Consent title: Pilot Study Evaluating Hypofractionated Pre-operative Radiation Therapy for Soft Tissue Sarcomas of the Extremity and Chest-wall

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Medical College of Wisconsin and Froedtert Hospital
CONSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

Pilot Study Evaluating Hypofractionated Pre-operative Radiation Therapy for Soft Tissue Sarcomas of the Extremity and Chest-wall

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You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, possible risks and benefits to you, your choices, and other important information. If there is anything that you do not understand, please ask questions. Then you can decide if you want to join this study or not.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

You are being asked to take part in this study because you have a soft tissue sarcoma of the extremity or chest-wall.

To be eligible, you must be 18 years of age or older with a soft tissue sarcoma of the upper extremity, lower extremity or trunk. Because of your condition, you may be eligible for a research study that investigates shortening the course of radiation therapy prior to surgery.

A total of no more than 32 people are expected to participate in this study at the Medical College of Wisconsin/Froedtert Hospital and St. Joseph's Hospital.

The Principal Investigator for the study is Manpreet Bedi, MD in the Department of Radiation Oncology. A study team works with Dr. Bedi. You can ask who these people are.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A research study is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the study procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The usual treatment for sarcomas that have not spread to other areas of the body is radiation followed by surgery. Sometimes chemotherapy is recommended by your doctor and given prior to radiation therapy. Typically, 25 treatments of radiation are given. Hypofractionated radiation is a radiation treatment that gives fewer but higher doses of radiation than standard radiation. The researchers will examine whether or not hypofractionation will result in local control and toxicity similar to conventional fractionation with less cost, more patient convenience and decreased overall treatment time compared to standard radiation therapy. Hypofractionation is used to treat many types of cancer but has not been used very often with patients who have sarcomas of their extremity or chest-wall. As part of this study, you will receive 5 radiation treatments.

The purpose of this study is to test the possibility of hypofractionated radiation therapy to the tumor on the extremity or chest-wall. We want to find out what effects (good and bad) hypofractionation has on you and your cancer.

In addition, this study also will gather information about your health and hospitalization history. This information will be used to find out if there are factors that can predict recovery or outcome of patients with metastatic disease to the lung from sarcoma.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE 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.

- A physical exam by your doctor
- Evaluation of your ability to carry out daily activities
- An MRI of the tumor site and CT chest
- Blood tests, a complete blood count

- For women who are able to have children, a urine pregnancy test
- Quality of Life (QOL) questionnaire (FACT-G) and the Musculoskeletal Tumor Society MSTS functional assessment
- Tissue from your biopsy for analysis
- Blood specimen for analysis

During the study

If you are eligible to be in the study, and you choose to take part, then you will be asked to complete the following activities. These tests and procedures would be part of your regular cancer care.

Before radiation treatment begins:

- You will have a treatment planning session. You will lie in a specific position, possibly in a customized immobilization device, and have a CT (Computed Tomography) scan of your tumor. A CT scan is a study using x-rays to look at one part of your body.
- Your ability to carry out daily activities will be evaluated.
- FACT-G questionnaire and MSTS score
- For women who are able to have children, a urine pregnancy test

After the treatment planning session, you will begin your radiation therapy. You will receive a total of five (5) radiation treatments to the tumor. You will have 1 to 3 treatments per week until your treatments are complete. Your doctor may give you pain medication before each treatment to decrease any discomfort you may have due to laying on a hard surface and/or due to laying with your arms held above your head for the one-hour duration of each treatment.

During radiation treatment:

- Toxicity evaluation

Prior to Surgery

- Your ability to carry out daily activities will be evaluated.
- MRI of the tumor site
- Toxicity evaluation
- FACT-G questionnaire and MSTS score

After completion of radiation treatment:

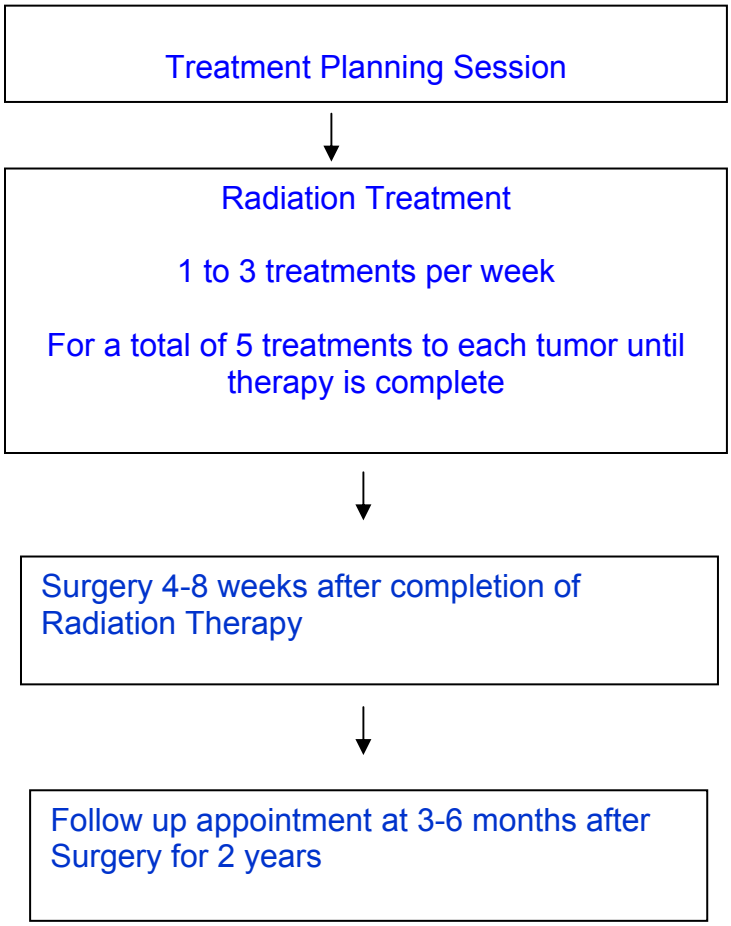
Every 3 to 6 months after surgery years 1 and 2

- Physical examination

- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having
- MRI of the tumor site and CT scan of the chest
- Questionnaire QOL(FACT-G) and MSTS functional assessment

Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



B2. HOW LONG WILL I BE IN THE STUDY?

After hypofractionation radiation therapy is completed, the study doctor will ask you to visit the office for follow-up exams every 3 to 6 months after surgery in years 1 and 2. Therefore you will be in the study for approximately 2 1/2 years.

B3. CAN I STOP BEING IN THE STUDY?

You are free to withdraw from the study at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the study doctor.

The doctor can evaluate any side effects from the hypofractionated radiation therapy and discuss what follow-up care and testing could be most helpful for you.

The study doctor may take you out of this study at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the study rules.
- The whole study is stopped.

If this happens, the study doctor will tell you.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM 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 hypofractionated radiation therapy is finished. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

We watch everyone in the study for problems (side effects). **You need to tell the study doctor or a member of the study team immediately if you experience any problems, side effects, or changes in your health.**

C2. RISKS OF Hypofractionated Radiation Therapy:

Very Likely

- Tiredness for no apparent reason, which is temporary

Less Likely

- The skin in the treatment area may become reddened and/or dry, and hair in the treatment area may fall out and may not grow back.
- Swelling in the radiation field (which is also seen in patients receiving standard therapy with RT
- Scar tissue in the RT field, which is also seen in patients receiving standard RT.
- Complications with wound healing post-operatively, which is also seen in patients receiving standard RT.

Less Likely, But Serious

- Severe peeling of the skin, which may lead to pain and desquamation of skin in radiation field.

- Irritation of the adjacent bone near the RT field which could increase the susceptibility to post-operative fracture.

C4. REPRODUCTIVE RISKS

Risks to women who could become pregnant

You should not become pregnant or father a baby while on this study because the radiation therapy in this study can affect an unborn baby. If you are a woman able to have children and have not been surgically sterilized (tubal ligation or hysterectomy), you must have a pregnancy test before enrolling in this study. Women should not breastfeed a baby while on this study. 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.

Birth control methods may include:

- Not having vaginal sex (abstinence)
- Taking birth control pills orally
- Having birth control shots or patches such as Depo-Provera
- Surgical sterilization (hysterectomy or tubal ligation)
- Use of an intrauterine device (IUD)
- Use of diaphragm with contraceptive jelly
- Use of condoms with contraceptive foam
- Use of diaphragm with condoms (“double barrier”)
- Limiting sexual activity to a male partner who has had a vasectomy

You should continue using birth control for until treatment has been completed.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study may or may not help you, but we hope that hypofractionated radiation therapy may work better to kill cancer cells with fewer side effects compared to standard radiation therapy; there is no proof of this yet. We do know that the information from this study will help researchers learn more about hypofractionated radiation therapy as a treatment for cancer and soft tissue sarcomas. This information could help future cancer patients.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?

Most of the medical care that you will receive in this study is considered routine care for your condition and would be recommended whether you join the study or not. Costs for routine care will be billed to you or your insurance carrier and the hypofractionation radiation therapy. There are no costs for the blood draw and storing blood and tissue specimens. Some insurers will not pay for drugs, tests or hospitalization that are part of research studies, so check with your insurer before you join this study. If you have questions regarding study costs, please contact Dr. Bedi.

If your study physician feels that it is necessary to order any additional tests, procedures or exams for your clinical care these will be billed to you or your insurance carrier.

D2. WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

There is no payment for being in this study.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this study. You are free to say yes or no. If you do not join this study, your doctor can discuss other healthcare choices with you.
Your other choices may include:

- Getting standard radiation treatment
- Taking part in another study.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?

If we learn any important new information about hypofractionated radiation therapy that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE STUDY?

If you have been following directions, the injury is directly related to the research, and not the result of an underlying condition, then MCW will compensate you for the injury.

If you think you have been injured because of this study, let the study doctors know right away by calling 414-805-4400.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

- If you have more questions about this study at any time, you can call Manpreet Bedi, MD at 414-805-4400 or Candice Johnstone, MD at 262-836-7200.
- If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?

To do this research study, we need your permission to collect and use some of your health information, or you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the study.

The health information to be collected and used for this study is:

- Medical records dating from when you were diagnosed with sarcoma until the end of study participation.

E2. Who will see the health information collected for this study?
The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the study team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law such as the FDA.

We will not use your personal health information for a different study without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented that identifies you.

The Medical College of Wisconsin Cancer Center Data Safety Monitoring Committee will meet to monitor safety and other data related to this trial. The Board members may receive confidential patient information, but they will not receive your name or other information that would allow them to identify you by name.

E3. What are the risks of sharing this health information?
One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study doctor about whether this could apply to you.

E4. How long will you keep the health information for this study?
If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to:

Manpreet Bedi, MD
Froedtert & Medical College of Wisconsin
Radiation Oncology
9200 W. Wisconsin Avenue
Milwaukee WI 53226
414-805-4400

The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

F1. FOR MORE INFORMATION ABOUT THE STUDY

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
You can look up this study by referring to the ClinicalTrials.gov number (NCT02634170) or by asking the study team for a printed copy.

CONSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Legally Authorized Representative (if applicable) *please print*	**Signature of Legally Authorized Representative**	**Date**
Name of Witness (if applicable**)** *please print*	**Signature of Witness**	**Date**
Name of person discussing/obtaining consent *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the study team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. In all esearch study protocols the Principal Investigator is responsible and accountable for the study.*