

The Ohio State University Consent to Participate in Research

Study Title: Feasibility of Assessing Radiation Response with MRI/CT Directed Preoperative Accelerated Partial Breast Irradiation in the Prone Position for Hormone Responsive Early Stage Breast Cancer

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Sponsor: Susan G. Komen for the Cure

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. The National Cancer Institute (NCI) booklet, "Taking Part in Clinical Trials: What Cancer Patients Need To Know," is available from your doctor.

You are being asked to take part in this study because you have breast cancer and are planning to receive breast radiotherapy.

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the 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 usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You will not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

You are being asked to participate in this study because you have early stage breast cancer and are undergoing breast radiation. .

This is a pilot study that aims to establish the feasibility of using a specific method of imaging for radiation planning. Advances in radiation technology have rapidly improved breast cancer treatment over the last decade, reducing both the length of treatment and the size of the area that must be treated. While radiation of the whole breast was previously the typical treatment choice after lumpectomy, recent research supports the use of accelerated partial breast irradiation (APBI) as an equally effective method of treating early stage breast cancer. APBI is an approach that reduces the area of breast tissue receiving radiation by only targeting the area around where the tumor was removed, rather than treating the entire breast. As a result, patients experience fewer side effects with APBI than with whole breast radiation. APBI also shortens the length of treatment, while still maintaining the same low rates of recurrence and survival as whole breast radiation.

Accelerated partial breast irradiation (APBI) is currently delivered after surgery. However, there have been two recent research studies that have treated patients with APBI *before* surgery i.e. *pre-operatively*. In these studies, magnetic resonance imaging (MRI: a way to visualize the tumor) of the breast was used to guide radiation treatment by providing more precise identification of the tumor. Scientists believe that this approach can help to increase the accuracy in targeting the breast tumor with radiation, potentially further reducing the chance of the cancer coming back and reducing the amount of breast tissue that is irradiated. Additionally, the preliminary results from the APBI approach before surgery have also had better cosmetic outcomes (the appearance of the breast) for patients than radiation after surgery.

The two studies that have tested APBI treatment before surgery have both performed the MRI (imaging) with the patient lying face-down and the radiation with the patient face-up. The investigators of this study believe that it will be easier to target the radiation to the correct location around the tumor if patients are in the same position (face-down/prone) for both the imaging and the radiation.

The purpose of this study is to test the safety and feasibility of imaging your early stage breast cancer with MRI and CT scan in the prone position. Only images from MRI and CT scan will be used for the research. No follow up visit is required.

2. How many people will take part in this study?

A total of 33 participants will take part in this study, which consists of 3 participants for optimizing the imaging method (Cohort 1), and 30 participants in the treatment (Cohort 2).

3. What will happen if I take part in this study?

Before you begin the study:

You will not need any additional tests or exam outside of regular cancer care.

- Discussion with your provider about toxicity (side effects) related to MRI and CT scan

During the study:

If you qualify for the study and choose to participate, you will undergo the procedures described below. CT scan would be performed to simulate the steps of radiation planning even if you are not receiving radiation as part of the research study.

- Breast computed tomography (CT) simulation in prone position (face down): a way to image the tumor and normal tissues for the planning radiation treatment
- Breast MRI (magnetic resonance imaging) in prone position (face down): a way to image the tumor

4. How long will I be in the study?

Ideally you will undergo MRI and CT scan on the same day. You may need to come back to hospital for one more day within 30 days of either MRI or CT scan in case both procedures cannot be scheduled on the same day. There is no follow up visit required.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You may have side effects while on the study. Most of these are listed here, but there may be other side effects that we cannot predict. Side effects will vary from person to person.

Everyone taking part in the study will be watched carefully for any side effects. However, doctors do not 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. 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.

Prone positioning is similar to the standard of care for breast radiation, and does not pose additional risks or side effects.

Risks related to Computed Tomography (CT):

You will get a small amount of radiation.

Risks related to Magnetic Resonance Imaging (MRI):

There are no known harmful side-effects associated with temporary exposure to the strong magnetic field used by MRI scanners. Patients with claustrophobia may have difficulty tolerating the MRI scanner. If you feel too confined in the MRI scanner, you can inform the technologist and the MRI scan will be stopped. We will ask you about metal within your body as the magnet could attract certain kinds of metal that may cause injury to you. Patients with metal objects in their bodies may be excluded from MRI scanning. The MRI machine makes loud knocking sounds when it is scanning. Because of this, you will be given earplugs and/or headphones to wear while getting your MRI examinations. This helps minimize discomfort from noise and keep the MRI noise within the safety range. If a contrast agent is used, there is a slight risk of an allergic reaction. MRI contrast agents can cause problems in patients with significant kidney disease.

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

7. What benefits can I expect from being in the study?

Taking part in this study will not make your health better. The information from the images will help doctors test the feasibility, and optimize the imaging/planning of radiation treatment using MRI and CT scan in the prone position. Doctors hope to use the optimized imaging method for the accelerated partial breast irradiation (APBI) before lumpectomy. Doctors hope that the treatment will help target the tumor cells and prevent cancer from coming back, reduce the side effects of radiation therapy, and to improve cosmetic appearance of the breast after radiation. However, there is no proof of this yet. This information could help future breast cancer patients.

8. What other choices do I have if I do not take part in the study?

Your other choices may include:

- Getting treatment or care for your cancer without being in this study
- Taking part in another study
- Getting no treatment

Talk to your study doctor about your options before you decide to participate in this study.

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. 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.

Costs that are considered standard of care (procedures or tests that you would receive whether or not you were participating in a research study) will be billed to you or your insurance company. For example, the breast CT scan will be billed to you/your insurance plan. You will be responsible for meeting copayment/ coinsurance and deductible requirements by your insurance plan while on study.

Those costs that are performed solely for the purpose of research will be paid by the sponsor of this study. For example, the study required breast MRI will not be billed to you/your insurance.

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.

11. Will I be paid for taking part in this study?

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

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

If you are injured as a result of your participation in this study, you may obtain immediate care at The Ohio State University Medical Center. The cost of this treatment will be charged to you or your insurance company. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study. The Ohio State University has no funding set aside for the payment of health care expenses for this study.

By signing this consent form, you will not be waiving any of the legal rights which you otherwise would have as a subject in a research study.

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

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact ***Dr. Sasha Beyer at (614) 293-3255.***

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***Dr. Sasha Beyer at (614) 293-3255.***

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____ Printed name of subject	_____ Signature of subject
	_____ Date and time
	AM/PM
_____ Printed name of person authorized to consent for subject (when applicable)	_____ Signature of person authorized to consent for subject (when applicable)
_____ Relationship to the subject	_____ Date and time
	AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____ Printed name of person obtaining consent	_____ Signature of person obtaining consent
	_____ Date and time
	AM/PM

Witness(es) - May be left blank if not required by the IRB

_____ Printed name of witness	_____ Signature of witness
	_____ Date and time
	AM/PM
_____ Printed name of witness	_____ Signature of witness
	_____ Date and time
	AM/PM