrelated peripheral blood stem cell donor.

Because there's no cure for MM, **maintenance treatment (chemotherapy)** is given to slow the return of your disease after an **allogeneic transplant**. We are doing this study to learn if maintenance treatment (chemotherapy) works better to control your disease than placebo (pill that doesn't have any active maintenance drugs).

For this study, the type of allogeneic transplant you will get is called a **peripheral blood stem cell (PBSC) transplant**. Your doctor also wants to use a **reduced-intensity or non-myeloablative conditioning regimen** for your transplant.

This study will take at least 3 years and will include 138 participants. Your participation will last **2 years**. After that time, selected additional data will be collected until all patients on the study have been followed for 2 years.

This Consent Form will tell you about the purpose of the study, the possible risks and benefits, other options available to you, and your rights as a participant in the study.

Everyone who takes part in research at [*insert facility name*] should know that:

- Being in any research study is voluntary.
- You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others.
- If you join the study, you can quit the study at any time.
- If you decide to quit the study, it will not affect your care at [insert name of facility or institution].
- Please ask the study staff questions about anything that you do not understand, or if you would like to have more information.

- You can ask questions now or any time during the study.
- Please take the time you need to talk about the study with your doctor, study staff, and your family and friends. It is your decision to be in the study. If you decide to join, please sign and date the end of the Consent Form.

You and your doctor will discuss other treatment choices if you do not want to participate in this study.

## 2. Study Background

The National Institutes of Health (NIH), through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), are providing staff support and money for this research study. The BMT CTN and the NIH will make decisions about how to manage the study.

For this study, you will receive a type of allogeneic transplant called peripheral blood stem cell (PBSC) transplant. Allogeneic transplant is a common treatment for patients with high risk MM. Having high risk MM means that:

- Your doctor found abnormal cells when he or she looked at the genetics of your bone marrow cells, OR
- Your disease came back (relapsed) less than 24 months after an autologous transplant, OR
- You have a fast growing type of myeloma called plasma cell leukemia.

An allogeneic transplant uses blood-making cells from a family member or an unrelated donor to remove and replace your abnormal blood cells. With a PBSC transplant, the donor cells come from his or her blood stream.

Your doctor also wants to use a reduced-intensity or non-myeloablative conditioning regimen for your transplant. The conditioning regimen is the chemotherapy used to destroy the diseased cells before you get your donor cells. A reduced-intensity or non-myeloablative conditioning regimen uses lower doses of chemotherapy.

There’s no cure for MM. After transplant, the disease will almost always return, or relapse. Some patients may keep getting treatment after transplant called maintenance treatment. Maintenance treatment is given to slow down relapse.

## 3. Study Purpose

We are inviting you to take part in this study because you have cancer of the plasma cells, your disease is high risk or relapsed after autologous transplant, and an allogeneic transplant is a treatment option for you. We are doing this study to learn more about ways to prevent or delay relapse of multiple myeloma (MM).

We will use 2 treatments to see which one is better at preventing or delaying relapse of MM (**Table 1**).

This study will help doctors make the best choice about treatment after allogeneic transplant for patients with MM.

**Table 1. Study Treatment Groups**

| **Treatment Group A (allogeneic transplant and experimental maintenance treatment)** | **Treatment Group B (allogeneic transplant and no maintenance treatment)** |
|---|---|
| ▪ Fludarabine<br>▪ Melphalan<br>▪ Bortezomib<br>▪ Allogeneic peripheral blood stem cell transplant<br>▪ Tacrolimus<br>▪ Methotrexate<br>▪ Ixazomib (experimental maintenance pill) | ▪ Fludarabine<br>▪ Melphalan<br>▪ Bortezomib<br>▪ Allogeneic peripheral blood stem cell transplant<br>▪ Tacrolimus<br>▪ Methotrexate<br>▪ Placebo (no maintenance) |

## 4. Rights to Ask Questions and/or Withdraw

You have the right to ask questions about the study at any time. If you have questions about your rights as a participant or you want to leave the study, please contact:

[*insert contact info*]

Being in this study is voluntary. You can choose not to be in this study or leave this study at any time. If you choose not to take part or leave this study, it will not affect your regular medical care in any way.

Your study doctor and study staff will be available to answer any questions that you may have about taking part in or leaving this study.

## 5. Study Treatment and Tests

We will check your health before you start treatment, while you receive treatment, and for 2 years after your transplant. After that time, selected additional data will be collected until all patients on the study have been followed for 2 years.

**Before You Start Your Treatment**

You will need to have several check-ups and tests to see if you can be in the study. All patients participating in this study need to have a matched donor. These check-ups and tests are part of your regular cancer and transplant care. You may need to have them even if you do not join the study. See **Table 2. Timeline of Tests for Your Transplant** for a schedule of when we will give you the physical tests.

**During Your Treatment**

Conditioning Regimen Before Transplant

The conditioning regimen is the chemotherapy you will receive before you get your donor cells. This helps the donor cells start to grow and make new cells in your bone marrow (engraft). It also helps to kill cancer cells. The regimen includes fludarabine, melphalan, and bortezomib, given by intravenous infusion (IV) in your arm. How often you will get these drugs is shown in **Table 3**.

1. Six days before your transplant, we will start giving you fludarabine, which you will get for 4 days.
2. Then, 4 days before your transplant, we will give you melphalan, which you will get for 2 days.
3. We will give you bortezomib once 3 days before your transplant.

You will have check-ups during the conditioning regimen to see how well your organs are working. If your organs are not working properly, your doctor will lower the dose of the chemotherapy drugs.

- **Infusion of Peripheral Blood Stem Cells (Transplant)**

On your transplant day (Day 0), the donor cells (stem cells) will be given to you through your catheter, like a blood transfusion. The cells will travel to your bone marrow where they will start to make healthy, new blood cells.

**Table 2. Timeline of Tests for Your Transplant**

| **Tests** | **Weeks Before/After Transplant** | | | | | | | | | | **Days After Transplant** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | -2 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 100 | 120 |
| Medical history | X | | | | | | | | | | | |
| Blood tests for cell counts, liver and kidney function | X | X | X | X | X | X | X | X | X | X | X | X |
| Heart and lung function tests | X | | | | | | | | | | | |
| Pregnancy test | X | | | | | | | | | | | |
| Tests to see how much cancer you have | X | | | | | | | | X | | | X |
| Bone marrow tests | X | | | | | | | | X | | | X |
| Optional blood sample for future research (if you consent) | X | | | | X | | | | | | X | |
| Optional bone marrow sample for research (if you consent) | X | | | | | | | | | | | |
| Tests to see how many donor cells you have | | | | | | | | | X | | | |
| Tests for GVHD | | X | X | X | X | X | X | X | X | X[2] | | X |
| Questionnaire about your Quality of Life[1] | X | | | | | | | | | | | |

[1]English- and Spanish-speaking patients only.
[2]Tests for GVHD will continue weekly until 14 weeks after transplant

**Table 3: Timeline of Transplant and GVHD Drugs**

| Drug | Treatment Day | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | -6 | -5 | -4 | -3 | -2 | -1 | 0* | +1 | +3 | +4 | +6 | +7 | +8 | +11 |
| Fludarabine | X | X | X | X | | | | | | | | | | |
| Melphalan | | | X | X | | | | | | | | | | |
| Bortezomib | | | | X | | | | | | | | | | |
| PBSC infusion | | | | | | | X | | | | | | | |
| Tacrolimus | | Tacrolimus will be given on a timeline that is determined by the institution's guidelines | | | | | | | | | | | | |
| Methotrexate | | | | | | | | X | X | | X | | | X |

*Day 0 = day of transplant

- **GVHD Prevention Drugs**

You will be given drugs (tacrolimus and methotrexate) to prevent **graft-versus-host disease (GVHD)**. GVHD is a common side effect of allogeneic transplant. It's a medical condition that can become very serious. GVHD happens because of differences between your own immune cells (host) and the immune cells from your donor (graft). Your new immune system, or the donated cells, might see your cells as foreign and attack them.

GVHD can cause:

- Skin rashes
- Nausea (feeling sick to your stomach)
- Vomiting (throwing up)
- Diarrhea
- Liver damage
- Hepatitis or jaundice
- Increased risk of infection

We will give you tacrolimus by pill or IV beginning 3 days before your transplant. We will give you less and less until we stop it completely. This can take several months.

After Your Transplant

To prevent GVHD, we will also give you methotrexate by IV on Days 1, 3, 6, and 11 after your transplant (**Table 3**).

We will test (evaluate) your health during the study. You will be watched closely for any signs and symptoms of GVHD. See **Table 2. Timeline of Tests for Your Transplant** for a schedule of when we will give you the physical tests.

Before Your Maintenance Treatment

At least 14 days before you start maintenance therapy, we will check to make sure you are healthy enough to start maintenance treatment. See **Table 4. Timeline of Tests for Your Maintenance Treatment** for a schedule of when we will give you the physical tests. If you are not healthy enough to start maintenance therapy, you will continue to be followed on this study until two years after your transplant regardless of what treatment you receive.

Randomization

We will use a computer program to assign you by chance to treatment group A or B. You won't be able to choose your group. Once you are assigned to a group, you can't change to the other group. The study doctor can't change your group either. You will have an equal chance of being placed in either group.

During Your Maintenance Treatment

- **Treatment Group A: Ixazomib**

If you are assigned to Treatment Group A, we will give you ixazomib as a pill on Days 1, 8, and 15 of each cycle (28 days in each cycle). This means that you will take ixazomib once a week for 3 weeks, and then have 1 week off. We will repeat the cycle 12 times or for about 1 year.

- **Treatment Group B: Placebo**

If you are assigned to Treatment Group B, we will give you the placebo as a pill (sugar pill). The placebo pills will look exactly like ixazomib, but don't have any drugs or treatment. We will give you the placebo pill on Days 1, 8, and 15 of each cycle (28 days in each cycle). This means that you will take the placebo once a week for 3 weeks, and then have 1 week off. We will repeat the cycle 12 times or for about 1 year.

- **Maintenance Treatment Dose (Treatment Group A and B)**

It's important that you take the pill at the same time with each dose. Also, you will have to keep a record of the pills you take. This means that you will write down what day and time you take every pill.

We will watch your health closely during maintenance treatment, including how well your organs work (function). We will raise your dose for Cycle 4 if your organs handle the treatment well. We will lower your dose if your organs don't handle the treatment well.

We won't start a new Cycle until your organ function returns to normal. If we lower your dose and then your organ function returns to normal, we won't raise your dose again.

We will stop the maintenance treatment if:

- Your disease progresses
- You have a serious side effect, like severe diarrhea or skin rash
- You have low blood cell counts
- You have serious GVHD
- You are a woman and become pregnant, or there is a chance that you are pregnant
- You go more than 56 days before starting a new maintenance treatment cycle
- You are unable to complete 12 cycles of maintenance treatment within 18 months of starting therapy
- You don't follow the study directions, or
- You choose to leave the study.

We will watch your health closely, especially if we change your treatment dose. You will need to have several check-ups and tests during your maintenance treatment. These tests are shown in **Table 4. Timeline of Tests for Your Maintenance Treatment.**

**Table 4. Timeline of Tests for Your Maintenance Treatment**

| **Tests** | **Cycle (28 days in each cycle)** | | | | | | | | | | | | | | **Month[1]** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | -1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | Follow Up | 18 | 24 |
| Tests for toxicities, and infections | X | X | X | X | X | | X | | | X | | | X | X | X | X |
| Tests for GVHD | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | |
| Blood tests for cell counts, liver and kidney function | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Tests to see how many donor cells you have | X | | | | | | X | | | | | | X | | | |
| Tests to see how much cancer you still have | X | | | X | | | X | | | X | | | X | | X | X |
| Tests to see how well your immune system is recovering | X | | | X | | | X | | | X | | | X | X | X | X |
| Bone marrow tests | X | | | X | | | X | | | X | | | X | X | X | X |
| Pregnancy blood test | X | | | | | | | | | | | | | | | |
| Optional blood samples for research (if you consent) | X | | X | | | X | | | | | X | | | X | | |
| Optional bone marrow samples for research (if you consent) | X | | | | | | | | | | | | | X | | |
| Questionnaire about your Quality of Life[2] | X | | | | | X | | | | | | | | X | | X |

[1]After 24 months of follow up, patients will continue to be monitored for the development of new cancers. This follow up period will end when all patients have been followed for 2 years.
[2] English- and Spanish-speaking patients only.

## 6. Risks and Discomforts

You may have side effects while on the study. Side effects can range from mild to serious. The risks and discomforts of peripheral blood stem cell transplant are the same if you join this study, or if you don't join this study.

You might do better or worse with a standard transplant. Your healthcare team may give you medicines to help with side effects like nausea (feeling sick to your stomach). In some cases, side effects can last a long time or may never go away.

**Risks of Medications**

The risks of the chemotherapy drugs, and or radiation you get as part of the treatment are listed below. How often patients get each of the side effects are shown in **Table 5**. **Risks and Side Effects**.

All immune suppressive drugs, except for bortezomib and ixazomib, are commonly used in allogeneic transplant.

**Table 5. Risks and Side Effects**

| | |
|---|---|
| **Likely** | What it means: This type of side effect is expected in more than 20% of patients. This means that 21 or more patients out of 100 might get this side effect. |
| **Less Likely** | What it means: This type of side effect is expected in 20% of patients or fewer. This means that 20 patients or fewer out of 100 might get this side effect. |
| **Rare, but Serious** | What it means: This type of side effect is expected in fewer than 2% of patients. This means that 1 or 2 patients (or fewer) out of 100 might get this side effect. It doesn't happen very often, but is serious when it does. |

**Melphalan**

| **Likely**<br><br>(May happen in more than 20% of patients) | **Less Likely**<br><br>(May happen in less than 20% of patients) | **Rare, but Serious**<br><br>(May happen in less than 2% of patients) |
|---|---|---|
| ▪ Loss of appetite<br>▪ Constipation<br>▪ Diarrhea<br>▪ Nausea (feeling sick to your stomach) and vomiting (throwing up)<br>▪ Temporary hair loss<br>▪ Sensitive skin<br>▪ Infection<br>▪ Low number of white blood cells<br>▪ Low number of platelets in the blood with increased risk of bleeding<br>▪ Anemia (low number of red blood cells)<br>▪ Mouth sores<br>▪ Sore throat (red with swelling)<br>▪ Skin breakdown (if drug leaks from vein) | ▪ Changes in heart beat that cause you to dizzy, faint and short of breath<br>▪ Hepatitis (swelling of the liver)<br>▪ Kidney failure<br>▪ Weight loss<br>▪ Feeling weak | ▪ Allergic reaction<br>▪ Lung infection<br>▪ Scarring of lung tissue<br>▪ Seizure<br>▪ Vasculitis (inflammation of blood vessels)<br>▪ Low blood pressure<br>▪ Excessive perspiration<br>▪ Sterility (unable to have children)<br>▪ Liver damage<br>▪ Heart stops beating<br>▪ Cancer of bone marrow cells |

**Bortezomib (Velcade®)**

| **Likely**<br><br>(May happen in more than 10% of patients) | **Less Likely**<br><br>(May happen in less than 10% of patients) | **Rare, but Serious**<br><br>(May happen in less than 1% of patients) |
|---|---|---|
| ▪ Anemia (low number of red blood cells)<br>▪ Low number of platelets in the blood with increased risk of bleeding<br>▪ Feeling weak and uncomfortable<br>▪ Feeling tired<br>▪ Fever, with shaking chills<br>▪ Weight loss because not feeling hungry<br>▪ Constipation<br>▪ Diarrhea<br>▪ Nausea and vomiting<br>▪ Upset stomach or pain in the belly<br>▪ Pain, numbness and tingling in hands and feet<br>• Lowered white blood cells called neutrophils that may increase your | ▪ Low number of white blood cells<br>▪ Low blood pressure<br>▪ Changes in heart beat and feeling dizzy, faint and short of breath<br>• Heartburn, acid reflux and stomach bloating<br>▪ Bleeding in stomach or lungs<br>▪ Blood in urine<br>▪ Fluid build-up around the lungs<br>▪ Confusion<br>▪ Mouth or throat sores<br>▪ Changes in the way things taste<br>▪ Abnormal liver tests<br>▪ Blurred vision<br>▪ Redness and swelling in the eye<br>▪ Nose bleeds | ▪ Coughing up blood<br>▪ Reversible posterior leukoencephalopathy syndrome [RPLS]/Posterior reversible encephalopathy syndrome [PRES] (headache, confusion, seizures, and vision loss caused by very high blood pressure that comes on quickly)<br>▪ Hepatitis (swelling of the liver) and liver failure<br>▪ Pancreatitis (swelling of the intestines, stomach, or pancreas)<br>▪ Swelling and fluid build-up in and around the lungs or heart<br>▪ Hearing loss<br>▪ Bleeding in the brain<br>▪ Loss of some or all vision in one or both eyes |

| **Likely**<br><br>(May happen in more than 10% of patients) | **Less Likely**<br><br>(May happen in less than 10% of patients) | **Rare, but Serious**<br><br>(May happen in less than 1% of patients) |
|---|---|---|
| risk of infection and is uncommonly associated with fever; commonly you may have lowered white blood cells called lymphocytes or have lowered red blood cells, white blood cells and platelets at the same time.<br>▪ Skin rash with itching and redness<br>▪ Insomnia (trouble sleeping)<br>▪ Anxiety (feeling worried and nervous)<br>▪ Aches, pain and weakness in arm and leg muscles, joints and bones<br>▪ Cough<br>▪ Headache<br>▪ Flu-like symptoms such as chills, sore throat, and runny nose<br>▪ Edema (swelling in the arms and legs with weight gain) | ▪ Changes in blood sugar<br>▪ Changes in levels of sodium, calcium and potassium in the blood<br>▪ New or worse heart failure<br>▪ Infections of the bladder, sinuses, mouth, throat, stomach, intestines and skin<br>▪ Infections in the blood that can lead to death<br>• Kidney function that gets worse<br>• Fungal infections in the mucous membrane such as the mouth and throat and uncommonly in the skin and nails<br>• Muscular weakness | ▪ Encephalopathy (brain disorder that can lead to death)<br>▪ Sore mouth and throat<br>▪ Allergic reactions (swelling, of the skin, face or throat) that can lead to death<br>▪ Blistering rash with skin peeling and mouth sores that can lead to death<br>▪ Pain, swelling and red skin where bortezomib is injected<br>▪ Intestinal blockage<br>▪ Fast death of cancer cells that can hurt organs like the kidneys<br>▪ Severe muscle weakness and paralysis |

| **Likely**<br><br>(May happen in more than 10% of patients) | **Less Likely**<br><br>(May happen in less than 10% of patients) | **Rare, but Serious**<br><br>(May happen in less than 1% of patients) |
|---|---|---|
| • Herpes virus such as shingles (herpes zoster) that can sometimes cause local pain that does not go away for a while and herpes simplex virus. Shingles can sometimes spread over large parts of the body. Both may also affect the eyes or brain, but this is uncommon<br>• Hair loss | | |

**Fludarabine**

| **Likely**<br><br>**(May happen in more than 20% of patients)** | **Less Likely**<br><br>**(May happen in less than 20% of patients)** | **Rare, but Serious**<br><br>**(May happen in less than 2% of patients)** |
|---|---|---|
| ▪ Mouth sores<br>▪ Nausea and vomiting<br>▪ Diarrhea<br>▪ Low number of white blood cells<br>▪ Low number of platelets in the blood | ▪ Pain, numbness and tingling in the hands and feet<br>▪ Feeling sleepy<br>▪ Weakness<br>▪ Changes in heartbeat<br>▪ Loss of appetite | ▪ Coma<br>▪ Inflammation of the lungs<br>▪ Cough<br>▪ Interstitial pneumonia (type of lung disease)<br>▪ Agitation or nervousness<br>▪ Confusion |

| | | |
|---|---|---|
| with increased risk of bleeding<br>▪ Anemia (low number of red blood cells)<br>▪ Infection<br>▪ Pneumonia<br>▪ Fever, with chills<br>▪ Swelling of hands and feet | ▪ Changes in vision<br>▪ Cough<br>▪ Skin rash | ▪ Severe brain injury and death<br>▪ Kidney damage that could require dialysis |

### Methotrexate

| **Likely**<br><br>(May happen in more than 20% of patients) | **Less Likely**<br><br>(May happen in less than 20% of patients) | **Rare, but Serious**<br><br>(May happen in less than 2% of patients) |
|---|---|---|
| ▪ Low number of white blood cells<br>▪ Infection<br>▪ Feeling tired<br>▪ Sensitivity to the sun (sunburn easily)<br>▪ Bruise easily<br>▪ Changes in skin<br>▪ Mouth and throat sores<br>▪ Loss of appetite<br>▪ Diarrhea<br>▪ Temporary hair loss | ▪ Nausea and vomiting<br>▪ Abdominal pain<br>▪ Fever, with chills<br>▪ Anemia (low number of red blood cells)<br>▪ Low number of platelets in the blood with increased risk of bleeding<br>▪ Kidney damage or failure<br>▪ High number of liver enzymes in the blood | ▪ Feeling dizzy<br>▪ Inflammation of the lungs<br>▪ Scarring of lung tissue<br>▪ Changes in vision<br>▪ Skin rash |

## Tacrolimus (FK506, Prograf®)

| **Likely**<br><br>(May happen in more than 20% of patients) | **Less Likely**<br><br>(May happen in less than 20% of patients) | **Rare, but serious**<br><br>(May happen in less than 2% of patients) |
|---|---|---|
| ▪ Kidney problems<br>▪ Low magnesium, calcium, and potassium in the blood<br>▪ High blood pressure<br>▪ Tremors (shaking)<br>▪ High cholesterol<br>▪ Low number of platelets in the blood with increased risk of bleeding<br>▪ Infection | ▪ Nausea and vomiting<br>▪ Liver problems<br>▪ Foggy thinking<br>▪ Trouble sleeping<br>▪ Unwanted hair growth<br>▪ Confusion<br>▪ Reversible posterior leukoencephalopathy syndrome [RPLS]/ Posterior reversible encephalopathy syndrome [PRES] (headache, confusion, seizures, and vision loss caused by very high blood pressure that comes on quickly) | ▪ Seizures<br>▪ Changes in vision<br>▪ Feeling dizzy<br>▪ The body stops making red blood cells (can lead to anemia)<br>▪ Lymphoproliferative disorder (the body makes too many lymphocyte cells) |

**It is very important that you do not eat grapefruit or drink grapefruit juice while taking Tacrolimus. Grapefruit has an ingredient called bergamottin, which can affect some of the treatment drugs used in this study.** Common soft drinks that have bergamottin are *Fresca*, *Squirt*, and *Sunny Delight*.

## Ixazomib (MLN9708)

| **Likely**<br><br>**(May happen in more than 10% of patients)** | **Less Likely**<br><br>**(May happen in less than 10% of patients)** | **Rare, but Serious**<br><br>**(May happen in less than 1% of patients)** |
|---|---|---|
| ▪ Low number of platelets in the blood with increased risk of bleeding<br>▪ Skin rash<br>▪ Feeling tired<br>▪ Feeling weak<br>▪ Nausea and vomiting<br>▪ Diarrhea<br>▪ Constipation<br>▪ Pain, numbness and tingling in hands and feet<br>▪ Anemia (low number of red blood cells)<br>▪ Low number of white blood cells<br>▪ Infection<br>▪ Loss of appetite<br>▪ Lung infection (pneumonia) | ▪ Changes in levels of potassium, calcium, sodium, and magnesium in the blood<br>▪ Flu-like symptoms such as chills, sore throat, runny nose, and sinus and throat infections<br>▪ Kidney failure that can require dialysis<br>▪ Shingles virus | ▪ Rash with skin peeling and mouth sores that can lead to death<br>▪ Posterior reversible encephalopathy syndrome (PRES) (headache, confusion, seizures and vision loss caused by very high blood pressure that comes on quickly)<br>▪ Progressive multifocal leukoencephalopathy (PML), a rare infection in the brain caused by a virus[1]<br>▪ Inflammation of the spinal cord with damage to nerves<br>▪ Fast death of cancer cells that can hurt organs like the kidneys<br>▪ Heart muscle injury (congestive heart failure) or lung tissue damage that can lead to death<br>▪ Liver failure |

| | | |
|---|---|---|
| ▪ Muscle weakness<br>▪ Swelling of the hands, feet, ankles or lower legs<br>▪ Upset stomach or pain in the belly or back<br>▪ Low blood pressure | | |

[1]PML has been observed rarely (< 0.1%) in patients taking ixazomib. It is not known if ixazomib may contribute to the development of PML in this patient.

Researchers for other studies of ixazomib are still watching patients to see how well they do on it. For this reason, there may be side effects that we don't know about yet. Also, we don't know if the side effects in the **Less Likely** group are caused by ixazomib, the patient's disease, or other drugs.

**Ixazomib and bortezomib <u>should not</u> be taken if you have ever had an allergic reaction to boron or products that contain boron.** Other drugs and supplements may affect the way Ixazomib works. It's important to tell your doctor about all drugs and treatments (for example, over-the-counter medicines and vitamins) you are taking while you are in this study.

<u>Previous Experience with Bortezomib</u>

The doctors who are conducting the study have gained some experience with a similar conditioning regimen used earlier in this study. They found that some patients who received 4 doses of bortezomib suffered a higher rate of expected severe side effects (including death) within 30 days of transplant. Because of these unanticipated early complications, the study doctors have reduced the number of doses of bortezomib given as a part of this study to one for new patients.

<u>Risk to the Unborn</u>

The treatments in this study <u>have not</u> been proven to be safe at any stage of pregnancy or nursing (breast feeding). If you are pregnant or nursing, you can't join this study.

Women <u>and</u> men must refrain from all acts of vaginal sex (abstinence) or use **2 types** of effective birth control while receiving chemotherapy, drugs to prevent GVHD, and maintenance treatment. You must use effective birth control during the entire study and for 90 days after stopping maintenance treatment. Effective birth control is defined as the following:

1. Consistent use of birth control pills

2. Injectable birth control methods (Depo-Provera, Norplant)

3. Tubal sterilization or male partner who has undergone a vasectomy

4. Placement of an IUD (intrauterine device)

5. Use of a diaphragm with contraceptive jelly and/or condoms with contraceptive foam every time you have sex.

You do not need to use effective birth control only if you are a woman and cannot have children because you:

- Had an effective tubal ligation (your tubes were tied), OR

- Had a hysterectomy (your ovaries and uterus were removed), OR

- Went through menopause (post-menopausal; i.e., have not had a menstrual period for at least 12 consecutive months).

Reproductive Risks

The drugs used in this research study may damage your reproductive organs, affect your ability to have children, or cause birth defects if you take them while you are pregnant or nursing.

Both women who can become pregnant and their male partners should use birth control while on this study and for 90 days after maintenance treatment is stopped. **If you or your partner becomes pregnant during this study, you must tell the study doctor immediately.**

Your doctor will discuss the risks to your unborn child and options with you.

It is important that females who aren't pregnant or nursing don't become pregnant while part of the study. If you are a woman and become pregnant while on this study, we will stop the maintenance treatment drug right away.

Your study doctor will watch your health closely while you are pregnant.

- **Females who join the study**

If you are female and can become pregnant, you will need to take a pregnancy test before you start the study. You should discuss ways to prevent pregnancy while you're in the study. Some women might experience irregular menstrual cycles or their cycle might stop forever. This doesn't mean that you can't become pregnant. You must still use 2 effective forms of birth control during the study and continue with it for 90 days after you finish maintenance treatment.

Be sure to talk with your doctor about options for fertility planning, like storing your eggs, before starting chemotherapy treatment.

- **Males who join the study**

If you are male, your body may not be able to produce sperm (become sterile). Be sure to talk with your doctor about options for fertility planning, like banking your sperm, before starting chemotherapy treatment.

**Risks of Transplant**

The following problems may happen after transplant. These problems might happen if you have a transplant as part of the study or as standard care:

Graft-Versus-Host Disease (GVHD)

GVHD develops when the white blood cells, which are called T cells, in the donor cells attack your body. You are more likely to get GVHD if your donor's tissue does not closely match your tissue.

There are 2 kinds of GVHD: acute and chronic. Acute GVHD usually develops within the first 3 months after transplant. Chronic GVHD usually develops later and lasts longer.

You may experience these side effects with acute GVHD:

- Skin rash
- Nausea (feeling sick to your stomach)
- Vomiting (throwing up)
- Diarrhea
- Abdominal (stomach area) pain
- Problems with your liver (your doctor will run tests for this)
- Infection

You may experience these side effects with chronic GVHD:

- Skin rash
- Hair loss

- Thickened skin
- Joint stiffness (knees, elbows, fingers)
- Dry eyes
- Dry mouth
- Liver disease (your doctor will run tests for this)
- Weight loss
- Diarrhea
- Infection

We don't know for sure if you will develop acute or chronic GVHD. The chance that you will get GVHD is 10-30%. This means that 10 to 30 people out of 100 might develop it. Your doctor will watch you closely for GVHD and treat it if it happens.

To know for sure if you have acute or chronic GVHD, we may do a biopsy of your skin. A biopsy is where we take a small piece of your skin and look at it under a microscope for signs of GVHD. There's a small chance that we might also do a biopsy of your intestine and liver. Risks of biopsy may include pain, infection, or bleeding.

In most cases, GVHD can be treated. If GVHD does not respond to the drugs, your doctor will talk with you about other treatment options. If you choose a different treatment option, we will give you information about the side effects.

You may need to be treated for GVHD for many months or years. GVHD treatments can cause your immune system to become very weak if it goes on for a long time. This means you may develop more infections and need to be admitted to the hospital often. GVHD can be very serious and hard to treat. It might also cause death.

<u>Slow recovery of blood counts</u>

The red blood cells, white blood cells, and platelets can be slow to recover after transplant. Until your blood counts recover, you will need blood and platelet transfusions. You'll be at risk for bleeding and infections. We may give you a drug called **Filgrastim** to speed up the recovery of the white blood cells as much as possible and lower the chance of bleeding and infections.

<u>Graft (donor cells) failure or rejection</u>

Some patients' bodies reject the donor cells (graft) with an allogeneic transplant. Also, a certain amount of your old blood and marrow cells will remain in your body.

If your body rejects the donor cells, your doctor may need to give you a donor lymphocyte infusion (DLI). A DLI is an extra dose of the donor cells. You may also get another transplant, but this is rare. If you need a DLI or second transplant, your doctor will explain the risks and benefits.

Damage to the vital organs in your body

Your vital organs include your heart, lungs, liver, intestines, kidneys, bladder and brain. The chemotherapy and GVHD drugs may hurt these organs. You may develop lung problems from chemotherapy or an infection.

Some patients can have veno-occlusive disease (VOD) of the liver. Patients with VOD become jaundiced (yellow skin), have problems with their liver, retain too much water (feel swollen and uncomfortable), and have stomach swelling and pain.

If there is serious damage to your vital organs, you may have to stay in the hospital longer or return to the hospital after your transplant. Many patients get better, but these complications can cause permanent damage to your organs or death.

Serious infections

It may take many months for your immune system to recover from the chemotherapy, GVHD and maintenance therapy drugs. There is an increased risk of infection during this time when your body is healing. We will give you drugs to reduce the chance of infection, but they may not work. If you have an infection, you may have to stay in the hospital longer or return to the hospital after transplant. Many patients get better, but some infections can cause death.

Return of disease

Your disease may come back even if the transplant is successful at first. Your doctor will discuss your treatment options with you if your disease returns and you are removed from study.

Development of a new cancer

In rare cases, a new type of cancer may develop from the donor cells. The risk of developing a new cancer after allogeneic transplant is less than 2% (1 or 2 patients (or fewer) out of 100).

Unforeseen Risks

New risks might appear at any time during the study. These risks might be different from what is listed in this Consent Form. We will promptly tell you about new information that may affect

your decision to take part in the study. We may learn new things about allogeneic transplants, GVHD prevention treatment, or maintenance treatment that might make you want to stop being in the study. If this happens, we will let you know so you can decide if you want to continue in the study.

Other Treatments or Medicines

Some medicines react with each other, and it is important that you tell the study doctor or staff about any other drugs, treatments, or medicines you are taking. This includes non-prescription or over-the-counter medicines, vitamins, and herbal treatments.

It is also important that you tell the study staff about any changes to your medicines while you're in the study.

For more information about risks and side effects, ask your study doctor.

## 7. Alternative Treatments

Participation in this study is optional. If you choose not to take part, you may still receive non-transplant treatments or an autologous or an allogeneic transplant to treat your disease. The treatment and evaluations you would receive could be very similar to what would receive if you join this study.

Your study doctor will talk with you about your options. If you decide not to participate in this study, your medical care will not be affected in any way.

Your other choices may include:

- Treatment with other drugs, radiation, or a combination of drugs and radiation without a transplant.
- An allogeneic (donor) blood or marrow transplant that is not part of the study, or another type of transplant
- Participation in another clinical trial, if available (check with your doctor)
- No treatment for your blood cancer at this time
- Comfort care

Every treatment option has benefits and risks. Talk with your doctor about your treatment choices before you decide if you will take part in this study.

## 8. Possible Benefits

Taking part in this study may or may not make your health better. The information from this study will help doctors learn more about drugs used to treat multiple myeloma.

This information could help people with multiple myeloma who may need a transplant in the future.

## 9. New Information Available During the Study

During this research study, the study doctors may learn about new information about the study drugs or the risks and benefits of the study. If this happens, they will tell you about the new information. The new information may mean that you can no longer participate in the study, or that you may not want to continue in the study.

If this happens, the study doctor will stop your participation in the study and will offer you all available care to suit your needs and medical conditions.

## 10. Privacy, Confidentiality and Use of Information

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

All your medical and demographic information (such as race and ethnicity, gender and household income) will be kept private and confidential. *(Name of Transplant Center)* and the organizations listed below will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission, or unless required by federal, state or local laws, or regulatory agencies.

Individuals authorized by the organizations below will have access to your research and medical information. They may use this information for inspections or audits to study the outcomes of your treatment. In agreeing to participate, you consent to such inspections and to the copying of parts of your records, if required by these organizations.

We may give out your personal information if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Information about your transplant from your original medical records may be seen or sent to national and international transplant registries, including:

- /Institution/
- The Center for International Blood and Marrow Transplant Research (CIBMTR)
- The National Marrow Donor Program (NMDP)
- The Food and Drug Administration (FDA)
- The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI)
- Data and Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
- Data and Safety Monitoring Board (DSMB), not part of /Institution/
- Study investigators.
- Millennium, its collaborators or designees

We will not identify you by name in any publications or reports that come from these organizations or groups.

Information that does not include personally identifiable information about this study has been or will be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registration, results, and other information about registered studies.

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

Data regarding your clinical situation, including follow-up after 2 years, may be obtained from the CIBMTR, which captures information on all U.S. transplants.

For questions about access to your medical records, please contact /name/ at /number.

## 11. Ending Your Participation

The study doctor or the study sponsor may stop the study at any time, and we may ask you to leave the study. We may ask you to leave the study if you do not follow directions or if you suffer from side effects of the treatment. If we ask you to leave the study, the reasons will be discussed with you. Possible reasons to end your participation in this study include:

- You do not meet the study requirements.
- You need a medical treatment not allowed in this study.
- The study doctor decides that it would be harmful to you to stay in the study.
- You are having serious side effects.
- You become pregnant.
- You cannot keep appointments or take study drugs as directed.
- The study is stopped for any reason.

You could have serious health risks if you stop treatment during the conditioning process before you receive your transplant. If you stop taking the immune suppressing drugs (see **Section 6: Risks and Discomforts**) too soon after transplant, your body could reject the donor stem cells or you could develop serious complications and possibly die.

We ask that you talk with the research doctor and your regular doctor before you leave the study. Your doctors will tell you how to stop safely and talk with you about other treatment choices.

If you decide to leave this study after getting the study treatment, or are asked to leave by your doctor for medical reasons, you will need to come back to the doctor's office for tests for your safety. Even if you leave the study, the information collected from your participation will be included in the study evaluation, unless you specifically ask that it not be included.

## 12. Physical Injury as a Result of Participation

It is important that you tell your doctor, _____ *[investigator's name(s)]* or study staff if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number]*.

You will get all available medical treatment if you are injured from taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

In case you are injured in this study, you do not lose any of your legal rights to ask for or receive payment by signing this form.

## 13. Compensation or Payment

You will not be paid for your participation in this research study. You will not get compensation or reimbursement for any extra expenses (travel, meals, etc.) you may have through your participation on this trial.

Your participation in this research study may contribute to the development of commercial products from which Millennium Pharmaceuticals, Inc. or others, may derive an economic benefit. You will have no rights to any patents or discoveries arising from this research, and you will receive no economic benefit.

## 14. Costs and Reimbursements

Most of the visits for this research study are standard medical care for your allogeneic transplant and will be billed to your insurance company. You and/or your health plan/insurance company will need to pay for some or all of the costs of standard treatment in this study. The study drugs bortezomib, ixazomib, and placebo will be provided by Millennium at no cost to you or your insurance.

You or your insurance will not be charged for optional blood samples for research on this study. You will not pay for any extra tests that are being done for the study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out if they will pay.

For questions about your costs, financial responsibilities, and/or medical insurance coverage for your transplant and this study, please contact /Center/ Financial Counselor at /Number/.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

## 15. For More Information

If you need more information about this study, or if you have problems while taking part in this study, you can contact the study doctor or his/her staff.

They can be reached at the telephone numbers listed here:

[*Insert name and contact details*]

## 16. Contact Someone about Your Rights

If you wish to speak to someone not directly involved in the study, or if you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

[*Insert appropriate contact details*]

The ethical aspects of this study have been reviewed and approved by *[name of IRB]*.

## 17. Blood and Tissue Samples for Future Research (Optional)

This section of the informed consent form is about future research studies that will use blood and tissue samples from people who are taking part in the main study. You may choose to give samples for these future research studies if you want to. You can still be a part of the main study even if you say 'no' to give samples for future research studies.

Researchers are trying to learn more about how the human body processes the drugs used for transplant and how the body recovers after transplant. This research is meant to gain knowledge that may help people in the future and make transplants even more successful.

If you agree to provide blood and tissue samples, here is what will happen:

- We will collect extra blood samples at the same time you have routine blood tests done. The amount of blood collected from you is about 7 teaspoons (36 mL) each time.
- We will collect blood samples at seven different dates in the study (see **Tables 3 and 4**):

- 2 weeks or less before transplant
- 4 weeks after transplant
- 2 weeks before maintenance treatment is started
- Cycles 2, 5 and 10 of maintenance treatment
- 28 days or less after your last dose of maintenance treatment

- We will collect three bone marrow tissue samples at the same time you have routine bone marrow biopsies done. The amount of tissue collected from you is about 2 teaspoons (10 mL) each time. We will collect samples at three different dates in the study (see **Tables 3 and 4**):
  - 2 weeks or less before transplant
  - 2 weeks before maintenance treatment is started
  - 28 days or less after your last dose of maintenance treatment
- Some of your samples will be stored and some will be used for research right now. The samples to be stored will be sent to the BMT CTN Repository for processing and storage. A repository is a place that protects, stores, and sends out samples for approved research studies. All seven of the blood samples will be sent to the BMT CTN Repository to be stored. A small amount of three out of the seven blood samples will be sent to Roswell Park Cancer Institute for a research study looking at how fast your immune system recovers after the transplant. There were will be no additional blood samples collected. All research samples, including the ones that will be stored, will be given a barcode that cannot be linked to you by future researchers testing your samples. The link between your patient identification and your sample barcode will be held in your study records at [*Insert Site Name*] only.
- The liquid bone marrow collected will be sent to the BMT CTN Repository and to Roswell Park Cancer Institute for testing. The bone marrow samples going to the BMT CTN Repository will be processed and stored similar to blood samples. The bone marrow samples sent to Roswell Park Cancer Institute will be tested to detect multiple myeloma cells. This test is called minimal residual disease and it will assist in understanding how much this treatment is controlling the cancer.
- Materials stored in the Repository will be used mainly by clinicians and researchers in the BMT CTN network. In the future, the unused research samples and clinical data will be made available outside of this network.

- Researchers can apply to study the materials stored in the Repository. The BMT CTN Steering Committee and/or the BMT CTN Executive Committee must approve each request before they will share samples or information with researchers. This is to make sure that the investigators requesting the samples are qualified, and that the research is of high quality.

- DNA from your stored blood samples might be used in genome-wide association (GWA) studies for a future project either done or supported by the National Institutes of Health (NIH). Genome-wide association studies are a way for scientists to find genes that have a role in human disease or treatment. Each study can look at hundreds of thousands of genetic changes at the same time.

  If your coded samples are used in such a study, the researcher is required to add your test results and sample information into a shared, public research database. This public database is called the NIH Genotype and Phenotype Database and it is managed by the National Center for Biotechnology Information (NCBI). The NCBI will never have any information that would identify you, or link you to your information or research samples.

Some general things you should know about letting us store your blood samples for research are:

- We will only store samples from people who give us permission.

- Research is meant to gain knowledge that my help people in the future. You will not get any direct benefit from taking part. Additionally, you or your doctor will not be given results and they will not be added to your medical record.

- A possible risk is the loss of confidentiality about your medical information. We will use safety measures with both your samples and clinical information to make sure that your personal information will be kept private. The chance that this information will be given to someone else is extremely small.

- Your blood and tissue samples will be used only for research and will not be sold. The research done with your blood may help to develop new products in the future. You will not get paid for any samples or for any products that may be developed from current or future research.

**You can change your mind at any time about allowing us to use your samples and health information for research**.

We ask that you contact [*Principal Investigator*] in writing and let him/her know you do not want us to use your research samples or health information for research. His/her mailing address is on the first page of this form. However, samples and information that have already been shared with other researchers cannot be taken back or destroyed.

**Making Your Choice**

Please read each sentence below and think about your choice. After reading each sentence, please indicate your choice below. If you have any questions, please talk to your doctor or nurse, or call our research review board at _____.

No matter what you decide to do, it will not affect your care.

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## Statement of Consent for Research Samples

The purpose of storing blood and tissue samples, the procedures involved, and the risks and benefits have been explained to me. I understand that if I provide consent, the liquid part of my bone marrow will be assessed for minimal residual disease and that my blood samples will be used to assess how quickly my immune system recovers. I have asked all the questions I have at this time and I have been told whom to contact if I have more questions. I have been told that I will be given a signed copy of this consent form to keep.

I understand that I do not have to allow the use of my blood and tissue for research. If I decide to not let you store research samples now or in the future, it will not affect my medical care in any way.

I voluntarily agree that my blood, tissue, and information can be stored indefinitely by the BMT CTN and/or NHLBI Repositories for research to learn about, prevent, or treat health problems. I also understand that my DNA and health information may or may not be used in genome-wide association studies.

**Blood**

❑ I agree to allow my blood samples to be stored for future and immune reconstitution research.

❑ I do not agree to allow my blood samples to be stored for future and immune reconstitution research.

**Bone marrow**

❑ I agree to allow my bone marrow tissue samples to be stored for future and MRD research.

❑ I do not agree to allow my bone marrow tissue samples to be stored for future and MRD research.

_____ _____

Signature Date

**Health Insurance Portability and Accountability Act 1 (HIPAA1) Authorization to use and disclose individual health information for research purpose**

**A. Purpose**:

As a research participant, I authorize the Principal Investigators and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research study:

A Multi-Center Phase II, Double-blind Placebo Controlled Trial of Maintenance Ixazomib after Allogeneic Hematopoietic Cell Transplantation for High Risk Multiple Myeloma

**B. Individual Health Information to be Used or Disclosed**:

My individual health information that may be used or disclosed to do this research includes:

- Demographic information (for example, date of birth, sex, weight)
- Medical history (for example, diagnosis, complications with prior treatment)
- Findings from physical exams
- Laboratory test results obtained at the time of work up and after transplant (for example, blood tests, biopsy results)

**C. Parties Who May Disclose My Individual Health Information**:

The researcher and the researcher's staff may collect my individual health information from:

[*List hospitals, clinics or providers from which health care information can be requested*]

**D. Parties Who May Receive or Use My Individual Health Information**:

The individual health information disclosed by parties listed in item c and information disclosed by me during the course of the research may be received and used by the following parties:

Dr. Parameswaran Hari, Co-Principal Investigator

Dr. Taiga Nishihori, Co-Principal Investigator

Dr. Qaiser Bashir, Co-Principal Investigator

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

Millennium, its collaborators or designees

Study Sponsors

- National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH),
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Data and Coordinating Center
- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)
- U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments.

**E. Right to Refuse to Sign this Authorization**:

I do not have to sign this Authorization. If I decide not to sign the Authorization, I will not be allowed to participate in this study or receive any treatment related to research that is provided through the study.

My decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

**F. Right to Revoke**:

I can change my mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of my decision.

If I withdraw this authorization, t he researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

**G. Potential for Re-disclosure**:

My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected.

Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

**H. Genetic Information Nondiscrimination Act (GINA)**

A new federal law (2009), called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information.

Health insurance companies and group health plans may not request your genetic information that we get from this research. This means that they must not use your genetic information when making decisions regarding insurability. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**I. This authorization does not have an expiration date.**

**TITLE:** A Multi-Center Phase II, Double-Blind Placebo Controlled Trial of Maintenance Ixazomib after Allogeneic Hematopoietic Cell Transplantation for High Risk Multiple Myeloma

**PROTOCOL NUMBER:** BMT CTN #1302

**PRINCIPAL INVESTIGATOR:**

Name:

Address:

Email:

Phone:

Fax:

I have read and understood this Consent Form. The nature and purpose of the research study has been explained to me.

- I have had the chance to ask questions, and understand the answers I have been given. I understand that I may ask questions at any time during the study.
- I freely agree to be a participant in the study.
- I understand that I may not directly benefit from taking part in the study.
- I understand that, while information gained during the study may be published, I will not be identified and my personal results will stay confidential.
- I have had the chance to discuss my participation in this research study with a family member or friend.
- I understand that I can leave this study at any time, and doing so will not affect my current care or prevent me from receiving future treatment.
- I understand that I will be given a copy of this signed consent form.

| | |
|---|---|
| Participant Name | Date |
| Signature | Date |

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

| | |
|---|---|
| Name of Counseling Physician | Date |
| Signature of Counseling Physician | Date |