

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: i071-341-03 (IRRC #6016): Phase II Trial of Twice Weekly Induction Followed by Once Weekly IV VELCADE with Dexamethasone in Patients with Relapsed and/or Refractory Multiple Myeloma Following at Least One Prior Therapy.

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You are being asked to participate in a research study. To make an informed judgment on whether or not you want to be part of this study, you should know its risks and potential benefits and the alternatives. This process is known as informed consent. This form serves two purposes. First, it gives you detailed information about the research study that your doctor will discuss with you. Second, this form seeks your authorization for the use and disclosure of the medical information that will be obtained from you in the course of the study. You will be asked to read this form and discuss anything that you need clarified with your doctor. Once you know the study, its risks, potential benefits, and alternatives, you will be asked to sign this form if you wish to participate in the study and authorize the use and disclosure of your medical information for purposes of the study. You will be given a copy for your records.

You are being asked to consider participating in this research study because you have multiple myeloma that is not responding to standard medical treatment. Your doctor has explained to you that your multiple myeloma is now advanced and standard medical treatment that you received before is no longer working against your disease.

VELCADE™ (bortezomib) for Injection is a drug under development by Millennium Pharmaceuticals, Inc. VELCADE has received FDA approval for the treatment of

multiple myeloma patients. VELCADE is still currently under investigation for other indications.

VELCADE is the type of drug known as a “proteasome inhibitor.” It has been studied in about 24,000 patients with various types of cancer. VELCADE enters cells and affects the way they divide. VELCADE interferes with a substance found inside cells in your body called the “proteasome” that is responsible for allowing cells to divide.

Dexamethasone is a corticosteroid that has been used for years in the treatment of multiple myeloma.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate how multiple myeloma in patients with your type of disease respond to treatment with VELCADE and dexamethasone given twice and once weekly and also to see what effects (good and bad) it has on you and on your cancer.

After 19 patients who are treated with VELCADE and dexamethasone according to the study plan have a sufficient response to warrant further study, accrual will continue.

The use of VELCADE and dexamethasone once weekly is experimental. Laboratory studies and disease assessments will be done throughout the study to check how well you are tolerating the drug and how the drug is working. Study participation will last until you have disease progression(worsening of your disease) followed by a long-term follow-up period.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

Up to 30 patients will be enrolled onto this study.

Study Medications

This is an “open-label study”, which means that both you and your doctor know what drug and dose you are receiving throughout the study. All patients will receive active study drug; there is no placebo (dummy or sugar pill) medication. Study medication will be given in cycles. One (1) cycle includes 11 days of treatment and 10 days of rest. Thus 21 days equals 1 cycle.

From Days 12 to 21 of each cycle you will not receive any study medication (VELCADE or dexamethasone).

Screening Procedures

During the three weeks before study treatment begins, you will have tests to determine if you are eligible to participate in this study. You will:

- Sign this informed consent and authorization form (if you choose to participate).
- Be asked questions about your age and race.
- Be asked questions about your medical history, including your cancer and any treatment for cancer you have received.
- Have a physical examination, and your vital signs (heart rate, respiratory rate, blood pressure, and temperature), height and weight will be measured.

- Have chest x-rays (front and side views) and an electrocardiogram (EKG or ECG) which records the electrical activity of your heart.
- Be asked to provide blood samples (about 4 tablespoons of blood) for tests that determine if your organs are working well enough to participate in this study and to ensure women of childbearing potential have a negative serum pregnancy test before study drug is administered.
- Be asked to provide blood samples (2 teaspoons for each test) to test for human immunodeficiency virus (HIV) or hepatitis. If HIV test is performed you may be asked to sign a separate consent for the HIV test.
- Complete a questionnaire to help assess any neuropathy (numbness or tingling in your hands or feet) you may be experiencing before you start treatment on study

You will have tests done to assess your disease which include:

- Evaluation of your disease-related symptoms and assessment of your ECOG performance status score (a number that tells doctors how much your cancer is affecting your daily activities).
- Bone marrow biopsy and aspirate
- 24 hour urine protein and urine tests for analysis of disease markers
- Skeletal survey to assess for any bone involvement
- A blood sample (one to two tablespoons, depending on what markers your type of disease has) for analysis of disease markers.
- Based on the tests done to assess your disease, your doctor will “stage” your disease (assign a number) to indicate how much cancer you have.

This visit will take approximately 2-3 hours.

WHAT IS INVOLVED IN THE STUDY?

Treatment Phase (Cycles 1 through 8) Procedures

If you are eligible to participate in the study and you wish to proceed you will begin treatment with VELCADE and dexamethasone. Dexamethasone will be given on day of and the day after VELCADE administration in the form of a pill. One treatment cycle lasts 21 days. The treatment cycle is repeated up to eight times for a total of up to 4 cycles. During each treatment cycle you will be asked to come to the clinic for four study visits in the first two weeks of the cycle (Day 1, 4, 8, and 11) to be evaluated and receive study drug. After each visit you will be monitored for one hour after you receive the study drug. Each of these study visits will last approximately 3-4 hours.

Treatment with VELCADE and dexamethasone

Once you are entered onto study, you will receive VELCADE through a device that allows medication to be put into your vein twice a week for 2 weeks on Days 1, 4, 8, and 11 of each cycle. It will take 3-5 seconds to inject VELCADE into your blood stream. A 10-day rest period (Days 12-21) will follow the 2 weeks of treatment; followed by once weekly VELCADE on Days 1, 8, 15, and 22.

A 13-day rest period will follow the once weekly treatments every 36 days until progressive disease. You will take Dexamethasone by mouth on day of and the day after VELCADE administration.

Patients who achieve a complete response (no evidence of disease in your blood or urine) while on the twice-weekly regimen will continue receiving VELCADE and dexamethasone on the twice-weekly regimen for 2 cycles beyond complete response utilizing the twice-weekly schedule. Patients who receive complete response on the weekly regimen will receive additional 2 cycles of the weekly regimen.

The following procedures will be conducted:

Day 1 Visit

Before you receive study drug on Day 1 of each treatment cycle, you will:

- Have an evaluation of your disease-related symptoms and assessment of your ECOG performance status score.
- Have vital signs and weight (heart rate, respiratory rate, blood pressure, and temperature) measured.
- Have blood collected (about 4 tablespoons) to assess if your organs are working well enough to receive study medication.
- Be asked about any changes in health, symptoms, medications or other treatments.

This visit will last approximately 2-3 hours.

Day 4 Visit

Before you receive study drug on Day 4 of each treatment cycle, you will:

- Have vital signs (heart rate, respiratory rate, blood pressure, and temperature) measured.
- Have blood collected (about 4 tablespoons) to assess if your organs are working well enough to receive study medication.
- Be asked about any changes in health, symptoms, medications or other treatments.

This visit will last approximately 1-2 hours.

Day 8 Visit

Before you receive study drug on Day 8 of each treatment cycle, you will:

- Have a brief physical examination to assess any symptoms you may report.
- Have vital signs (heart rate, respiratory rate, blood pressure, and temperature) measured.
- Have blood collected (about 4 tablespoons) to assess if your organs are working well enough to receive study medication
- Be asked about any changes in health, symptoms, medications or other treatments.

This visit will last approximately 2-3 hours.

Day 11 Visit

Before you receive study drug on Day 11 of each treatment cycle, you will:
Have vital signs (heart rate, respiratory rate, blood pressure, and temperature) measured.

- Have blood collected (about 4 tablespoons) to assess if your organs are working well enough to receive study medication.
- Be asked about any changes in health, symptoms, medications or other treatments.

This visit will last approximately 1-2 hours.

Disease Assessment

Beginning with Week 6, the following assessments will be performed every 6 weeks during the Treatment period.

- Have blood collected (about 1 to 2 tablespoons) for analysis of disease markers
- Bone marrow and aspirate to confirm complete response only
- 24 hour urine protein specimen

Your doctor will assess your response to the study drugs based on the results of these tests.

Treatment will be terminated for any of the following criteria:

- There is no evidence of disease. This is called a complete response. If a complete response is noted on a skeletal survey a second skeletal survey will be completed 4 weeks later to confirm the results of the previous skeletal survey. Once a complete response is confirmed, 2 additional cycles of treatment will be given and then treatment will stop.
- Your disease gets worse.
- The side effects of the treatment are too severe.
- If the investigator feels it will be in your best interest.
- If you require other anti-cancer therapy.

If any of the criteria above are met an End-of-Treatment visit will be performed.

End-of-Treatment Visit: (30 days after the last dose of study drug)

At this visit you will:

- Be asked about any changes in your health, symptoms, medications or other treatments.
- Have a physical examination and vital signs (heart rate, respiratory rate, blood pressure, and temperature).

- Have an evaluation of your disease-related symptoms and assessment of your ECOG performance status score.
- Bone marrow biopsy and aspirate
- 24 hour urine protein
- Skeletal survey
- Be asked to provide blood samples (about 4 tablespoons of blood) for tests that determine if your organs were affected by the study medication.

Your doctor will assess your response to the study drugs based on the results of these tests. The tests done at this visit will also be done in the event you are terminated early from the study.

Long-Term Follow-Up Period Procedures

After the End-of Treatment visit, you will enter the Long-term Follow-up period of the study. You will be contacted by telephone to assess how you are doing every 3 months.

Prohibited Therapies While on Study

You cannot receive the following treatments during study participation:

- Therapies that help your immune system fight your cancer
- Chemotherapy drugs
- Radiation therapy
- Surgery for your cancer

WHAT ARE THE RISKS OF THE STUDY?

VELCADE should not be taken if you have ever had a serious allergic reaction to bortezomib (VELCADE), boron, or mannitol. While on the study you are at risk of side effects from VELCADE as described below. You may experience some, none, or all of these side effects and the side effects may vary in severity. The severity may be mild, moderate, or severe, up to and including death. In addition, there is always the risk of a very rare or previously unknown side effect occurring. If any of these symptoms occur, you must tell your doctor who may prescribe medications to ease discomforts you are experiencing. Your doctor may decrease or withhold the dose of VELCADE. In addition, if a severe reaction to the drug occurs, your doctor may discontinue the study treatment.

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

Most Common VELCADE Side Effects:

Most common side effects are those that have occurred in greater than or equal to 30% [30 or more out of 100] of patients who have received VELCADE:

- Fatigue, weakness, lethargy, malaise, and general discomfort.
- Gastrointestinal effects such as constipation, diarrhea, nausea, vomiting and loss of appetite, which may result in dehydration and/or weight loss
- Fever very commonly with shaking chills
- Painful sensations or numbness and tingling in hands and feet, which may not resolve after discontinuation of VELCADE
- Lowered platelets; that may increase the chance of bleeding

Very Common VELCADE Side Effects:

Very Common side effects are those that have occurred in 10-29% [10 to 29 out of 100] of patients who have received VELCADE:

- Lowered white blood cells called neutrophils that may increase your risk of infection and is uncommonly associated with fever; lowered red cells or anemia which may make you feel tired; 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.
- Abdominal (belly) pain
- Flu-like symptoms (fever, shaking chills and muscle cramps and/or aches) and other respiratory tract infections, such as chills, sore throat, or runny nose
- Aches and pains in muscles and joints
- Skin rash with itching and redness. An uncommon risk is a severe, life-threatening or deadly rash with skin peeling, and mouth sores.
- Lowered blood pressure that can commonly cause you to feel light headed or faint when you stand up, swelling, and fluid build up 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 shortness of breath, lung infections including pneumonia and uncommonly bronchitis
- Headache
- Herpes virus such as shingles (herpes zoster) that can sometimes cause local pain that does not go away for a while and herpes simplex virus. Shingles can sometimes spread over large parts of the body. Both may also affect the eyes or brain, but this is uncommon.
- Feeling anxious
- Problems sleeping (insomnia)

Common Side Effects of VELCADE:

Common side effects are those that have occurred in 1-9% [1 to 9 out of 100] of patients who have received VELCADE:

- Changes in heart rate and heart rhythm (possibly with the feeling of confusion, light-headedness, dizziness, fainting, shortness of breath, and/or chest discomfort). Rarely, potentially life threatening heart rhythm abnormalities have been observed
- New or worsening heart failure or decreased heart function has been seen (which may appear as shortness of breath, swelling in the legs, and/or chest pain) or decreased heart function. If you have heart failure or other diseases that put you at risk of developing heart failure, you should be closely monitored
- Fluid around the lungs
- Eye 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 associated with low platelet counts and blood clotting changes. Uncommonly this bleeding may result in bloody diarrhea and/or bloody vomit.
- Nosebleeds and thin watery nasal discharge (rhinorrhea)
- Deterioration in kidney function, including renal impairment/failure and increased serum creatinine, hematuria
- Infections of the bladder, urinary tract, sinuses, throat, mouth, stomach, intestines, and 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 receiving oral antidiabetic medicine. If you are taking oral antidiabetic agents you may require close monitoring of your blood sugar levels
- Blood in the urine
- Confusion
- Abnormal liver tests. (Such as increased ALT and AST, and increased alkaline phosphatase)
- Changes in the way things taste
- Decrease in the amount of potassium and sodium in your blood and increase in the amount of calcium in your blood

Rare, but serious VELCADE Side Effects:

Uncommon side effects are those that have occurred in less than 1% [less than 1 out of 100] of patients who have received VELCADE:

- inflammation and fluid build up in the lungs, or fluid 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, and liver failure (in patients who also got many drugs and had other serious medical problems).
- Pain in the mouth and throat when swallowing, including oral skin spots
- Fungal infections of the throat, skin and nails
- Loss of hearing
- Intestinal obstruction (blockage in the gut) that may get better on its own and not need surgery and inflammation of the intestines, pancreas or stomach
- Coughing up or vomiting blood
- Bleeding in the brain and subdural hematoma which is bleeding between the skull and your brain
- Rapid death of cancer cells that may cause the release of toxins into the blood and injure organs, such as the kidneys
- Allergic reactions that could include skin swelling and/or facial or throat swelling and could be severe or life threatening
- Severe muscle weakness and paralysis (not being able to move your arms and legs)
- Changes in the brain that may cause convulsions and confusion
- Reversible posterior leukoencephalopathy syndrome affects the brain and may cause headaches, changes in your vision, changes in your mental status, or seizures (fits), but is usually reversible

Risks and side effects related to the Dexamethasone include those which are:

Very Likely (10-30% [10 to 30 out of 100])

- Increased weight around the stomach
Puffiness (especially in the face)
- Mood swings
- Depression
- Trouble with sleeping

Likely (1-10% [1 to 10 out of 100])

- Stomach and throat ulcers or worsening or irritation of existing ulcers
- Inflammation of the pancreas
- Retaining of salt and fluids which could cause an increase in blood pressure
- A possible rise in the blood sugar, and problem with the level of potassium in the blood
- Muscle weakness
- Brittle bones
- Menstrual changes
- Changes in personality
- Increased risk of infections
- Increased risk of blood clots

Less Likely (less than 1% [less than 1 out of 100])

- Itching, and other allergic reactions (including severe allergic reactions)
- Convulsions and dizziness

Rare but serious (less than 1% [less than 1 out of 100])

- If you are more prone to heart disease, you may experience heart failure
- Participants with glaucoma or a family history of glaucoma may experience a rise of inner eye pressure or glaucoma. Dexamethasone may also affect the skin by causing stretch marks (stomach, lower back, breasts, and groin area), slow wound healing, increased sweating, and easy bruising. Continued use (more than 25 mg for 2 weeks) can lower the function of the adrenal glands. This drug may also alter the body's defense system increasing the chance of infections.
- Dexamethasone may interact with several medications. Please be sure to tell your study doctor of any other medicine, including over-the-counter medicines, vitamins, and herbal products that you may be taking. Vaccines may not work as well while you are using Dexamethasone. You should talk with your doctor before getting flu shots or other vaccines.

Venous puncture risks

In addition to the side effects of VELCADE, routine needle sticks for blood samples may cause pain, bruising, and rarely infection at the site where blood is drawn.

Pregnancy and Contraception

Both men and women will be included in this study. Because the drugs in this study might affect an unborn baby, you should not become pregnant or father a baby while on this study. You must use a highly effective birth control method or a combination of 2

additionally effective birth control methods while in this study.while on this study. Examples of effective birth control are: a condom or a diaphragm, either with spermicidal jelly; oral, injectable, or implanted birth control, or abstinence. The effect of VELCADE on reproduction and its safety in pregnancy are unknown. If you are a woman capable of becoming pregnant (anyone who has not undergone a hysterectomy, removal of the womb), has not had both ovaries removed or has not been post-menopausal (stopped menstrual periods) for more than 24 months in a row, you must have a negative pregnancy test before beginning treatment. In addition, you must not be breastfeeding a baby during this study.

If you think that you have become pregnant or may have fathered a child or your partner becomes pregnant while taking part in this study you must tell the study doctor immediately. The study doctor will advise you of the possible risks to your unborn baby and discuss options for managing the pregnancy with you. You should also notify the doctor managing your pregnancy that the mother/father received a study drug (name of study drug or drugs.)

If you are a female study subject and you become pregnant during your participation in this study, your treatment with study drug will be stopped and you may be withdrawn from some of the study procedures but not from follow-up by your study doctor.

The study doctor will ask for your permission to stay in contact with you throughout the length of the pregnancy.

If you are a male study subject and your partner becomes pregnant, the study doctor will ask for your partner's permission to collect information about her pregnancy and the health of the baby. Because of possible risks to your unborn baby, the study drug will be stopped permanently.

Laboratory tests show that VELCADE may damage DNA (which makes up a person's genes). Based on this information, it is possible that VELCADE may cause infertility in men or women.

WHAT HAPPENS IF YOU ARE INJURED BECAUSE YOU TAKE PART IN THIS STUDY?

Marquette General Health System will not be responsible for any injury or care that is related to the use of VELCADE. If you are injured or become ill from taking part in this study emergency medical treatment is available and will be provided at the usual charge. No funds have been set aside to pay you in case you are injured. You or your insurance company will be charged for medical care an/or hospitalization. By signing this consent and authorization form, however, you have not given up any of your legal rights.

NEW INFORMATION

You will be informed of any new findings related to the development or safety of VELCADE that may affect your willingness to continue to take part in this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

The study drug is still being clinically tested so it is not possible to predict whether it will be of benefit to you. You may or may not benefit personally from participating in this

study. However, the results of this study may help investigators learn about this new treatment and may help other patients in the future.

WHAT OTHER OPTIONS ARE THERE?

You are asked to participate in this study because your disease has not responded to standard medical treatments. Your doctor will discuss with you any other investigational drugs that may be available for the treatment of your disease. You may also decide to receive no treatment at all. If you decide not to take part in this study there will be no effect on your subsequent care.

COMPENSATION

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

WHAT ARE THE COSTS?

The study drug VELCADE will be provided free of charge by Millennium Pharmaceuticals, Inc. Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You will be discontinued from this study for any of the following reasons:

- You have maintained a complete response to treatment for 2 treatment cycles after it was confirmed that you had a complete response.
- Your disease progressed after completing at least 2 treatment cycles on your current medication schedule.
- You had unacceptable side effects from treatment in this study.

You can also be withdrawn from the study with or without your consent by your doctor or the coordinating investigator of this study for the following reasons: if you do not comply with the study requirements, if you experience a research-related injury or unacceptable side effects, if your doctor determines that the study treatment is not effective for you, or for administrative reasons. If your participation is stopped, you may be asked to undergo a routine medical exam and/or blood testing for safety reasons. Any patient who is withdrawn from the study for any reason may not re-enter the study at any time.

Your participation in this study is voluntary. You may refuse to participate in this study or discontinue your participation in the study at any time with no penalty or loss of benefits to which you are otherwise entitled. If you do decide to discontinue your participation in the study, please inform your study doctor. He/she will ask you to have medical evaluations performed and blood drawn for safety reasons.

WHAT ABOUT CONFIDENTIALITY?

This clinical study may be performed only by collecting and using your medical information. Your study records will be kept confidential. Only a number and initials will be used to identify you. You will not be personally identified in any reports or publications that may result from this research study. Because of the research goals of this study, however, your study records cannot be kept absolutely confidential.

The study personnel, the coordinating Investigator, the Millennium Pharmaceuticals and its agents will need to review the medical information collected from you for use in this study in order to accurately record information for the study. In addition, in order to review the study findings, FDA (the U.S. drug agency) and other regulatory agencies may review your medical records. The following sections provide a specific description of how your information will be used and disclosed if you participate in this research study. If you decide to participate in the study, you will be asked to authorize those uses and disclosures by signing this form. If you choose not to authorize these uses and disclosures of your information, you will not be able to participate in the study.

The medical information that will be collected from you if you participate in the study includes:

- Information obtained from procedures used to determine your eligibility to participate in the trial, including a routine medical history, physical exam, x-rays, electrocardiogram (ECG), blood and urine tests,; and information that is created or collected from you during your participation in the study, including the results of the urine and blood tests, and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, or other identifying information.

If you sign this form and participate in the study, the study personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the information described above to the following parties involved in the research study:

- Millennium Pharmaceuticals, Inc. or other agents designated by Millennium to collect or review study data
- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) that oversees the research study at your site
- Government regulatory agencies including FDA (the U.S. drug agency).

Once your information is disclosed to the study personnel, Millennium Pharmaceuticals, the IRB/IEC or government agencies as described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations. The laws of your state may provide further protection.

While the study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the research is completed. You have the right to see and copy the medical information collected from you in the course of the study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation.

This authorization has no expiration date. In signing this form, you authorize the use and disclosure of you information for purposes of the study at any time in the future.

You may revoke your authorization at any time by sending a written request to the Research Dept and/or your oncologist. If you revoke your authorization, your participation in the study will end and the study personnel will stop collecting medical information from you. In addition, study personnel will stop using your information and will stop disclosing your information to the parties described above, except to the extent study personnel have relied on information that has already been collected from you.

For example, the study personnel may need to use or disclose information obtained before you revoked your authorization in order to preserve the scientific integrity of the study.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you seek emergency care at any time during the study or if additional hospitalization is required up to one month after taking the last dose of study drug, tell the treating physician that you are or were enrolled in this research study and also inform your study physician. If at any time, during or after the study, you have any questions about this study or study procedures, or if you feel you have had a research-related injury, you may contact the doctor listed below, day or night:

Dr. Aaron Scholnik
Hematology Oncology Associates
1414 West Fair Ave. Suite 332
Marquette, MI 49855
(906) 225-3922 (office hours)
(906) 228-9440 (on-call physician)

If you have any questions regarding this research, your rights as a research subject, or any other related concerns about your participation you may contact the Patient Advocate at 906-225-3433.

WHERE CAN YOU GET MORE INFORMATION:

You may call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

Visit the NCI's Web site: Cancer Trials: comprehensive clinical trials information at <http://cancertrials.nci.nih.gov>

Cancer Net: accurate cancer information including PDQ at <http://cancer.net.nih.gov>

You will get a copy of this form. You may also request a copy of the protocol (full study plan).

Institutional Funding:

Funds are provided from the study sponsor to Marquette General Hospital on a per patient basis to help with the institution's costs of participating in this study.

WHOM DO I CALL IF I HAVE PROBLEMS OR QUESTIONS?

In the event that physical injury occurs as a result of this research, facilities for treatment of injury will be available; however, you will not automatically be provided with reimbursement for medical care or other compensation. For more information concerning the research and research-related risks or injuries, you can notify Dr. _____, or his/her associates, who may be reached by phoning the office at (906) 225-3922. During the evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the oncology physician on call. You can also call the Patient Advocate at Marquette General Hospital at (906) 228-9440, if you have any questions, comments, or concerns about the study or your rights as a research subject.

VOLUNTARY CONSENT:

You certify that you have read the preceding or it has been read to you and that you understand its contents. Any questions you have pertaining to the research or research related injuries have been and will be answered by Dr. _____ or his/her associates, who may be reached by phoning the office at (906) 225-3922. During evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the medical oncologist on call. Any questions you have concerning your rights as a research subject will be answered by the Patient Advocate at Marquette General Hospital, who may be reached by phoning (906) 228-9440. You will be given a copy of this consent form.

Your signature below means that you have freely agreed to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting

Date

INFORMED CONSENT DISCUSSION

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this research study have been explained to the patient indicated, and that any questions about this information have been answered.

Investigator's Signature

Date

Your signature below means that you do not wish to participate in this investigational study.

Patient's Signature

Date

Signature of person conducting
Informed consent discussion

Date

Investigator's Signature

Date

IRB approved consent form 5/14/08
IRB approved Revision #4, 11/12/2008