

**NCT 03839459**  
**RESEARCH SUBJECT INFORMED CONSENT FORM**

**TITLE:** Denosumab for Smoldering Multiple Myeloma

**PROTOCOL NO.:** UMMY18121  
RSRB# STUDY00003431

**SPONSOR:** Amgen

**INVESTIGATOR:** Brea Lipe, MD

**SITE(S):** University of Rochester 601 Elmwood Avenue  
Rochester, New  
York 14642  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** [REDACTED]

**This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.**

**Key Information**

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you have smoldering multiple myeloma.  
The purpose of this study is evaluate the impact of the denosumab as a treatment to prevent your smoldering multiple myeloma from becoming multiple myeloma.
- Your participation in this study will last for about 13 months with a 5 year follow-up.  
Procedures will include a medical history/physical exam, performance status, assessment of your tumor by X-rays, blood collection, urine collection, oral examination, and study drug (denosumab) administration. Some of these procedures may be optional.

- There are risks from participating.
  - The most common risk is muscle and bone pain.
  - One of the most serious risks is osteonecrosis of the jaw (ONJ). See the “Risks of Participation” section in this consent form for more information. You should discuss these risks in detail with the study team.
- This study might not help you. This study might help researchers learn things that might help people in the future.
- If you do not want to take part in this study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

#### **A. INTRODUCTION**

You are being asked to take part in a clinical trial, a type of research study, because you have smoldering multiple myeloma. This research study is to evaluate the impact of the denosumab as a possible treatment to prevent your smoldering multiple myeloma from becoming multiple myeloma.

The name of the intervention involved in this study is denosumab. For purposes of this research, you will be referred to as a “subject”.

It is expected that about 20 people will take part in this research study at the University of Rochester.

Amgen, a pharmaceutical company, will be providing the study drug and funding for the research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research subject.

The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future.

#### **B. WHY IS THIS RESEARCH STUDY BEING DONE?**

This research study is a Phase II clinical trial. Phase II clinical trials test the safety and effectiveness of an investigational intervention to learn whether the intervention works in treating a specific disease. “Investigational” means that the intervention is being studied.

The FDA (the U.S. Food and Drug Administration) has not approved denosumab for your specific disease, but it has approved denosumab for use in other cancers to treat cancer-related bone disease.

In this research study, we are treating subjects with smoldering multiple myeloma. This study will assess the safety and tolerability of denosumab in smoldering multiple myeloma subjects as well to see if denosumab can reduce subjects' risk of getting multiple myeloma.

Smoldering multiple myeloma is a pre-cancerous condition that gives you a lifelong risk of developing multiple myeloma cancer. Several risk factors are known to increase the risk of smoldering multiple myeloma becoming multiple myeloma. Standard therapy for smoldering multiple myeloma includes frequent blood monitoring and imaging studies to decide if a person is developing multiple myeloma. There is currently no treatment offered for smoldering multiple myeloma.

Denosumab is a monoclonal protein that targets RANK ligand and neutralizes it. RANK ligand is elevated in patients with smoldering multiple myeloma and can cause bone damage in patients with multiple myeloma. Blocking this protein might prevent bone damage. We are doing this study to see if blocking this protein will prevent bone damage and also reduce the risk of getting multiple myeloma in patients with smoldering multiple myeloma.

#### **C. WHAT OTHER OPTIONS ARE THERE?**

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following:

- Receive standard of care (observation only) which will include blood draws and doctor visits.
- Take part in another research study.

Please talk to the research doctor about your options before you decide whether you will take part in this research study.

#### **D. WHAT IS INVOLVED IN THE RESEARCH STUDY?**

Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study.

##### **Before the research starts (screening):**

After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not

have to be repeated.

- A medical history/physical exam**, which includes questions about your health, current medications, and any allergies. Your weight and vitals will be taken during the physical exam.
- Performance status**, which evaluates how you are able to carry on with your usual activities.
- An assessment of your tumor** to confirm smoldering multiple myeloma by either low dose whole body CT scans, CT-PET scan, or MRI. Your physician will determine the right radiology testing for you. These are all non-invasive radiology tests that will check your bones to make sure you have no bone damage and confirm a diagnosis of smoldering multiple myeloma.
- DXA or bone mineral density testing** is a non-invasive test that measures a risk for osteoporosis or fracture.
- A bone marrow aspiration and biopsy**: (about 6 teaspoons of blood)
  - If you have previously had a bone marrow biopsy and aspirate at the University of Rochester, we will contact the pathology department to obtain any stored but unused samples for use in this study.
- Blood collection**, (about 4 teaspoons).
- Urine collection**,
- Serum pregnancy test**, if applicable.
- Oral examination** by the study doctor looking inside your mouth.

If these tests show that you are eligible to participate in the research study, you will begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

**Study Visit:** Every Cycle (a cycle lasts 4 weeks) and End of Treatment

**This visit will involve the following:**

- A medical history/physical exam**, which includes questions about your health, current medications, and any allergies. Your weight and vitals will be taken during the physical exam.
- Performance status**, which evaluates how you are able to carry on with your usual activities.
- Blood collection**, (about 6 teaspoons)
- Urine collection**
- Oral examination** by the study doctor looking inside your mouth.
- Study drug (denosumab) administration**

**Research Study Plan:**

	Screening	Day 1	Week 2-4	Cycle (C) 2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	Off Treatment
Medical History & Physical Exam	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Performance Status	X	X		X	X	X	X	X	X	X	X	X	X	X	X
DXA scan <sup>a</sup>	X								X						X
Radiology <sup>b</sup>	x														
Blood collection	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urine collection	X														X
Pregnancy Test	X (If applicable)														
Oral examination	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Bone marrow biopsy	X														X
Denosumab (SC) <sup>c</sup>		X		X	X	X	X	X	X	X	X	X	X	X	

- a. X-rays in this study table are Bone Density scans.
- b. Radiology testing will be either low dose whole body CT scan, CT-PET scans, or MRI of the spine and pelvis to confirm smoldering multiple myeloma. The choice of test will be per your treating physician.
- c. Denosumab Administration: denosumab will be administered at a dose of 120 mg subcutaneously {SC} every four weeks {Q4W}.

**Planned Follow-up:**

We may want to keep track of your medical condition for two or more years after the End of Treatment. We would like to do this by calling you to see how you are doing. Keeping in touch with you and checking your condition helps us look at the long-term effects of the research study.

The following information about your study participation will be included in your electronic health record:

- Documenting you are in this study
- A copy of your signed consent form
- Results of all testing done as part of this study
- 

**E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?**

You will be in this research study for up to 13 months with a 5 year follow-up up.

The research doctor may decide to take you off the research study for many reasons including if:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- Your condition worsens
- A decision is made to close the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

If you are removed from the research study, the research doctor will explain to you why you were removed.

In addition, you can stop participating in the research study at any time; however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

**F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?**

There are risks to taking part in any research study. One risk is that you may get a study drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild, but others can be long lasting and may never go away. Some may be life-threatening or fatal.

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study; your research doctor will review this information with you.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

#### **Risks Associated with Denosumab:**

Denosumab 120 mg may cause all, some, or none of the side effects listed below. These side effects can be mild but could also be serious or life-threatening or even result in death. There may also be other side effects from taking denosumab alone or with other drugs you may be taking. You may also experience an allergic reaction that has not been seen before.

As of 26 September 2019, approximately 9,518 people have received denosumab 120 mg in research studies. Since it was first approved for sale in November 2010, approximately 1,477,176 people have been prescribed denosumab 120 mg (XGEVA®) for treatment.

Side effects that other people have had in research studies that are thought to have been caused by denosumab 120 mg are:

#### **Very Common side effects (which may affect more than 1 person in 10**

- low blood calcium (see description below)
- shortness of breath
- muscle and bone pain (see description below)

#### **Common side effects (which may affect between 1 and 10 people in every 100):**

- osteonecrosis of the jaw (see description below)
- decreased phosphorus in the blood

- hair loss (alopecia)

**Uncommon effects (which may affect between 1 and 10 people every 1,000):**

- high blood calcium in patients with Giant Cell Tumor of Bone (GCTB) after stopping denosumab (see description below)
- unusual thigh bone fracture (atypical femoral fracture) (see description below)
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruption)

**Rare side effects:**

- allergic reaction (drug hypersensitivity) (see description below)
- high blood calcium in children and adolescents after stopping denosumab (see description below)
- broken bones in your spine after stopping denosumab (see description below)

**Description of side effects**

**Allergic Reaction (drug hypersensitivity).** Allergic reactions, including severe symptoms, have been reported. Symptoms of an allergic reaction may include headache, rash, flushing, swelling, shortness of breath, nausea and sometimes vomiting. Severe allergic reactions can cause dizziness, difficulty breathing or swallowing, a decrease in blood pressure, and could be life-threatening. If you have symptoms of an allergic reaction, you should contact the study doctor or the study staff immediately.

**Low blood calcium.** Temporary lowering of blood calcium levels below normal have been observed in subjects treated with denosumab. The risk of this happening may be higher in subjects with severe kidney disease. You may not have any symptoms of low blood calcium; however, with very low levels of calcium, symptoms may occur such as a tingling sensation, muscle cramping, abnormal heart rate, decreased alertness or confusion, or seizures; deaths have been reported in cancer patients with low blood calcium who have been treated with denosumab 120 mg. Your physician may ask you to take calcium tablets by mouth to correct the low blood calcium or in rare cases, the doctor might decide to give the calcium through the veins. During the study, if you experience any of these symptoms you should notify your doctor immediately. Taking calcium and vitamin D supplements as directed by your physician will lower the risk that your calcium level will drop below normal.

**Osteonecrosis of the Jaw (ONJ).** ONJ is a potentially serious condition that can present as a sore in the mouth through which the jaw bone is sometimes visible. The gum tissue over the bone may heal slowly or not heal at all. How this happens is poorly understood. The symptoms of ONJ include pain or infection in the jaw bone and gums. If you develop any of these symptoms, your doctor should examine your mouth to determine if you have ONJ. The risk of developing ONJ is higher in patients who have had tooth removal, gum surgery, infections in the mouth, dental implants or other dental procedures.

In clinical trials in patients treated with denosumab, osteonecrosis of the jaw (ONJ) has been reported. The frequency of ONJ is higher in patients who took

denosumab for a longer period of time.

In studies of patients in whom cancer has spread to bone who received up to 3.5 years of treatment, ONJ occurred with a similar frequency in denosumab (2.2%) and zoledronic acid (1.6%) treatment groups. In patients with prostate cancer without bone involvement, who received treatment for up to 4 years, ONJ occurred with a greater frequency in denosumab (4.6%) than in placebo (0%) treatment groups.

It is important that you maintain good oral hygiene and avoid dental procedures immediately before and during your participation in the study, if possible. Your study doctor and dentist should discuss the benefits and risks of any dental procedure. Tell your dentist that you are taking a medicine to strengthen your bones before a dental procedure is planned.

**Unusual thigh bone fractures (atypical femoral fracture)** Atypical femoral fracture is an unusual thigh bone fracture that may occur with little or no trauma. Fractures can occur in both thighs at the same time. The risk of atypical femoral fracture continues after stopping therapy and increases with longer duration of treatment with denosumab. Some patients had fractures up to 9 months after treatment with denosumab was discontinued. It can present with new or unusual hip, thigh, or groin pain weeks to months before the fracture is diagnosed. If you develop any of these symptoms, you should report them to your doctor.

**Muscle and bone pain.** The pain may be severe (intense pain, difficulty walking or pain in several parts of the body). If you have any of these symptoms, notify your doctor.

Symptoms of high blood calcium may include stomach upset, nausea, vomiting, headache, and decreased alertness. High blood calcium may also lead to dehydration and kidney failure if not treated as soon as possible. Notify your physician if you are having any of these symptoms after stopping denosumab. After you stop the study drug, the study doctor may check calcium levels in your blood. The doctor should also talk with you about whether to change your calcium and vitamin D supplements.

**Possible changes in your bones after stopping denosumab.** Denosumab prevents bone loss and can make bones stronger. The effect of denosumab on bone is fully reversible. When denosumab is stopped, there may be an increased chance of having more than one broken bones in your spine especially in people who have had a fracture before and people with osteoporosis, a condition in which the bones become thin and fragile. If you stop denosumab, you should discuss with your doctor whether you should receive medication for preventing osteoporosis-related fractures.

#### **Other possible side effects:**

**Antibodies.** After you start taking denosumab 120 mg, it is possible that your body may make antibodies (proteins that may stop denosumab from working) or may cause side effects. The development of antibodies to denosumab in

patients has been uncommon and has had no clinical effects and has not reduced the effect of denosumab on bones. Blood tests will be used to check antibodies during the study. Blood tests will be used to check for antibodies during the study.

**Injections site reaction.** You may have a reaction near the area where the denosumab is injected. In general, symptoms may include redness, tenderness or pain, bruising, warmth, swelling, itching, and/or infection at the injection site.

#### **What are the risks of using denosumab 120 mg in combination with other drugs?**

Tell the study doctor or the study staff about any drugs you are taking, have recently taken, or are planning to take, including herbal remedies, supplements, and drugs you take without a prescription. The side effects of using denosumab in combination with other drugs are unknown at this time. Please discuss any concerns you may have with the study doctor.

Calcium and vitamin D are not being studied, but you are required to take them as part of this study. These drugs are often included as part of your routine care. The study doctor will talk with you about the risks of taking calcium and vitamin D.

#### **Risks of blood draws:**

You will have your blood drawn during the study. Possible side effects of having blood drawn are tenderness, pain, bruising, bleeding, and/or infection where the needle goes into the skin and blood vein. Having your blood drawn may also cause you to feel nauseated and/or lightheaded.

#### **Risks of a bone marrow biopsy:**

The bone marrow aspiration and biopsy may cause pain, bruising, bleeding and infection. Soreness near the site may last for a couple of days after the procedure. You may have more pain, risk of bleeding and bruising if you complete both aspiration and biopsy rather than just the aspiration. If your pain is severe or you develop a fever, please contact your treating physician immediately.

#### **Radiation Risks Associated with DXA scans and radiology testing**

While you are in this research study, bone density scans utilizing radioactivity may be used to evaluate your disease. In the long term, over many years, there is a very low risk of developing a new cancer as a result of the radiological evaluation and treatment for your cancer. Certain types of drugs or combinations of these drugs with radiation may further slightly increase the risk of developing a new cancer.

This research study requires baseline assessment of your bones with either a low dose whole body CT scan, CT-PET scan, or MRI of the spine and pelvis. These scans are standard of care for patients with smoldering multiple myeloma. You will not get more of these scans than you would for routine care.

This research study involves exposure to radiation from 2 bone density scans. The frequency of these exams is slightly greater than what you would receive as standard care. Please note that this radiation exposure is not necessary for your medical care but is required to obtain the desired research information. From participating in this study, the maximum amount of additional radiation your body will be exposed to in one year is less than what the average person living in the United States receives in one year due to natural background sources of radiation such as the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil.

#### **Reproductive Risks:**

It is not known if denosumab is harmful to an unborn or breastfed baby. Denosumab has been found to cause abnormal fetal development in animals. In animals exposed to denosumab during pregnancy, increased stillbirths, abnormal fetal development, birth defects, and increased death of animals soon after birth have occurred.

We can provide counseling about preventing pregnancy for either male or female study subjects. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

#### **Female Subjects**

Pregnant or breastfeeding women and women planning to become pregnant or planning to breastfeed should not participate in this study. If you are unable to become pregnant for one of the following reasons, the use of birth control methods is not required during this study.

- Your healthcare provider has confirmed that you are postmenopausal.
- You have had your uterus, both ovaries, or both fallopian tubes removed.

If you could become pregnant, you:

- Should let your sexual partner know you are in this study
- Must agree to practice abstinence (not have sex) or you must agree to use a highly effective method of birth control during treatment with denosumab and for an additional 5 months after the last dose of denosumab.
- Must discuss your pregnancy prevention method with the study doctor to ensure it is the best option for you; even with the use of a highly effective method of birth control, there is still a small chance that a pregnancy could occur.

Highly effective methods of birth control include:

- Combined (estrogen and progestogen) hormonal methods (pills, vaginal ring, or skin patch)
- Single hormonal methods (progesterone) to stop release of the egg from the ovary (pills, shots/injections, or implants placed under the skin by a healthcare provider)
- Intrauterine device (IUD)
- Intrauterine hormonal-releasing system (IUS)
- Surgery to tie both fallopian tubes (bilateral tubal ligation/occlusion)
- Your male partner has had a vasectomy and testing shows there is no sperm in the semen
- Sexual abstinence (not having sex)

It is not known if denosumab is transferred into breast milk. If you are breastfeeding and wish to be in this study, you will be required to discontinue nursing during treatment with denosumab, and for an additional 5 months after the end of treatment with denosumab.

### **Male Subjects**

Male subjects are not required to use birth control during exposure to denosumab. However, you should let your female partner know that you are in this study.

### **Female and Male Subjects**

The pregnancy, breastfeeding, and birth control information in this document is specific to denosumab. There may be additional risks to an unborn child or breastfed baby from other drugs, such as vitamin D and calcium that you may receive during the study. This may require that you change the type and/or length of time that you must use birth control or length of time that you must avoid breastfeeding. Please discuss this with the study doctor.

### **What if you become pregnant or breastfeed during the study?**

If you agree to participate in this study, you must not become pregnant or breastfeed. If you become pregnant, think you are pregnant, or breastfeed while you are taking denosumab and for an additional 5 months after stopping denosumab, you must tell the study doctor or the study staff right away. The use of the denosumab may be stopped and the study doctor will notify Amgen. You will be asked to provide information on the pregnancy or breastfeeding outcome for you and the baby.

### **What if your partner is pregnant when you enroll in this study or become pregnant during the study?**

If your partner is pregnant when you enroll in the study or becomes pregnant while you are taking denosumab, or within 5 months after stopping denosumab, you must tell the study doctor or the study staff right away. The

study doctor will notify Amgen of the pregnancy and ask you and/or your pregnant partner for contact information to obtain the pregnancy outcome for both the mother and baby.

#### **Non-Physical Risks:**

Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

The study team may be notified if you receive other health care services at URMC and Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

#### **G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?**

This study might not help you. This study might help researchers learn things that might help people in the future.

#### **H. SPONSOR SUPPORT**

The University of Rochester is receiving payment from AMGEN, Inc. for conducting this research study.

#### **I. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?**

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the drug. In

some cases, the abrupt stopping of a drug can have risks in itself. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

#### **J. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?**

You will not be paid to take part in this study.

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

#### **K. WHAT ARE THE COSTS?**

The sponsor, Amgen will provide the study drug denosumab free of charge while you are participating in this study. However, while study drug is provided free of charge, you and/or your insurance company will be charged for the usual costs associated with preparing and administering drug treatment(s). Tests and procedures that are required only for the study, that are not a part of your regular medical care, will also be provided at no charge. You will be

responsible for the costs associated with the calcium and vitamin D supplements.

You or your insurance company will be billed for any standard medical care given during this research study. You will be responsible for any co-pays, insurance deductibles and/or co-insurance required by your health insurance carrier for your standard medical care. This standard medical care includes any care that you would receive for the treatment of your type of cancer whether you were participating in a study or not, such as:

- Routine clinic visits with your doctor or nurse practitioner
- Tests (Including but not limited to routine items such as: laboratory blood tests, CT, PET/CT, and/or FDG/PET scans, X-rays, lung function, or cardiac testing.)
- Procedures (Including but not limited to routine items such as: bone marrow biopsies and/or aspirates, other tumor biopsies)
- Medications: other standard medications to treat your cancer. This can include other chemotherapies or non-chemotherapy medications used to treat your cancer, and/or medications to treat or prevent side-effects.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study prior to enrolling on a research study.

Depending on how your insurance company processes payments for standard medical care given during a research study, you might have unexpected expenses from being in this study. If your insurance company does not pay for your standard medical care, you will be billed for those charges.

Ask your study doctor to discuss the specific costs that will or will not be covered

by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:  
[www.cancer.gov](http://www.cancer.gov) or 1-800-4-CANCER (1-800-422-6237)

**L. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?**

If you are directly injured by the drug(s) being studied, or by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

**M. WHAT ABOUT CONFIDENTIALITY and AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES.**

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all study related records in our office with access limited to study personnel. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one

*What information may be used and given to others?*

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

*Who may use and give out information about you?*

- The study doctor and the study staff
- URMC and Affiliates

*Your information may be given to:*

- The Department of Health and Human Services,
- The University of Rochester,
- The National Institutes of Health, the Office for Human Research Protections and/or the National Cancer Institute,
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported,
- The funder of the study, its subcontractors, and its agent(s): Amgen
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards, Privacy Boards, Data and Safety Monitoring Boards and their related staff that have oversight responsibilities for this study.

*Why will this information be used and/or given to others?*

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

*What if I decide not to give permission to use and give out my health information?*  
Then you will not be able to be in this research study.

*May I review or copy my information?*

Yes, but only after the research is over.

*How long will this permission be valid?*

This permission will last indefinitely.

*May I withdraw or cancel my permission to use and disclose information?*

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to

others for the validity of the study.

*May I withdraw from the study?*

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

*Is my health information protected after it has been given to others?*

No. There is a risk that your information will be given to others without your permission.

**Where Can I Get More Information?**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by

U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

N. The Investigator, Dr. Brea Lipe, receives payment for her consulting activities from Amgen. Please feel free to ask Dr. Lipe or other study staff any questions you may have about her role as a consultant for the sponsor.

**O. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?**

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact: Dr. Brea Lipe at [REDACTED] (24 hours).

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone [REDACTED] for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

\*\*\*\*\* End of Section \*\*\*\*\*

### **CONSENT TO FUTURE USE OF INFORMATION / SAMPLES**

May we share your samples, health information, with other researchers to study smoldering multiple myeloma?

Yes    No

May we share your samples, and health information with other researchers for future research projects related to other topics?

Yes    No

### **CONSENT TO RE-CONTACT**

May your study doctor, or someone from the study team, contact you in the future about using your samples or information for research that is not described in this consent form?

Yes    No

### **OPTIONAL SAMPLE STORAGE**

The research team would like your permission to keep the remaining bone marrow, bone marrow aspirate or blood specimens, if any, from the study to be used for anonymous (your name will not be associated with these specimens) future research related to identifying biomarkers and understanding bone physiology.

Please initial one choice:

Yes, I agree to allow any remaining bone marrow aspirate or blood specimens collected during the study to be used for future research. I understand my name will not be connected to any of the specimens.

No, I do not want any remaining bone marrow or blood specimens collected during the study to be used for future research. Please destroy any remaining specimens after the study is over.

## **DOCUMENTATION OF CONSENT**

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

### **Subject Consent**

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

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Subject Name (Printed by Subject)

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Signature of Subject

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Date

### **Person Obtaining Consent**

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

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Name of Person Obtaining Consent (print)

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Signature of Person Obtaining Consent

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Date