

**MARQUETTE GENERAL HEALTH SYSTEM**  
**Regional Medical Center**

**CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY**

**TITLE:** SWOG S0421, "Phase III Study of Docetaxel and Atrasentan versus Docetaxel and Placebo For Patients with Advanced Hormone Refractory Prostate Cancer"

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This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have prostate cancer that is not responding well to treatment.

**Why is this study being done?**

**The purpose of this study is to compare the effects (good and bad) of the combination of docetaxel and prednisone plus atrasentan against the combination of docetaxel and prednisone plus placebo on you and your prostate cancer to see which is better.**

**This research is being done because many people think that the new combination of docetaxel and prednisone plus the investigational drug atrasentan may be better than the commonly used combination of docetaxel and prednisone alone, but these two treatments have not been compared. Atrasentan is an investigational drug. It has not been approved by the FDA for commercial use. We do not know which of these two treatments is better. We also want to find out how these two treatments affect your quality of life.**

**How many people will take part in the study?**

Nationally, about 930 people will take part in this study

**What will happen if I take part in this research study?**

## Before you begin the study ...

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- History and physical
- CT scan of your abdomen and pelvis
- Chest x-ray
- Bone scan
- Blood prostate specific antigen (PSA) test
- Other blood tests including those to assess your blood counts and kidney and liver function.

## During the study ...

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

Before you receive treatment, you will also be asked to complete the following Quality of Life forms:

- Symptom Questionnaire (questions about pain and fatigue)
- Pain Medication Log
- FACT-P (questions about your physical, functional, emotional, and social well-being)

Every 3 weeks:

- History and physical
- Blood prostate specific antigen (PSA) test
- Other blood tests including those to assess your blood counts and kidney and liver function.
- Symptom Questionnaire before every treatment cycle for a maximum of 12 cycles and once again when you have completed your treatment.
- Pain Medication Log before every treatment cycle for a maximum of 12 cycles and once again when you have completed your treatment.

Every 12 weeks:

- CT scan of your abdomen and pelvis
- Chest x-ray
- Bone scan
- The FACT-P quality of life questionnaire will be completed a total of five times: before treatment begins; three times during your treatment; and once again when you have completed your treatment.

Continued Treatment:

- If you continue receiving study treatment after 12 cycles, you will be asked to answer one question about your pain and to report the pain medications you are taking for a maximum of 5 more cycles of treatment.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is

decided by a computer. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group. Once you are placed into one of the groups, neither you nor your doctor will know which group you are in. The treatment in each group will be identical except that half of the patients will be given the investigational drug atrasentan (one capsule each day) and half will take an identical placebo capsule. Placebo capsules do not contain any medication. These capsule will look just like the capsules containing atrasentan.

The schedule of treatment will be the same in both groups. It will consist of cycles of treatment that last 21 days and are repeated every three weeks for a maximum of twelve cycles of docetaxel and prednisone. On the first day of the treatment cycles, you will be given docetaxel as an intravenous infusion (given into a vein). Prior to receiving docetaxel, you will be given dexamethasone as directed by your doctor. Dexamethasone reduces some of the side effects of docetaxel. In addition, on the first day of treatment, you will take prednisone (10 mg) by mouth. You will take prednisone (10 mg) each and every day of the twelve cycles. You will also take another capsule each and every day of the twelve cycles. This capsule will contain either the investigational drug atrasentan or placebo. You may continue to take the investigational drug atrasentan or placebo capsule every day after the twelve cycles is completed for up to 52 weeks or for as long as the therapy is of benefit to you. As part of your therapy for prostate cancer, you will either have been treated with removal of your testes or have been treated with injections to suppress the male hormone testosterone. If you have taken or are taking these injections, you must resume or continue taking these injections while you are on this study. Due to interaction with docetaxel, you must not consume grapefruit juice or take St. John's Wort while receiving docetaxel. You should tell your doctor about all medications (over the counter, herbal, and prescription) that you are taking as they may interact with your treatment.

We want to know your view of how your life has been affected by cancer and its treatment. This "Quality of Life" study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities. You will be asked to complete three questionnaires (the Symptom Questionnaire, a Pain Medication Log, and the FACT-P) at the times outlined above. It takes less than 15 minutes to complete each questionnaire. This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer. If any questions make you feel uncomfortable, you may skip those questions and not give an answer. Just like in the main study, we will do our best to make sure that your personal information will be kept private.

## Study Chart

The chart below shows what will happen to you during Cycle 1 and future treatment cycles as explained previously. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

### Cycle 1

Day	What you do
Before starting study	<ul style="list-style-type: none"> <li>• Get routine blood tests including a blood prostate specific antigen (PSA test), CT scan of your abdomen and pelvis, chest x-ray, bone scan. Complete Quality of Life forms (Symptom Questionnaire, Pain Medication Log, and FACT-P).</li> </ul>

Day before you get docetaxel	<ul style="list-style-type: none"> <li>• Take dexamethasone as directed by your doctor.</li> </ul>
Day 1	<ul style="list-style-type: none"> <li>• Begin taking prednisone (10 mg) and atrasentan/placebo once a day. Keep taking them until the end of study, unless told to stop by your health care team.</li> </ul>

## Future cycles

Day	What you do
Days 1-20	<ul style="list-style-type: none"> <li>• Keep taking prednisone (10 mg) and atrasentan/placebo once a day if you have no bad side effects and cancer is not getting worse. Call the doctor at _____ [<i>insert phone number</i>] if you do not know what to do.</li> <li>• Get routine blood tests including a PSA test and exams every cycle (more if your doctor tells you to).</li> <li>• Complete the Symptom Questionnaire and Pain Medication Log before every treatment cycle for a maximum of 12 cycles and once again when you have completed your treatment.</li> <li>• Complete the FACT-P after every 3rd cycle and once again when you have completed your treatment.</li> <li>• Get routine CT scan of your abdomen and pelvis, chest x-ray and bone scan after every 4th cycle (more if your doctor tells you to).</li> </ul>
Day 21	<ul style="list-style-type: none"> <li>• Return to your doctor's office at _____ for your next exam and to begin the next cycle, which will include docetaxel as an intravenous infusion (given into a vein).</li> </ul>

## How long will I be in the study?

You will be asked to take dexamethasone, docetaxel, prednisone (10 mg), and either the investigational drug atrasentan or placebo for up to 36 weeks (12 cycles). You may continue to take the investigational drug atrasentan or placebo after the twelve cycles is completed for up to 52 weeks or for as long as the therapy is of benefit to you. Your doctor may decide to take you off this study if your disease gets worse despite treatment; the side effects of the treatment are too dangerous for you; or new information about the treatment becomes available and this information suggests the treatment will be ineffective or unsafe for you. After you are finished taking the study medications, the study doctor will ask you to visit the office for follow-up physical exams, routine blood tests, and routine CT scans of your abdomen and pelvis every three months for the first year, then every 6 months for up to three years. A PSA test will be done every month and a bone scan every 3 months during follow-up.

## Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

## What side effects or risks can I expect from being in the study?

**You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drugs. In some cases, side effects can be serious, long lasting, or may never go away.**

**You should talk to your study doctor about any side effects that you have while taking part in the study.**

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

### **Likely**

- Lowered white blood count which may increase the risk of infection,
- Lowered platelets which may lead to an increase in bruising or bleeding,
- Lowered red blood cells which may lead to anemia, tiredness or shortness of breath,
- Nausea, vomiting or diarrhea,
- Complete hair loss,
- Numbness or tingling in fingers or toes,
- Pain in muscles or joints,
- Loss of appetite,
- High or low blood pressure,
- Swelling of the legs and abdomen,
- Fluid in the space around the lungs resulting in shortness of breath (requiring drainage or additional treatment),
- Headache,
- Dizziness,
- Nasal congestion or rhinitis,
- Constipation,
- Sleepiness,
- Nail changes.

### **Less Likely**

- Allergic reactions which may occur during injection causing skin rash, flushing and difficulty breathing,
- Irregular heart beat which may result in fluid build-up in the body and the potential for heart failure,
- Inflammation of the liver,
- Infection,
- Lack or loss of strength,
- Dry mouth,
- Heartburn,
- Abdominal pain,
- Shortness of breath,

- Rash,
- Conjunctivitis (irritation and redness to the thin membrane covering the eye) resulting in red, itchy eyes with a possible discharge.

**In studies of men with metastatic prostate cancer taking atrasentan or placebo ("sugar pill"), events of heart failure and/or heart attack occurred in less than 5% of the patients taking atrasentan. The events tended to occur in men with previous heart disease. Signs of heart failure (heart not able to deliver blood adequately to the body) may include excessive weight gain, greater than 4.4 lbs in two weeks, shortness of breath, and/or swelling (especially of the legs). You should weigh yourself regularly especially during the first month of treatment. If your weight increases more than 4.4 lbs, especially in the first two weeks of the study, you should report this to your study doctor as soon as possible. It is important for you to report these or any side effects or symptoms to your study doctor right away.**

**Reproductive risks: You should not father a baby while on this study because the drugs in this study can affect an unborn baby. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.**

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

**Are there benefits to taking part in the study?**

**Taking part in this study may or may not make your health better. While doctors hope this treatment will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about atrasentan's role as a treatment for cancer. This information could help future cancer patients.**

**What other choices do I have if I do not take part in this study?**

**Your other choices may include:**

- Getting treatment or care for your cancer without being in a study
- 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.**

**Will my medical information be kept private?**

**We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.**

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people,
- The Southwest Oncology Group,
- A qualified representative of the manufacturer of atrasentan (Abbott Laboratories).
- A qualified representative of the manufacturer of docetaxel (Sanofi-Aventis).

## What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Administration of the drug will be *charged in the usual way*.. The parts of the research consisting of keeping research records will be paid by those organizing and conducting the research. The research requires that you receive certain standard medical tests and examinations. These standard tests and examinations will be *charged in the usual way*.

Abbott will provide you with the investigational agent atrasentan or placebo at no cost to you. If, during the study, atrasentan becomes approved for use in your cancer, you and/or your health plan may have to pay for drug needed to complete this study. Docetaxel and prednisone are commercially available.

You will not be paid for taking part in this study.

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

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

## What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, \_\_\_\_\_, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 906-225-3922..

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

## What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your

regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about important new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

## Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor \_\_\_\_\_ at 906-225-3922.

For questions about your rights while taking part in this study, call the Patient Advocate at 906-225-3433.

Please note: This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be a part of the main study even if you say 'no' to taking part in any of these additional studies.

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

### **Future Contact**

**I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.**

Yes                      No

## Consent Form for Use of Specimens for Research

### About Using Specimens for Research

You have had a biopsy (or surgery) to identify your cancer and your doctor has removed some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care. We would like to keep some of the tissue for future research. We would also like to collect blood samples for future research. If you agree, you will have about 1 ½ tablespoons of blood drawn before your first and second treatment, about 1 tablespoon of blood drawn before your third treatment, about 1 ½ tablespoons drawn before your fourth treatment, and about one tablespoon drawn when you go off protocol treatment.

We would like to keep some of the tissue and blood for future research. If you agree, these specimens will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How are Specimens Used for Research" to learn more about specimen research.

Your specimens will be kept at:

Cecilia M. Fenoglio-Preiser, M.D.  
University of Cincinnati  
231 Albert Sabin Way  
PO Box 670529  
Cincinnati, OH 45267-0529  
Phone: 513/558-4500  
FAX: 513/558-2289  
E-mail: [cecilia.fenogliopreiser@uc.edu](mailto:cecilia.fenogliopreiser@uc.edu)

The research that may be done with your specimens is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

### Things to Think About

The choice to let us keep the left over specimens for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimens can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens. Then any specimens that remains will no longer be used for research.

In the future, people who do research may need to know more about your health. While the Southwest Oncology Group may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if your specimens are used for this kind of research, the results will not be put in your health records.

Your specimens will be used only for research and will not be sold. The research done with your specimens may help to develop new products in the future.

### Benefits

The benefits of research using specimens include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

### Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

## Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

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

1. **My specimens may be kept for use in research to learn about, prevent, treat or cure cancer.**

Yes          No

2. **My specimens may be kept for use in research about other health problems (for example: diabetes, Alzheimer's disease, or heart disease).**

Yes          No

3. **Someone may contact me in the future to ask me to allow other uses of my specimens.**

Yes          No

**If you decide to withdraw your specimens from a Southwest Oncology Group Specimen Repository in the future, a written withdrawal of consent should be submitted through your treating physician to the Southwest Oncology Group Operations Office. Please designate in the written withdrawal whether you would prefer to have the specimens destroyed or returned to the treating physician.**

## Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://cancer.gov/>

- For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

## Specimen Consent Supplemental Sheets

### How are Specimens Used for Research?

#### Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by the Southwest Oncology Group. Your doctor does not work for the Southwest Oncology Group, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

#### Why do people do research with specimens?

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

### **What type of research will be done with my specimen?**

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

### **How do researchers get the specimen?**

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact the Southwest Oncology Group and request samples for their studies. The Southwest Oncology Group reviews the way that these studies will be done, and decides if any of the samples can be used. The Southwest Oncology Group gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. The Southwest Oncology Group will not send your name, address, phone number, social security number or any other identifying information to the researcher.

### **Will I find out the results of the research using my specimen?**

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

### **Why do you need information from my health records?**

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to the Southwest Oncology Group. If more information is needed, the Southwest Oncology Group will send it to the researcher.

### **Will my name be attached to the records that are given to the researcher?**

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

### **How could the records be used in ways that might be harmful to me?**

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members.

### **How am I protected?**

The Southwest Oncology Group is in charge of making sure that information about you is kept private. The Southwest Oncology Group will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

### **COSTS AND PAYMENTS:**

You understand that the study group and Marquette General Hospital furnish no funds providing medical treatment for, or financial compensation to, human subjects in the event the investigational therapy results in loss or injury. You will be responsible for the cost of emergency medical treatment provided by this

institution and/or by your physician. You are also aware that the study group and Marquette General Hospital will not take financial responsibility for non-acute medical problems.

Lab tests (blood), x-rays and other diagnostic tests will be done frequently to check the effects of the investigational therapy. You understand that the costs of your medication and treatment may exceed what your insurance company is willing to pay, and that you will be responsible for payment. In many instances, however, all or a portion of those costs may be reimbursed by your insurance company.

**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.

**CONFIDENTIALITY:**

We will keep any information we learn from this study confidential and disclose it only with your permission, except as required by law. By signing this form, however, you allow us to make your records available to the National Cancer Institute, the Food and Drug Administration, a qualified representative of the drug manufacturer, and the Southwest Oncology Group. If we publish the information we learn from this study in a medical journal, you will not be identified by name.

**RIGHT TO WITHDRAW:**

Whether or not you take part in this study will not affect your future relations with your doctors or Marquette General Hospital. If you decide to take part, you are free to stop whenever you want to. You understand that you have the right to refuse to participate in this research study if you so desire without any fear of prejudice to additional treatment for yourself. In addition, you understand that you may refuse to continue on this study, at any time after the start of therapy, without fear of prejudice to additional treatment you may need. You recognize that you have received a copy of this consent form, and your signature indicates that you have volunteered to participate in the study having read the information provided to you.

**WHERE CAN I 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 sites...

cancerTrials: comprehensive clinical trials information <http://cancertrials.nci.nih.gov>

CancerNet™: accurate cancer information.

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

**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  
Informed consent discussion

\_\_\_\_\_  
Date

**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 8 /8 /07  
IRB approved Rev. #3 and #4 08/12/09