Consent Title: Pilot Study Evaluating Stereotactic Body Radiation Therapy (SBRT) and Adaptive Radiation Therapy (ART) for Pulmonary Metastases from Soft Tissue Sarcomas

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

Name of Study Subject: _____

Pilot Study Evaluating Stereotactic Body Radiation Therapy (SBRT) and Adaptive Radiation Therapy (ART) for Pulmonary Metastases from Soft Tissue Sarcomas

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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 metastatic disease in your lungs from a soft tissue sarcoma. This disease cannot be removed surgically due to medical problems or you do not wish to pursue surgery.

A total of no more than 20 people are expected to participate in this study; 5 patients per year at the Medical College of Wisconsin/Froedtert Hospital and 5 patients per year at Kraemer Cancer Center, West Bend.

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 spread to the lungs is to remove the cancer with surgery. However, some patients do not want to have surgery or may not be able to have standard surgery. Some patients cannot have surgery because of the location of their tumors. Some patients cannot have surgery because of other serious health problems like emphysema, diabetes, or heart disease.

Patients who cannot have surgery can receive radiation therapy. Standard radiation therapy involves several weeks of daily treatment sessions. While this therapy is sometimes successful at killing the cancer, it is not as effective as surgery and may seriously damage normal surrounding lung tissue.

Stereotactive body radiation therapy (SBRT) is a radiation treatment that gives fewer but higher doses of radiation than standard radiation. It uses special equipment to position the patient and guide focused beams toward the cancer and away from normal surrounding lung tissue. The higher dose of radiation with this technique is better at killing cancer cells with fewer side effects than standard radiation therapy, but has not been tested in metastases to the lungs. SBRT is used to treat metastases to the lung from many types of cancer but has not been used very often with patients who have metastatic disease to their lungs from sarcomas.

The purpose of this study is to test the possibility of SBRT to the lung for metastatic disease to the lung. We want to find out what effects (good and bad) SBRT 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 several doctors
- Evaluation of your ability to carry out daily activities
- A chest x-ray (and CT scan: see "Before radiation treatment begins" below)
- Optional: A PET scan of your body: A small amount of radioactive material is injected into a vein, and a scanner makes a detailed picture of areas inside the body (may be omitted if not covered by insurance)
- Tests of your lung function, only as clinically indicated
- For women who are able to have children, a urine pregnancy test
- QoL(FACT-L)

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 these tests and procedures that are part of regular cancer care.

Before radiation treatment begins:

- You will be asked questions about your health and hospitalization history. Answering these questions will take approximately 10 minutes.
- 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 lung with contrast injection. A 4-dimensional CT scan will be done which is used to assess the motion of the tumor during your breathing cycle. A CT scan is a study using x-rays to look at one part of your body. Contrast means that dye is injected into your vein to increase the differences between normal and abnormal tissue.

After the treatment planning session, you will receive a total of three to five radiation treatments to each tumor. You will have 1 to 3 treatments per week until your treatments are complete.

Before each radiation treatments:

You will have a physical examination to evaluate any side effects from treatment you may be having.

- Your ability to carry out daily activities will be evaluated.
- You may be given an anti-inflammatory medication (corticosteroid) before each treatment to decrease possible inflammation and/or swelling that the treatment may cause in the lung.
- 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.

You will need these tests and procedures in follow-up visits:

At 4 to 6 weeks after the completion of radiation treatment:

- You will have a physical examination to evaluate any side effects from treatment you may be having.

Every 6 months for 2 years:

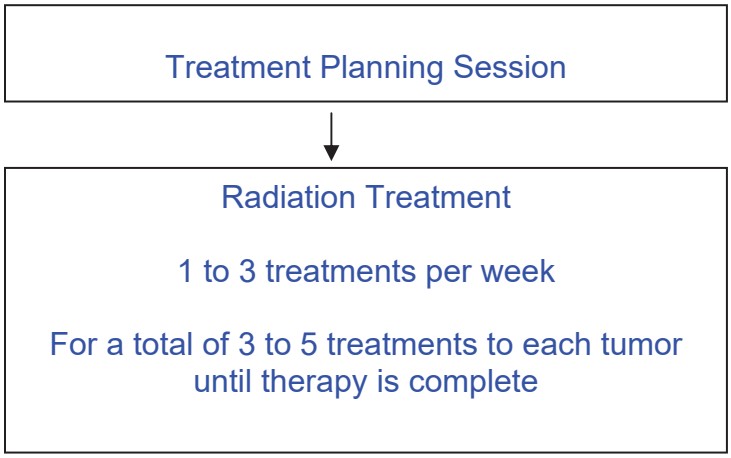
- Physical examination
- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having
- CT scan of your chest with contrast
- QoL(FACT-L)

If your study doctor recommends:

- A PET scan to check for recurrence of the cancer

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 SBRT is completed, the study doctor will ask you to visit the office for follow-up exams at 4-6 weeks from the completion of radiation treatment, every 6 months for 2 years. Therefore you will be in the study for approximately 3 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 risks from the SBRT.
⇒ So your doctor and you can 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 SBRT 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 STEREOTACTIC RADIATION THERAPY (SBRT) TO THE CHEST:

Very Likely

- Tiredness for no apparent reason, which is temporary
- Small amounts of "scarring" in the lung seen on CT scans that does not cause symptoms.

Less Likely

- Cough
- Irritation of the esophagus, which may result in heartburn or pain on swallowing
- The skin in the treatment area may become reddened and/or dry, and chest hair in the treatment area may fall out and may not grow back.
- Chest wall discomfort or pain
- Rib fracture, which may cause pain

Less Likely, But Serious

- Lung damage that leads to symptoms such as chest pain, shortness of breath, cough, or fever. Rarely, these symptoms can be severe or life threatening. Treatment for this lung damage involves pain medicines, anti-inflammatory medicines (corticosteroids), and rarely, oxygen therapy, which may be permanent. You should tell your doctors immediately if you have any of these symptoms.
- Eventual collapse of a portion of the treated lung. This collapse generally affects a limited portion of the lung, but the collapse appears to be permanent. Efforts will be made to reduce this risk and limit its effect. If collapse of a portion of the treated lung occurs, you will have shortness of breath at rest or during exercise, may need to receive oxygen, and/or may have chest wall pain. A few subjects may need oxygen therapy permanently. A collapse of a portion of the lung may be life threatening.
- Irritation of the lining around the heart, which can cause chest pain, shortness of breath, and irregular or rapid heartbeat; rarely, this can require surgery to correct.
- Irritation and/or damage to the muscle of the heart; rarely, this can cause a heart attack, heart failure, and/or death.
- Irritation and/or damage to the spinal cord (the major nerve within the spine), which can lead to weakness, tingling or numbness of the lower body and legs; very rarely, this can lead to inability to move or control the lower half of the body.
- Damage or scarring of nerves in the chest, which may result in a hoarse voice or a tingling “pins and needles” sensation, or pain in the chest and rib area, depending on the nerve affected
- Damage or scarring of nerves at the top of the lungs, which may result in a tingling “pins and needles” sensation or pain or weakness of the muscles of the arm and hand, since these nerves provide sensation and muscle control for the arm and hand
- Narrowing of the esophagus (tube to the stomach), which can result in swallowing difficulty
- Thinning of the wall of the esophagus; rarely, this can cause a hole in the esophagus and/or communication between the esophagus and airway
- Irritation of the large blood vessels surrounding the heart; rarely, this can cause bleeding (coughing up blood) and/or death.

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.

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

This study may or may not help you, but we hope that SBRT will 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 SBRT as a treatment for cancer. This information could help future cancer patients.

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

All 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. 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.

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

You will not be paid for taking part 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 without being in a study.
- Taking part in another study.
- Getting no treatment.

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

If we learn any important new information about SBRT 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 HARMED BECAUSE I TOOK PART IN THE STUDY?

No funds have been set aside to pay any costs if you become ill or are harmed because of this study. If you think that you have become ill or were harmed because of this study, let the study doctors know right away by calling 414-805-4400. By signing this form, you do not give up your right to seek payment for harm you receive while participating in this study.

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.
- 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:

- ⇨ Hospital/Medical Records
- ⇨ Physician/Clinical Records
- ⇨ Lab and/or Pathology Records
- ⇨ Radiology Reports

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.

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.

A Data 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.

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* (for short form consent process, or consent of blind or illiterate subject)	**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 research study protocols the Principal Investigator is responsible and accountable for the study.*