

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: RTOG 0415 A PHASE III RANDOMIZED STUDY OF HYPOFRACTIONATED 3D-CRT/IMRT VERSUS CONVENTIONALLY FRACTIONATED 3D-CRT/IMRT IN PATIENTS WITH FAVORABLE-RISK 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 and your doctor has recommended external beam radiation therapy.

Why is this study being done?

One of the standard treatment options for your stage and type of prostate cancer is external beam radiation therapy. More recent radiation therapy planning methods with three-dimensional therapy or intensity modulated radiation therapy (IMRT) allow safer delivery of higher than conventional daily doses of radiation. The purpose of this study is to compare the effects (good and bad) on you and your cancer of the standard dose of radiation therapy (41 treatments over 8 weeks) with a higher daily dose (experimental) of radiation (28 treatments over 5 and a half weeks) to see if the effects of the treatments are similar.

How many people will take part in the study?

About 1067 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.

- History and physical exam, including a digital rectal exam (DRE) and an assessment of your ability to carry out activities of daily living (which will include questions such as whether you are able to feed, bathe, and dress yourself)
- A biopsy of your prostate to determine your Gleason score (a value that helps determine the stage of your prostate cancer)
- A blood test to determine your PSA (a value that helps determine the stage of your prostate cancer). About 2 teaspoons of blood will be drawn from a vein or, if you have one, a catheter. The study doctor may also test your testosterone and alkaline phosphatase levels.

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.

- History and physical exam, including an assessment of your ability to carry out activities of daily living (*Weekly during radiation treatment*)

You will need this assessment to see how the study is affecting your body.

- Assessment of any side effects you may be experiencing from the treatment (*Weekly during radiation treatment*)

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are in group 1 (often called "Arm A") ...

You will receive the standard daily dose of three-dimensional radiation or IMRT. You will receive radiation therapy once daily, 5 days a week, Monday through Friday, for a total of 41 treatments. Each radiation treatment will take 15-30 minutes.

If you are in group 2 (often called "Arm B")...

You will receive a higher daily dose of three-dimensional radiation or IMRT. You will receive radiation therapy once daily, 5 days a week, Monday through Friday, for a total of 28 treatments. Each radiation treatment will take 15-30 minutes.

When you are finished receiving radiation...

You will need these tests and procedures:

- History and physical exam, including a digital rectal exam (DRE) and an assessment of your ability to carry out activities of daily living (*Every 3 months for the first 2 years following the start of radiation, every 6 months for the next 3 years, and then annually*)
- Assessment of any side effects you may be experiencing from the treatment (*Every 3 months for the first 2 years following the start of radiation, every 6 months for the next 3 years, and then annually*)
- If your disease progresses, your study doctor may request a needle biopsy of your prostate to microscopically evaluate response to treatment

How long will I be in the study?

You will receive radiation treatments for either 5 and a half or 8 weeks. After you are finished receiving radiation, the study doctor will ask you to visit the office for follow-up exams every 3 months for the first 2 years following the start of radiation, then every 6 months for the next 3 years. After that, the study doctors would like to keep track of your medical condition indefinitely by seeing you for follow-up exams every year.

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 radiation can be evaluated by him/her. Another reason to tell your study 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 decide to take you off 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, researchers 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 radiation. In some cases, side effects can be serious, long lasting, or may never go away. In addition, some of the side effects may be life threatening and, in rare instances, may cause death.

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 radiation include those which are:

Likely

- Tanning, redness, or darkening of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary fatigue, nausea or diarrhea
- Abdominal cramps
- Bladder irritation with a stinging sensation
- Frequency or urgency of urination
- Rectal irritation with more frequent bowel movements
- Mild rectal bleeding that does not require treatment

Less Likely

- Urinary obstruction requiring the placement of a temporary urinary catheter

Rare but Serious

- Injury to the bladder, urethra, bowel, or other tissues in the pelvis or abdomen
- Intestinal or urinary obstruction
- Inability to achieve an erection (inability of the penis to become hard)
- Rectal bleeding that requires medication or surgery to stop

Reproductive Risks

You should not father a baby while on this study because the radiation 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. It is not known whether the higher daily dose of three-dimensional radiation therapy or IMRT is equivalent to the standard daily dose. We do know that the information from this study will help researchers learn more about these different doses as a treatment for prostate cancer. This information could help future patients with prostate cancer.

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; this could include the following options, either alone or in combination with each other:
 - External (non–three-dimensional) radiation therapy
 - Internal radiation (seed implants or brachytherapy)

- Three-dimensional radiation therapy or IMRT similar to the therapy described in this study
- Surgery
- Hormone therapy
- Taking part in another study
- Getting no treatment (With this choice, your tumor could continue to grow and your disease could spread)

Talk to your study 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 Radiation Therapy Oncology Group
- The National Cancer Institute (NCI) and other government agencies involved in keeping research safe for people, like the Central Institutional Review Board (CIRB) and the Food and Drug Administration (FDA)
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials [for CTSU participants only]
- A Data Monitoring Committee (DMC) that regularly meets to monitor safety and other data related to this study

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 (or less) than the cost of getting regular cancer treatment.

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://www.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 study doctor in person or call him/her at _____.

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.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the 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 _____.

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

You can say “yes” or “no” to each of the following studies. Below, please mark your choice for each study.

Consent Form for Quality of Life Study

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.

This information will help doctors better understand how patients feel during treatments and what effects the treatments are having. In the future, this information may help patients and doctors as they decide which treatments to use to treat cancer.

You will be asked to complete four questionnaires at the following time points: immediately before you enroll in the study, at 6, 12, and 24 months following the start of your radiation treatment, and at 5 years following the start of your radiation treatment. It takes about 25-30 minutes to fill out the questionnaires.

One of the questionnaires requires data from Medicare on reimbursement amounts; due to the need for this data, you will be asked to provide your Social Security number. Your Social Security number will not be used for any other purpose. We will do our best to make sure that your personal information is kept private; the chance that this information will be given to someone else is very small.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the four questionnaires. You may change your mind about completing the questionnaires at any time, and you may chose to discontinue answering the questionnaires altogether at any time.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. You will not be paid for taking part in this study.

Please circle your answer.

I choose to take part in the Quality of Life study. I agree to fill out the four Quality of Life questionnaires.

Yes

No

Consent Form for Use of Tissue and Blood for Research

About Using Tissue and Blood for Research

You have had a biopsy (or surgery) to see if you have cancer. Your doctor has removed some of your 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 that is left over from your biopsy for future research. If you agree, this tissue will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research. This information sheet is available to all at the following web site: http://www.rtog.org/tissue%20for%20research_patient.pdf

In addition, you will have blood tests before you start treatment. We would like to keep about four tablespoons of blood for future research as well. If you agree, this blood will be kept and may be used in research to learn more about cancer and other diseases

Your tissue and blood may be helpful for research. The research that may be done with your tissue and blood 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 tissue and blood 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 tissue and blood for future research is up to you. No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

If you decide now that your tissue and blood 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 tissue and blood. Then any tissue or blood that remains will no longer be used for research; remaining tissue will be returned to the institution that submitted it and remaining blood will be destroyed.

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

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

Your tissue and blood will be used only for research and will not be sold. The research done with your tissue and blood may help to develop new products in the future. You will not be paid for taking part in this study.

Benefits

The benefits of research using tissue and blood 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 tissue/blood may be kept for use in research to learn about, prevent, or treat cancer.

Yes **No**

2. My tissue/blood may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes **No**

3. My blood may be kept for use in future research to learn about the correlation between genes and radiation side effects.

Yes **No**

4. Someone may contact me in the future to ask me to take part in more research.

Yes **No**

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://www.cancer.gov/>

- **For NCI's clinical trials information, go to <http://www.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.

CONTACT PERSONS:

Whom can I call if I have questions or problems?

If injury occurs as a result of this research, treatment will be available. You understand, however, you will not be provided with reimbursement for medical care other than what your insurance carrier may provide nor will you receive other compensation. For more information concerning the research and research-related risks or injuries, you can notify Dr. _____ the investigator in charge at Dickinson County Health System at 906-776-5975. During evenings, weekends, and holidays you may phone Dickinson County Health System at 906-774-1313 and request to speak with the Radiation Oncologists on call. In addition, you may contact the Patient Advocate at Marquette General Hospital at (906) 228-9440 for information regarding patients' rights in research studies.

COSTS AND PAYMENTS:

You understand that the RTOG 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 RTOG 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.

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 _____. During evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the radiation therapist 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 01/10/2007
IRB approved consent form/Amend. #2 – 2/13/2008