

## Informed Consent to Participate in Research



**Your Name:** \_\_\_\_\_

**Study Title:** Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702

**Protocol:** BMT CTN 0702 Long-Term Follow-Up

**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). Celgene is supplying the study drug lenalidomide.

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## 1. Introduction

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

1. You took part in the study, A Trial of Single Autologous Transplant with or without Consolidation Therapy versus Tandem Autologous Transplant with Lenalidomide Maintenance for Patients with Multiple Myeloma, also called **BMT CTN 0702**
2. After your autologous transplant, you finished 3 years of maintenance treatment for the BMT CTN 0702 study
3. Your disease did not return or worsen (this is also called **disease progression**) during the BMT CTN 0702 study.

Because there's no cure for Multiple Myeloma (MM), **maintenance treatment (chemotherapy)** is given to slow the return of your disease after an **autologous transplant**. We are doing this study to learn how well maintenance treatment works to control your disease long-term (more than 3 years after transplant).

For this study, the type of maintenance treatment you will get is **lenalidomide**. Lenalidomide is the same medication you have received for the first 3 years as maintenance following your autologous transplant. Lenalidomide is a chemotherapy drug used to slow down relapse.

This study will include 450 participants. Your participation on this study is expected to last until your disease returns or progresses.

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 follow-up treatment choices if you do not want to participate in this study.

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## 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.

Celgene will supply the drug, lenalidomide, for this study.

For this study, we will give you maintenance treatment (lenalidomide) to slow down the relapse of your disease. We will watch your health closely (this is also called follow-up) after your autologous transplant.

There's no cure for multiple myeloma (MM). After transplant, the disease will almost always return, or relapse. Even with maintenance treatment, MM will relapse. Your doctor doesn't know how long it will take for the disease to return.

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## 3. Study Purpose

We are inviting you to take part in this study because you finished the BMT CTN 0702 study and your disease did not return or worsen. We are doing this study to learn more about ways to prevent or delay relapse of multiple myeloma (MM). We also want to know how well you do long-term (more than 3 years) after transplant.

You will get maintenance treatment and have a physical evaluation (test) every 6 months to see if you still have MM in your body. This study will help doctors make the best choice about long-term treatment after autologous transplant for patients with MM.

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## 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.

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## 5. Study Tests

We will check (test) your health every 6 months until the end of the study. This is called long-term follow-up maintenance treatment, after transplant. We will stop the study tests if your disease returns or relapses.

### Before You Start Maintenance Treatment

You will need to have several check-ups and tests before you begin maintenance therapy. These tests include:

- Physical exam, including height and weight
- A pregnancy test using a blood sample (if you are a woman able to have children). This test will be done about 2 weeks before you start maintenance treatment. If you are pregnant or breastfeeding, you can't take part in this study.
- Tests to check for cancer as decided by your doctors. These tests would normally be done even if you were not on a research study and may include:
  - Bone marrow aspiration and biopsy (see **Section 6: Risks and Discomforts**)
  - Blood tests (up to 4 – 5 tablespoons)
  - Urine tests
- Optional blood samples for future research (see **Section 17: Blood Samples for Future Research**).

We will also ask you to take a quality of life survey. The survey will ask about:

- Any side effects of your treatment
- Any health problems
- How well you can do things that are important to you
- How you relate to other people
- Your feelings.

An interviewer will contact you to take the survey. These interviews will take about 30 minutes and will be done at a time that works for you. You may skip any questions you wish.

### **During Your Maintenance Treatment**

You will keep taking lenalidomide during long-term maintenance treatment. If you stopped taking lenalidomide for the BMT CTN 0702 study, you will start taking it again. You will stay on maintenance treatment until your cancer returns, or relapses. If your cancer does not relapse during the study, you will keep taking lenalidomide until the study ends.

We will give you the same dose of lenalidomide that you were taking when you finished the BMT CTN 0702 study. We will give you lenalidomide as a pill to take once a day.

- Swallow the lenalidomide pills whole, with water, at the same time each day. Don't break, chew or open the pills. If you take more lenalidomide than you were prescribed, you should seek emergency medical care and contact the study staff immediately.
- If you miss a dose of lenalidomide, take it as soon as you remember on the same day. If you miss taking your dose for the entire day, take your regular dose the next scheduled day. Don't take 2 doses to make up for the missed dose.

We will watch your health closely during maintenance treatment, including how well your organs work (function). We will lower your dose or stop the treatment if your organs don't handle the treatment well. We will raise your dose or re-start the treatment when your organs start to work well again.

We will modify the dose and/or may stop the maintenance treatment if you:

- Have a serious side effect, like severe diarrhea or skin rash
- Have low blood cell counts

We will stop the maintenance treatment if you:

- Are a woman and become pregnant, or there is a chance that you are pregnant
- Don't follow the study directions, or
- Choose to leave the study.

You'll get lenalidomide for this study through the RevAssist for Study Participants (REVLIMID REMS™ Program). You will only get a 28-day supply of lenalidomide at a time. Because you took part in the BMT CTN 0702 study, you are already registered for the program.

Return all leftover lenalidomide pills through the REVLIMID REMS™ Program. Your doctor will tell you how to return the pills.

Females that are pregnant or can become pregnant shouldn't touch the lenalidomide pills or pill bottles, unless they wear gloves.

#### Health Evaluations (tests)

You will visit the clinic every 6 months. At each clinic visit you will have:

- Physical exam, including height and weight
- A pregnancy test using a blood sample (if you are a woman able to have children). If you are pregnant or breastfeeding, you must leave the study. We will give you a pregnancy test:
  - 24 or less hours before your first dose of lenalidomide
  - Next, once a week for 4 weeks
  - Then, once every 4 weeks until the study ends. If you have irregular periods (the number of days in your menstrual cycle is different each month), you will take a pregnancy test once every 2 weeks until the study ends.
  - Last, 4 weeks after you stop taking lenalidomide.
- Counseling once every 4 weeks on the risks of lenalidomide including:
  - Reasons not to share lenalidomide or donate blood
  - Risks to the unborn
  - Risk of changes in numbers of blood cells and blood clots

- Reminder not to break, chew or open the lenalidomide pills.

This counseling is part of the Revlimid REMS™ education program for the study drug. You get the Lenalidomide Information Sheet for Patients Enrolled in Clinical Research Studies with each new supply of lenalidomide.

- Tests to check for cancer as decided by your doctors. These tests would normally be done even if you were not on a research study and may include:
  - Bone marrow aspiration and biopsy (see **Section 6: Risks and Discomforts**)
  - Blood tests (up to 4 – 5 tablespoons)
  - Urine tests
- Optional blood samples for future research (see **Section 17: Blood Samples for Future Research**).

You can do these tests at a clinic near your home. Your clinic will send your test results to the study doctor.

We will also ask you to take a quality of life survey once per year (see **Before You Start Maintenance Treatment**).

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## 6. Risks and Discomforts

You will have side effects while on the study. Side effects can range from mild to serious. The risks and discomforts of long-term maintenance treatment after transplant are the same if you join this study, or if you don't join this study.

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 you get as part of the treatment are listed below. How often patients get each of the side effects are shown in **Table 1. Risks and Side Effects**.

**Table 1. Risks and Side Effects**

<b>Likely</b>	What it means: This type of side effect is expected in <u>more than 20% of patients</u> . This means that 21 or more patients out of 100 might get this side effect.
<b>Less Likely</b>	What it means: This type of side effect is expected in <u>20% of patients or fewer</u> . This means that 20 patients or fewer out of 100 might get this side effect.
<b>Rare, but Serious</b>	What it means: This type of side effect is expected in <u>fewer than 3% of patients</u> . This means that 3 patients (or fewer) out of 100 might get this side effect. It doesn't happen very often, but is serious when it does.

### Lenalidomide (Revlimid®)

<p><b>Likely</b></p> <p>(May happen in more than 20% of patients)</p>	<p><b>Less Likely</b></p> <p>(May happen in 20% of patients or less)</p>	<p><b>Rare, but Serious</b></p> <p>(May happen in less than 3% of patients)</p>
<ul style="list-style-type: none"> <li>▪ Low number of white blood cells (neutrophil/granulocyte)</li> <li>▪ Low number of platelets in the blood with increased risk of bleeding</li> <li>▪ Feeling tired</li> <li>▪ Itchy skin</li> <li>▪ Skin rash with flaky, bumpy skin</li> <li>▪ Constipation</li> <li>▪ Diarrhea</li> <li>▪ Nausea (feeling sick to your stomach)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Anemia (low number of red blood cells)</li> <li>▪ Low number of white blood cells (leukocytes)</li> <li>▪ Cough</li> <li>▪ Fever, with chills</li> <li>▪ Trouble sleeping</li> <li>▪ Excessive sweating</li> <li>▪ Weight loss because not feeling hungry</li> <li>▪ Belly pain</li> <li>▪ Vomiting (throwing up)</li> <li>▪ Low amount of thyroid hormone in the blood</li> <li>▪ Swelling and redness of the skin with sores</li> <li>▪ Sores in the mouth, intestines, and anus</li> <li>▪ Infection</li> <li>▪ Feeling dizzy</li> <li>▪ Headache</li> <li>▪ Swelling, pain and ache in</li> </ul>	<ul style="list-style-type: none"> <li>▪ Allergic reactions (swelling of the skin, face or throat) that can cause you to pass out (faint) or lead to death</li> <li>▪ Rash with skin peeling and mouth sores that can lead to death</li> <li>▪ Outer layer of skin (epidermis) comes apart from the middle layer (dermis), which can lead to death</li> <li>▪ Pancreatitis (swelling of the intestines, stomach, or pancreas)</li> <li>▪ High number of enzymes in the blood</li> <li>▪ Fast death of cancer cells that can hurt organs like the kidneys</li> <li>▪ Temporary growth in tumor or worsening of tumor-related problems</li> <li>▪ Reversible damage to brain tissue that can lead to coma</li> <li>▪ Kidney damage that could require dialysis</li> </ul>

<b>Likely</b>  (May happen in more than 20% of patients)	<b>Less Likely</b>  (May happen in 20% of patients or less)	<b>Rare, but Serious</b>  (May happen in less than 3% of patients)
	joints and muscles of back, arms and legs  <ul style="list-style-type: none"> <li>▪ Trouble breathing</li> <li>▪ Blood clots (clumps of solid blood in your vein) that can lead to death</li> </ul>	<ul style="list-style-type: none"> <li>▪ Second cancers</li> </ul>

We don't know if second cancers are caused by lenalidomide or other drugs. Other research looked at the number of patients who got second cancers after taking lenalidomide for:

- Diseases other than multiple myeloma, AND
- Relapsed multiple myeloma.

In these studies, no difference was shown in the number of patients who got second cancers.

Researchers for other studies of lenalidomide are still watching patients to see if they get second cancers. We will give you any new information that we learn about second cancers.

Risk to the Unborn

The treatments in this study haven't 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. **If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby.**

Women and men must refrain from all acts of vaginal sex (abstinence) or use **2 types** of effective birth control while receiving maintenance treatment. You must use effective birth control during the entire study and for 28 days after stopping maintenance treatment. Effective birth control is defined as the following:

1. Refraining from all acts of vaginal sex (abstinence)
2. Consistent use of birth control pills
3. Injectable birth control methods (Depo-Provera, Norplant)

4. Tubal sterilization or male partner who has undergone a vasectomy
5. Placement of an IUD (intrauterine device)
6. Use of a diaphragm with contraceptive jelly and/or condoms with contraceptive foam every time you have sex.

Females taking lenalidomide have blood clots more often. Because of this, you should talk to your doctor about birth control pills and hormone replacement therapy, and the risks and benefits.

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

- Had a hysterectomy (your ovaries and uterus were removed), OR
- Had a bilateral oophorectomy (your ovaries were removed), OR
- Went through menopause (post-menopausal).

### 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 28 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 and for 30 days after the pregnancy ends.

- **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. Women who have gone through puberty 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 28 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.

#### 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.

#### Relapse (return) of disease or a new blood cancer

Your disease may come back even if the transplant was successful at first. In rare cases, a new blood cancer may develop from your cells. If cancer develops in your blood cells, you may need more chemotherapy or another transplant.

### 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.

### **Risks of Blood Draws**

The risks and side effects of having blood taken from your arm with a needle include:

- Pain, like a pinch
- Swollen, red and sore skin where the needle went
- Bruising
- Feeling faint or dizzy

### **Risks of Bone Marrow Aspiration and Biopsy**

The risks and side effects of anesthesia drug injection include:

- Pain, like a pinch
- Burning feeling in your skin and hip bone

The risks and side effects of a bone marrow aspiration and biopsy include:

- Pressure and pain in hip
- Bleeding
- Bruising
- Ache in hip bone and muscles
- Infection (this is rare)

### **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.

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

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**Statement that You Understand the Study Drug Risks and Side Effects****Females Who Can Become Pregnant**

Please read each statement carefully. Next to each statement that you agree with, write your initials in the space provided.

\_\_\_\_\_ My doctor discussed the risks and side effects of lenalidomide with me. I understand that if I am pregnant or become pregnant while taking lenalidomide, my unborn baby may have birth defects or could die.

\_\_\_\_\_ I understand that effective birth control includes:

- Refraining from all acts of vaginal sex (abstinence)
- Consistent use of birth control pills
- Injectable birth control methods (Depo-Provera, Norplant)
- Tubal sterilization or male partner who has undergone a vasectomy
- Placement of an IUD (intrauterine device)
- Use of a diaphragm with contraceptive jelly and/or condoms with contraceptive foam every time you have sex.

\_\_\_\_\_ I must not take lenalidomide if I am pregnant or can become pregnant and am not using **2 types** of effective birth control. Also, I must not take lenalidomide if I am nursing.

\_\_\_\_\_ I understand that I can become pregnant if:

- I have vaginal sex,
- My uterus and/or ovaries haven't been removed (no hysterectomy),
- I've had one or more menstrual periods in the last 2 years, and
- I haven't gone through menopause.

\_\_\_\_\_ I must refrain from all acts of vaginal sex (**abstinence**) or use **2 types** of effective birth control:

- For 28 or more days before starting lenalidomide
- While taking part in the study, even if you stop taking lenalidomide

- For 28 or more days after you stop taking lenalidomide.

\_\_\_\_\_ I understand that I must have pregnancy tests done at my clinic at:

- About 2 weeks before starting lenalidomide
- 24 or less hours before my first dose of lenalidomide
- Once a week for 4 weeks
- Once every 4 weeks until the study ends. If I have irregular periods, I will take a pregnancy test once every 2 weeks until the study ends.
- When I have been taken off lenalidomide
- 4 weeks after I stop taking lenalidomide.

\_\_\_\_\_ I will immediately stop taking lenalidomide and tell my doctor if I become pregnant or think I might be pregnant during the study. I must talk to my doctor if I stop using 2 types of effective birth control or before changing types of birth control.

\_\_\_\_\_ I am not pregnant now, and I will not try to become pregnant for 28 days or longer after I finish the study.

\_\_\_\_\_ I understand that lenalidomide will be prescribed only for me. I will not share it with anyone, not even someone that has symptoms like mine. I will keep it out of reach of children. I will never give it to females who are pregnant or able to have children.

\_\_\_\_\_ I will return all leftover study drugs through the Revlimid REMS™ Program.

\_\_\_\_\_ I understand that I can't donate blood while taking lenalidomide. Also, I can't donate blood for 28 days after I stop taking lenalidomide.

### **Females Who Can't Become Pregnant**

Please read each statement carefully. Next to each statement that you agree with, write your initials in the space provided.

\_\_\_\_\_ My doctor discussed the risks and side effects of lenalidomide with me. I understand that if a female is pregnant or becomes pregnant while taking lenalidomide, her unborn baby may have birth defects or could die.

\_\_\_\_\_ I am not pregnant now and I'm not able have children because:

- I went through menopause 2 years ago or longer (no periods or spotting)

- I had my uterus removed (hysterectomy) and/or both ovaries removed (bilateral oophorectomy).

\_\_\_\_\_ I understand that lenalidomide will be prescribed only for me. I will not share it with anyone, not even someone that has symptoms like mine. I will keep it out of reach of children. I will never give it to females who are pregnant or able to have children.

\_\_\_\_\_ I will return all leftover study drugs through the Revlimid REMS™ Program.

\_\_\_\_\_ I understand that I can't donate blood while taking lenalidomide. Also, I can't donate blood for 28 days after I stop taking lenalidomide.

## Males

Please read each statement carefully. Next to each statement that you agree with, write your initials in the space provided.

\_\_\_\_\_ My doctor discussed the risks and side effects of lenalidomide with me. I understand that if a female is pregnant or becomes pregnant while taking lenalidomide, her unborn baby may have birth defects or could die.

\_\_\_\_\_ I understand that effective birth control includes:

- Refraining from all acts of vaginal sex (abstinence)
- Consistent use of birth control pills
- Injectable birth control methods (Depo-Provera, Norplant)
- Tubal sterilization or male partner who has undergone a vasectomy
- Placement of an IUD (intrauterine device)
- Use of a diaphragm with contraceptive jelly and/or condoms with contraceptive foam every time you have sex.

\_\_\_\_\_ I understand that I must never have vaginal sex without **2 types** of effective birth control, even if I had a vasectomy. I must use 2 types of effective birth control while I take lenalidomide and for 28 days after I stop taking lenalidomide.

\_\_\_\_\_ I will tell my doctor if I have vaginal sex with a female and don't use **2 types** of effective birth control. I will tell my doctor if I think that my sexual partner might be pregnant. I will tell my sexual partner to tell her doctor immediately if she becomes pregnant or thinks she might be pregnant.

\_\_\_\_\_ I understand that lenalidomide will be prescribed only for me. I will not share it with anyone, not even someone that has symptoms like mine. I will keep it out of reach of children. I will never give it to females who are pregnant or able to have children.

\_\_\_\_\_ I will return all leftover study drugs through the Revlimid REMS™ Program.

\_\_\_\_\_ I understand that I can't donate blood while taking lenalidomide. Also, I can't donate blood for 28 days after I stop taking lenalidomide.

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## 7. Alternative Treatments

Participation in this study is optional. If you choose not to take part, you may still receive long-term follow-up after your transplant. The evaluations you would have could be very similar to what would have 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.

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## 8. Possible Benefits

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

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

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## 9. New Information Available During the Study

During this research study, the study doctors may learn about new information about 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 confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy.

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.*

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.

This data bank can be accessed by you and the general public at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). Federal law requires clinical trial information for certain studies to be submitted to the data bank.

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

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## 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 tests. 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:

- Your disease returns or worsens during the study.
- 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 cannot keep appointments as directed.
- The study is stopped for any reason.

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.

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.

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## 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.

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## 13. Compensation or Payment

You will not be paid for taking part in this study. You will not be paid or reimbursed for any extra costs (for example, travel and meals) from taking part in this study.

You will have no rights to any patents or findings from this study. You will not be compensated for any patents or findings from this study.

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## 14. Costs and Reimbursements

Most of the visits for this research study are standard medical care after your autologous 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.

You will get the study drug, lenalidomide, for free from Celgene. You and your health insurance plan will not be charged for the drug.

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.

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## 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]*

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## 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 Samples for Future Research (Optional)

This section of the informed consent form is about future research studies that will use blood 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 samples, here is what will happen:

- We will collect two extra blood samples at the same time you have routine blood tests done. The amount of blood collected from you is about 6 teaspoons (31 ml) each time.

We will collect blood samples at two times during the study:

- First clinic visit after you join the study
- Last clinic visit at the end of the study

- The blood samples 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 research samples will be given a bar code that cannot be linked to you by future researchers testing your samples.
- 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 may 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 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 [redacted].

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 samples, the procedures involved, and the risks and benefits have been explained to me. 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 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 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 research.
- I do not agree to allow my blood samples to be stored for 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:

Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702

**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. Amrita Krishnan, Study Chairperson and staff/laboratories at City of Hope National Medical Center
- Dr. George Somlo, Study Chairperson and staff/laboratories at City of Hope National Medical Center

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<sup>1</sup> HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

- Dr. Edward Stadtmauer, Study Chairperson and staff/laboratories at University of Pennsylvania Cancer Center.

### Study Sponsors

- National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH),
1. 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)
  2. 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
  3. Celgene (the manufacturer of lenalidomide)
  4. Biologics, Inc (the distributor of lenalidomide).

### **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, the 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:** Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702

**PROTOCOL NUMBER:** BMT CTN #0702 Long-term Follow-Up Study

**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
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Signature	Date
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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
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Signature of Counseling Physician	Date
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**PATIENT INFORMED CONSENT FORM**

**Informed Consent to Participate in Long-Term Follow-Up Research**



**Your Name:** \_\_\_\_\_

**Study Title:** Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702

**Protocol:** BMT CTN 0702 Long-Term Follow-Up

**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). Celgene is supplying the study drug lenalidomide.

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## 1. Introduction

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

- You took part in the study, A Trial of Single Autologous Transplant with or without Consolidation Therapy versus Tandem Autologous Transplant with Lenalidomide Maintenance for Patients with Multiple Myeloma, also called **BMT CTN 0702**
- Your disease did not return or worsen (this is also called **disease progression**) during the BMT CTN 0702 study.

Because there's no cure for Multiple Myeloma (MM), the disease almost always returns or worsens. We are doing this study to learn how well patients do more than 3 years after autologous transplant.

This study will include 450 participants. Your participation on this study is expected to last until your disease returns or progresses.

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 follow-up treatment choices if you do not want to participate in this study.

This consent form tells you about the study. The Principal Investigator (the person in charge of this research) or a co-worker of the Principal Investigator will also describe this study to you and answer all of your questions. Furthermore, throughout your follow up questions will be answered as needed. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. Taking part in this follow-up study is entirely your choice.

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## 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, we will watch your health closely (this is also called follow-up) after your autologous transplant.

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. Even with maintenance treatment, MM will relapse. Your doctor doesn't know how long it will take for the disease to return.

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## 3. Study Purpose

We are inviting you to take part in this study because you completed the BMT CTN 0702 study and your disease did not return or worsen. We are doing this study to learn more about ways to prevent or delay relapse of multiple myeloma (MM). We also want to know how well you do long-term (more than 3 years) after transplant.

You will have a physical evaluation (test) every 6 months to see if you still have Multiple Myeloma (MM) in your body. This study will help doctors make the best choice about long-term treatment after autologous transplant for patients with MM.

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## 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.

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## 5. Study Tests

We will check (test) your health before you enter the study and every 6 months after that. This is called long-term follow-up after transplant. We will stop the study tests if your disease returns or relapses.

You will need to have several check-ups and tests for this study. You will visit the clinic every 6 months. At each clinic visit you will have:

- Physical exam, including height and weight
- Tests to check for cancer as decided by your doctors. These tests would normally be done even if you were not on a research study. These tests may include:
  - Bone marrow aspiration and biopsy (see **Section 6: Risks and Discomforts**)
  - Blood tests (up to 4 – 5 tablespoons)
  - Urine tests
- Optional blood samples for future research (see **Section 17: Blood Samples for Future Research**).

You can do these tests at a clinic near your home. Your clinic will send your test results to the study doctor.

We will also ask you to take a quality of life survey each year. The survey will ask about:

- Any side effects of your treatment
- Any health problems
- How well you can do things that are important to you
- How you relate to other people
- Your feelings.

An interviewer will contact you before you start long-term follow-up. These interviews will take about 30 minutes and will be done at a time that works for you. You may skip any questions you wish.

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## 6. Risks and Discomforts

You will have side effects while on the study. Side effects can range from mild to serious. The risks and discomforts of long-term follow-up after transplant are the same if you join this study, or if you don't join this study.

### Risks of Blood Draws

The risks and side effects of having blood taken from your arm with a needle include:

- Pain, like a pinch
- Swollen, red and sore skin where the needle went
- Bruising
- Feeling faint or dizzy

### Risks of Bone Marrow Aspiration and Biopsy

The risks and side effects of anesthesia drug injection include:

- Pain, like a pinch
- Burning feeling in your skin and hip bone

The risks and side effects of a bone marrow aspiration and biopsy include:

- Pressure and pain in hip
- Bleeding
- Bruising
- Ache in hip bone and muscles
- Infection (this is rare)

### 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.

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

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## **7. Alternative Treatments**

Participation in this study is optional. If you choose not to take part, you may still receive long-term follow-up after your transplant. The evaluations you would have could be very similar to what you would have 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.

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## **8. Possible Benefits**

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

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

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## **9. New Information Available During the Study**

During this research study, the study doctors may learn about new information about 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 confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy.

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.*

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.

This data bank can be accessed by you and the general public at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). Federal law requires clinical trial information for certain studies to be submitted to the data bank.

For questions about access to your medical records, please contact [/name/](#) at [/number/](#).

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## 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 tests. 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:

- Your disease returns or worsens during the study.
- 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 cannot keep appointments as directed.
- The study is stopped for any reason.

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.

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.

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## 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 taking part in this study. You will not be paid or reimbursed for any extra costs (for example, travel and meals) from taking part in this study.

You will have no rights to any patents or findings from this study. You will not be compensated for any patents or findings from this study.

---

## 14. Costs and Reimbursements

Most of the visits for this research study are standard medical care after your autologous 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.

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.

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## 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 Samples for Future Research (Optional)

This section of the informed consent form is about future research studies that will use blood 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 samples, here is what will happen:

- We will collect two extra blood samples at the same time you have routine blood tests done. The amount of blood collected from you is about 6 teaspoons (31 ml) each time.

We will collect blood samples at two times during the study:

- First clinic visit after you join the study
- Last clinic visit at the end of the study
- The blood samples 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 research samples will be given a bar code that cannot be linked to you by future researchers testing your samples.

- 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 may 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 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 [redacted].

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

---

### **Statement of Consent for Research Samples**

The purpose of storing blood samples, the procedures involved, and the risks and benefits have been explained to me. 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 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 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 research.
- I do not agree to allow my blood samples to be stored for research.

---

Signature

---

Date

**Health Insurance Portability and Accountability Act 1 (HIPAA2) 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:

Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702

**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. Amrita Krishnan, Study Chairperson and staff/laboratories at City of Hope National Medical Center
- Dr. George Somlo, Study Chairperson and staff/laboratories at City of Hope National Medical Center

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<sup>2</sup> HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

- Dr. Edward Stadtmauer, Study Chairperson and staff/laboratories at University of Pennsylvania Cancer Center.

### 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
- Celgene (the manufacturer of lenalidomide)
- Biologics, Inc (the distributor of lenalidomide).

### **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, the 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:** Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702

**PROTOCOL NUMBER:** BMT CTN #0702 Long-term Follow-Up Study

**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