RESEARCH CONSENT FORM

An exploratory trial to estimate the proportion of patients with tumor cell contaminated, flow positive leukapheresis products collected with and without bortezomib as in-vivo purging prior to autolgous stem cell harvest for multiple myeloma

Protocol # 2015-IIT-BMT-MM-AutoSCT
Sponsor: The University of Kansas Cancer Center

TO BE CONDUCTED BY:
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You are being asked to join a research study. Participating in research is different from getting standard medical care. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC) and its affiliates.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating. You may be asked to sign a new consent form if this occurs.

This research study will take place at the University of Kansas Medical Center (KUMC) with Siddhartha Ganguly, MD as the researcher. About 100 people will be in the study at KUMC.

Why am I being asked to take part in this study?
You are being asked to take part in this study because you have been diagnosed with multiple myeloma (MM) and are planning to have what is called an "autologous stem cell transplantation".

Multiple myeloma is a blood cancer that affects the parts of your blood called "plasma cells". Plasma cells are a kind of white blood cell found in the soft insides of your bones, called marrow. Plasma cells are part of your body's immune system. They make antibodies to help fight off infections.

There is no cure for multiple myeloma, but treatment can often help you feel better and live longer.

Patients with certain types of cancer require treatment with very high doses of chemotherapy. A side effect of high chemotherapy doses is damage to the bone marrow where our blood and immune system cells are produced.

Stem cells (or progenitor cells) are the source of all blood cells. They are formed in the bone marrow (the spongy cavity in the center of large bones). The stem cells receive signals that direct them to become red cells, white cells or platelets. This happens before they are released into the blood stream. Stem cells circulating in the blood stream can be collected through a process called "apheresis" or "stem cell collection". The cells are then processed and frozen to preserve them. After chemotherapy has been given the stem cells are thawed and given back intravenously (IV: into the vein), like a blood transfusion. The stem cells in the collection will find their way back into the bone marrow space and, after a few days, will start to produce the blood and immune cells as they normally would. Having your own stem cells collected and returned to you later is called an "autologous transplant". The goal of doing this is to help your bone marrow start to work right again.

In this study, half of the people in the study will have the routine, standard of care treatment for multiple myeloma, and according to that treatment, a sample of stem cells will be collected before the routine chemotherapy and radiation is done.

Other people in this study will have a certain dose of chemotherapy given before the stem cells are collected.

Why is this study being done?
Following the routine, standard of care process for treatment of multiple myeloma, the blood that is removed from your body is collected before any transplant-related chemotherapy or radiation. This means that some of the diseased cells in the blood stay in the sample that is processed and put back into your body during the stem cell transplantation.

There is a difference in opinion of whether the presence of diseased cells in the sample affects how well the overall multiple myeloma treatment works. Some doctors say the presence of the diseased cells does make a difference; others say it doesn't make a difference.

Doctors have tried killing the diseased cells in the sample while it is outside of the body, but this has not seemed to make a difference in whether or not the blood cancer comes back after the sample is put back in the person's body.

Good results have been noted from giving patients medicines to kill the diseased cells in the blood before the stem cell sample is taken out, but this has not been tried yet in people who have the specific kind of blood cancer you have.

In this study, we want to find out if giving patients a chemotherapy drug called "bortezomib" before the stem cell collection will decrease or eliminate the number of cancer cells remaining in the sample of blood collected for stem cells.

What is being tested in this study?
The drug being tested in this study is called "bortezomib" (also called VELCADE®). It is a drug that is approved by the US Food and Drug Administration (FDA) for the treatment of people with multiple myeloma (MM).

Another drug that will be used in this study is called "G-CSF" (sometimes it is called "Filgrastim"). It is a drug that is approved by the FDA for people who need a medicine to help their bodies keep certain blood cells at a healthy level, such as people with blood cancer and people having stem cell transplants.

"Mozobil" is another drug that may be used in this study, and it is also approved by the FDA to use for people with multiple myeloma who are having autologous stem cell transplants. It is used with G-CSF and helps your body release stem cells from your bone marrow so there will be plenty of them in the blood sample that will be given back to you. It is used as needed.

The study will have two groups.

Patients in **Group A** will have "regular, standard of care" collection of the blood needed for the stem cell sample – that means they will not receive the study drug bortezomib before collection of the stem cell sample.

Patients in **Group B** will have two doses of the study drug bortezomib before collection of the stem cell blood sample. The stem cell blood sample will be collected approximately eight to 12 days after the second dose of bortezomib.

Both groups will also have G-CSF and may have Mozobil as needed.

You should know, the goal of this study, is NOT to see if one study treatment works better than another for treatment of your cancer. The goal is to see if adding the study drug bortezomib before the routine, standard of care treatment for the type of cancer you have will reduce the number of cancer cells in the stem cell sample that is collected and used for stem cell transplantation.

How long will I be in the study?
Your participation in this study is expected to last approximately 2 months.

Your participation in this study is voluntary and you can choose to withdraw from the study at any time.

What will I be asked to do?
If you decide to join the study, you will be asked to read and sign this consent form before any study procedures take place.

You will be assigned to one of the following two treatment groups:

- **Group A** will have "routine, standard of care" collection of the blood needed for the stem cell sample. This group will not receive study drug bortezomib before stem cell collection.

- **Group B** will receive two doses of bortezomib before collection of the stem cell blood sample. The stem cell blood sample will be collected eight to 12 days after the second dose of bortezomib. Bortezomib doses are per institutional standard.

If you are eligible and you decide to join this study, you will be randomly assigned (like flipping a coin) to either Group A or Group B. You have an "equal" or 50% chance of being in Group A or Group B. A computer will decide which group you are in.

If it is determined that you are eligible for participation in this study, you will then continue with stem cell collection, high dose chemotherapy and autologous stem cell transplantation, as described below.

The entire process of stem cell collection and transplantation will be discussed with you as a part of your standard of care consenting process.

Study Periods
This study will be divided into the following 3 periods: Screening, Treatment and Follow-Up. Each period is described below and includes procedures and tests that will be discussed later in this consent form.

Screening: If you would like to be in this study, your study doctor will check that you are qualified. This is called "screening". The procedures and tests performed during this period will determine if you can safely take part in the study and may be performed over the course of 1 or more days.

If the results of the procedures and tests indicate that you can take part in the study, then you may enter the **Treatment Period**.

If not, then the study doctor will discuss with you the treatment options that are available.

Study Treatment: During this period, the computer will assign you to one of the following treatment groups:

- **GROUP A:** Routine, Standard of Care stem cell collection with NO study drug (bortezomib). G-CSF will be used and Mozobil will be used if needed.
  OR
- **GROUP B: BEFORE stem cell collection, the study drug bortezomib will be given under the skin with a needle (like a shot) as follows:**
  - 11 days before stem cell collection (day -11), participants in this group will receive 1.3 mg/m^2 of the study drug
  - 8 days before stem cell collection (day -8), participants in this group will receive 1.3 mg/m^2 of the study drug.
  - G-CSF will be given each day during the days before stem cell collection is started, and continued until the collection is completed.
  - Mozobil will be used if needed.

NOTE: There must be at least 72 hours between each dose of bortezomib. Bortezomib doses are per institutional standard.

Follow-up: Any illnesses or side effects that you have will be followed for this study from the time you sign the consent form until 30 days after your stem cells are transplanted back into your body.

Your health status will also be followed after the stem cell transplant according to the routine, standard of care procedures for stem cell transplantation as required by KUMC. That follow-up is NOT a part of this study.

Below, you will find a study calendar that lists the study tests and procedures, along with the estimated time for visits. Most of these tests and procedures are part of regular cancer care, while others are for research purposes only and may be done more often for the purposes of this study. Some tests and procedures may not need to be repeated if they have already been done recently (your study doctor will let you know if this applies). After the study calendar, you will find descriptions of the study tests and procedures.

Study Calendar

	Screening Period	**Treatment Period**					**Follow-Up**
Study Procedures And Tests for Screening, Treatment and Follow-up	Screening/ Baseline	Day –11	Day –8	Day –4 Day –3 Day –2	Day -1 The day before Stem Cell Collection	Day 0 This is Stem Cell Collection Day (Collection may happen from 8 to 12 days after your last dose of Bortezomib, depending on your blood counts)	Day 1 to Day 30 After stem cell transplant
Estimated visit time (in hours)	2-7	1	1	1	1	1	Ongoing Side Effects/ Illnesses Review
Informed Consent, discuss and sign	X						
Medical history review and Demographics	X						
Performance status	X						
Physical Exam	X						
Current medications review	X						
Routine Blood Tests	X				X		
Pregnancy Test	X						
Side effects/illnesses review	X	X	X	X	X	X	
Bortezomib (Doses per institutional standard)		X	X				
G-CSF (Mozobil as needed)				X	X	X	
Stem Cell Collection						X	

STUDY PROCEDURES & TESTS

Below are descriptions of the procedures and tests that will be done during this study.

Medical history, demographics, illnesses, and side-effects review: You will be asked questions about your medical history, demographics (personal information such as date of birth, age, gender, race, and ethnicity), any illness you have, and prior treatments. Your study doctor will also ask about any side-effects you may have at every visit during the study.

Performance status: You will be asked questions about your ability to do daily tasks (called your performance status).

Physical exam: The complete physical exam will include an evaluation of your head, neck, abdominal area, hair, nails, and limbs. The study doctor will also listen to your heart and lungs. Your vital signs (heart rate, blood pressure and body temperature), height and weight will also be measured and recorded.

Current medications review: There are some medications (both prescribed and over-the-counter, i.e., OTC), natural or herbal medicines, alternative medicines, and vitamins that may interact with the drugs on this study. If you are now being treated with any medicines, some of them may need to be stopped. This is to avoid a mix-up of effects between the old medicine and the study treatment. Please follow your study doctor's instructions carefully and tell your doctor about any medications, vitamins, and treatments you would like to take while on study.

Blood tests: A needle will be used to draw blood from a vein in your arm. Sometimes a blood test may need to be repeated for safety reasons or if there are any problems with the sample. If this happens the total amount of blood drawn will be more than this.

Your blood will be used for:

- Routine laboratory tests to monitor your general health - Approximately 2-3 tablespoons of blood will be collected at screening and the day before your stem cell collection.
- Pregnancy tests (if applicable) – Approximately 1 teaspoon of blood will be collected each time this test is required for all women of child-bearing potential. ***If the pregnancy test is positive, you will not be able to participate in this study.***

What are the possible risks or discomforts?

The study drugs and procedures may cause side effects or other problems, including death. The researchers will be checking your medical information during the study to watch for side effects. However, you should tell the research team about anything that is bothering you or any changes in your health since the last visit. The researchers may be able to take steps to reduce side effects.

You may experience none, some, or all of the side effects listed below. There may be other side effects or risks that are not yet known.

Allergic Reaction Risks

You could have an allergic reaction to any of the drugs being used in this study. Sometimes, people have serious allergic reactions to drugs. A severe allergic reaction could be life-threatening and may result in death. Symptoms of allergic reactions include:

- Swelling of the mouth, throat or eyes
- Rash
- Difficulty breathing
- Coughing
- Wheezing
- Sudden drop of blood pressure
- Seizures
- Flushing
- A fast pulse
- Sweating

You should call 911 if you think you are having a severe allergic reaction. Please also contact the study team if you have any of these or other side effects during the study.

Possible Risks of Bortezomib (also called VELCADE®)

The study drug called bortezomib should not be taken if you have ever had a serious allergic reaction to bortezomib, boron, or mannitol. You face some risks or discomforts when you are treated with the study drug, bortezomib. You are at risk of having all, some, or none of these symptoms and they may vary in severity. The severity may be mild, moderate or severe, up to and including death. Any symptoms or conditions that you have before you start study drug may get worse. Also, there is always a chance that a risk that is rare or not yet known may occur. If any of these symptoms occur, you must tell your doctor who may give you other drugs to ease discomforts you have. Your doctor may lower or withhold the dose of bortezomib. Also, if you have a very bad reaction to the study drug, your doctor may permanently stop the study treatment.

Other drugs and supplements may affect the way bortezomib works. Tell your doctor about all drugs and supplements you are taking while you are in this study.

Most Common Bortezomib Risks (occurs in 20% or more patients):

- Feeling weak, tired, and generally uncomfortable
- Gastrointestinal effects such as constipation, diarrhea, nausea, vomiting, and loss of appetite. These may result in dehydration and/or weight loss
- Fever commonly with shaking chills
- Painful feelings or numbness and tingling in hands and feet which may not get better after stopping bortezomib. Uncommonly, the nerves that control things like your heart rate, gut movement and urinary bladder may be affected.
- Lowered platelets; that may increase the chance of bleeding
- Lowered red cells or anemia which may make you feel tired

Very Common Bortezomib Risks (occurs in 10 to 19% of patients):

- Lowered number of white blood cells which may increase your risk of infection and is uncommonly associated with fever; commonly you may have lowered white blood cells called lymphocytes or have lowered red blood cells, white blood cells and platelets at the same time
- Flu-like symptoms and other upper respiratory tract infections, such as chills, sore throat, and runny nose and sinus and throat infections
- Abdominal (belly) pain
- Aches and pains in muscles and joints pain in bones and in arms and legs
- Swelling or fluid buildup in the arms and legs, and feeling dizzy and weight gain. You should not drive or operate any dangerous tools or machines if you have these or any other symptoms.
- Cough, feeling short of breath, lung infections including pneumonia and commonly bronchitis
- Headache
- Skin rash with itching and redness. An uncommon risk is a severe, life-threatening or deadly rash with skin peeling and mouth sores.
- Herpes virus such as shingles (herpes zoster) that can sometimes cause local pain that does not go away for a while. Shingles can sometimes spread over large parts of the body. Both may also affect the eyes or brain, but this is uncommon
- Feeling anxious
- Problems sleeping (insomnia)
- Back pain

Common Bortezomib Risks (occurs in 1 to 9% of patients):

- Lowered blood pressure that can commonly cause you to feel light headed or faint when you stand up.
- Changes in heart rate and heart beat that can cause you to possibly feel light-headed, dizzy, faint, short of breath, and/or have chest pain. This may also cause you to feel confused. An uncommon risk is a possible life threatening abnormal heart beat.
- New or worsening heart failure that can show up as feeling short of breath, swelling in the legs, and/or chest pain, or decreased heart function and can uncommonly be severe. If you have heart failure or other diseases that put you at risk of getting heart failure, you should tell your doctor.
- Fluid buildup around the lungs
- Infection and/or inflammation of the eye or eyelids
- Blurred vision
- Painful sores of the mouth and/or throat, which may make swallowing difficult
- Heartburn, acid reflux and stomach bloating
- Severe bleeding, including bleeding in the stomach and intestines (gut) that maybe linked with low platelet counts, and blood clotting changes. Uncommonly, this bleeding may cause bloody diarrhea and/or bloody vomit.

- Nosebleeds
- Kidney function that gets worse
- Infections of the bladder, sinuses, throat, stomach and intestines (gut), skin and at the area of skin where your catheter is placed
- Fungal infections in the mucous membrane such as the mouth and throat and uncommonly in the skin and nails
- Life-threatening infections in the blood (sepsis)
- Changes in blood sugar have been reported in a few diabetic patients who took oral antidiabetic medicine. If you are taking oral antidiabetic medicines you may need your blood sugar levels watched more closely.
- Blood in the urine
- Feeling confused
- Changes in the way things taste
- Abnormal liver tests and decreased protein in the blood
- Lowered amount of potassium and sodium in your blood and increase in the amount of calcium in your blood
- Infection
- Fall that may cause injury
- Muscular weakness

Uncommon Bortezomib Risks (occurs in less than 1% of patients):

- Inflammation and fluid buildup in the lungs, or pus build up between the layers surrounding the lungs that may cause breathing problems, and can be life-threatening or lead to death. Increased blood pressure in the lungs, called pulmonary hypertension, has also been reported. This can cause breathing problems and can be life-threatening. If you have new or worsening breathing problems you should tell your doctor.
- Inflammation of the layers surrounding your heart or collection of fluid around the heart may cause chest pain or breathing problems and can be life-threatening or lead to death. If you have new or worsening chest pain or breathing problems you should tell your doctor.
- Hepatitis (inflammation of the liver) and liver failure (in patients who also got many drugs and had other serious medical problems).
- Pain, redness, swelling and infection in the area of the skin where bortezomib is injected
- Pain in the mouth and throat when swallowing
- Loss of hearing
- Intestinal obstruction (blockage in the gut) that may get better on its own and may need surgery and inflammation of the intestines, pancreas or stomach
- Coughing up blood
- Bleeding in the brain and subdural hematoma which is bleeding between the skull and your brain
- Fast death of cancer cells that may let toxins into the blood and injure organs, such as the kidneys

- Allergic reactions that may include skin swelling and/or swelling of the face or throat and could be severe or life threatening
- Severe muscle weakness and paralysis (not being be able to move your arms and legs)
- Changes to the brain that may cause convulsions and confusion
- Inflammation of the back side of the brain, which is reversible (also called "posterior leukoencephalopathy syndrome") and may cause headaches, changes in your vision, changes in your mental status, or seizures (sudden abnormal electrical activity in the brain that causes you to lose control of part or all of your body, such as jerking, shaking, drooling, staring, etc.)
- Cardiac arrest (fatal outcome have been reported)
- Loss of some to all vision affecting one or both eyes, which may be caused by damage to the nerve in the eye. Loss of vision may or may not be reversible.

Possible Risks of G-CSF

Most Common (occurs in 5% or more of patients)

- aching bone pain (usually relieved by Tylenol™)
- headache
- muscle ache
- tiredness
- nausea
- vomiting
- trouble sleeping

Rare but Serious (occurs in an estimated 1 out of 10,000 patients)

There is a small risk of pain and bleeding from the spleen reported among people receiving G-CSF. Symptoms of this side effect are pain on the upper left side just below the rib cage. If you feel pain in this area, you should contact your transplant physician immediately.

Possible Risks of Mozobil

Most Common (occurs in 10% or more of patients)

- diarrhea
- nausea
- fatigue
- reaction where mozobil is injected
- headache
- dizziness
- vomiting
- joint pain

Risks of Stem Cell Collection and Transplantation: Because stem cell collection and transplantation procedures are a standard of care procedure for the type of cancer you have, the risks of stem cell collection and transplantation will be discussed with you as a part of your standard of care consenting process.

Blood Draw Risks
You will need to have samples of blood taken during the study for laboratory testing. You may experience temporary discomfort from these periodic blood draws. These needle sticks may cause local pain, bruising and swelling, lightheadedness, dizziness and rarely, fainting and/or a local infection.

Pregnancy Risks
The study drugs used in this study might hurt an unborn child or a child who is breast-feeding. You cannot be in this study if you are a woman who is pregnant, nursing a baby, or if you are trying to get pregnant.

Women (of child-bearing potential) will have a pregnancy test before the study starts. Men and women (of child-bearing potential) must agree to take appropriate precautions to avoid becoming pregnant, or fathering a child. Even men that have been surgically sterilized (had a vasectomy) must agree to follow these precautions.

Women must either completely abstain from sexual intercourse (abstinence) or use two acceptable forms of birth control from the time you sign this informed consent form through at least 30 days after your last treatment. Acceptable forms of birth control (besides abstinence) are:

- Barrier method (cervical cap with spermicide plus male condom; diaphragm with spermicide plus male condom)

PLUS

- Hormonal method (oral contraceptives, implants, or injections) or an intrauterine device (e.g., Copper T).

Men must agree to one of the following:

- Use the barrier method as described above from the time of signing this consent form through at least 30 days after the last treatment, or
- Completely abstain from sexual intercourse.

The study doctor must approve the form of birth control. You must talk to your study doctor before changing any birth control methods you have already agreed to use.

There may be pregnancy risks that are not known yet. For this reason, you must tell the researcher right away if you get pregnant during the study.

Are there benefits to being in this study?
You may or may not benefit from this study. If the study drug is effective, and you are randomized to receive the study drug, you may lower your risk of the cancer coming back at a later time. Researchers hope that the information from this research study may be useful in the treatment of other patients with multiple myeloma.

Will it cost anything to be in the study?
Most of the procedures performed in this study are part of your regular cancer care (typically called "standard of care") and will not be paid for by the study. This includes the cost of any medications to treat side effects. The study will collect data from the standard of care you receive. The standard of care procedures (those that would be part of your cancer care whether or not you participate in the study) will be charged to your insurance or Medicare, if applicable.

It is possible that your insurance or Medicare will not pay for these standard of care charges because they take place within a research study. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study. Some procedures require Pre-Certification from your insurance company and representatives of the clinic or hospital will be helping you with that process. Pre-Certification is not a guarantee of payment. If you have further questions about tests covered by the study, please talk to a member of the study team.

You can still be in the study even if your insurance denies coverage for your standard of care treatment or if you are uninsured. The University of Kansas Hospital may have a financial assistance program to patients who qualify. If you do not qualify for the financial assistance (or your hospital does not provide financial assistance), you will be charged for all bills that are not the responsibility of the study. Please contact The University of Kansas Hospital's Patient Financial Services for more information.

The study drug bortezomib and the other drugs (G-CSF and Mozobil) used in this study are commercially available. You or your insurance company will be responsible for the cost of the drugs, as well as for the costs associated with preparing the drugs and giving the drugs to you.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at:
http://www.cancer.gov/clinicaltrials/learningabout/payingfor

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.

Will I get paid to participate in the study?
You will not receive any payment for participating in the study.

Will the researchers get paid for doing the study?
The University of Kansas Medical Center (KUMC) is being paid to perform this study.
The University of Kansas (KU) is paid a royalty based on the sales of the drug, bortezomib (VELCADE). None of the investigators conducting this study will receive personal monetary benefit from the study's success.
Two committees at the University of Kansas Medical Center have independently reviewed this project. The University's relationship will be reviewed by those two committees on an annual basis. Their goal is to minimize any influence of the financial interests on the conduct of the study. However, you should make your own decision about whether these financial interests affect your decision to participate. If you would like more information, please ask the person obtaining informed consent from you. You may also contact the Office of Compliance at (913) 588-1288 or toll-free 1-877-588-5757 and TDD (913) 588-7963.

What happens if I get hurt or sick during the study?
If you have a serious side effect or other problem during this study, you should immediately contact Dr. Siddhartha Ganguly at **913-588-6030**, which is also listed on the front of this consent form.

If it is after 5:00 p.m., a holiday or a weekend, you should call **913-588-5000** and ask for the hematologist on call. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. You may also call (913) 588-1240. Under certain conditions, Kansas s state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

Do I have to be in the study?
Being in research is voluntary. You can choose whether or not to participate. Even if you decide not to join the study, you can still come to KUMC for services and treatment.

What other choices do I have?
You can choose not to be in the study. Instead of being in this study, you can receive treatment that is already available, such as autologous stem cell transplantation without the study drug, bortezomib.

Your other choices may include:

- Getting treatment or care for your cancer without being in a study. The treatment on this study may be available at this center or at other locations.
- Taking part in another study
- Getting no treatment
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

How will my privacy be protected?
The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. Your medical records at KUMC may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KUMC by Dr. Ganguly, members of the research team, The University of Kansas Hospital Medical Record Department, the KUMC Research Institute, Data Safety Monitoring Committee and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Ganguly, and the research team permission to share information about you with persons or groups outside KUMC. Your information will be shared with the laboratory that processes study lab samples, the study's Data and Safety Monitoring Committee, the U.S. Food and Drug Administration (FDA) and U.S. agencies that oversee human research (if a study audit is performed), and similar agencies in foreign countries.

These groups or agencies may make copies of study records for audit purposes. The purpose for using and sharing your information is to make sure the study is done properly and to evaluate the safety and effectiveness of the study drug, bortezomib.

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there may be other laws that protect your information from improper use.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely.

While you are participating in this study, you may see and copy any study information that is placed in your KUMC medical record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Can I stop being in the study?
You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. If you would be harmed by stopping the study drug suddenly, the researchers may ask you to gradually reduce the dose. You might be asked to come back for a final study visit.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please contact Dr. Ganguly. The mailing address is:

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2330 Shawnee Mission Parkway, Suite 210
Westwood, KS 66205

If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the study drug, bortezomib. They are permitted to use and share information that was gathered before they received your cancellation.

Could my participation be stopped early?
This study might be stopped, without your consent, by the FDA. Your participation also might be stopped by the investigator or by the University of Kansas Medical Center if it is in your best interest or if you do not follow the study requirements.

If necessary, the study doctor may decide to discontinue your treatment in this study if:

- Your disease worsens despite treatment
- The side effect(s) of the drug(s) are too unsafe for you
- New information about this combination of drugs becomes available that suggests the drugs may not be helpful or are unsafe for you

Neither the investigator nor the University of Kansas Medical Center will be obligated to provide you with any study drug (bortezomib) or treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Who can I talk to about the study?
Before you sign this form, Dr. Ganguly or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at:

Human Subjects Committee
Mail Stop #1032
University of Kansas Medical Center
3901 Rainbow Blvd.
Kansas City, KS 66160

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

CONSENT

Dr. Siddhartha Ganguly or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date