Consent and Authorization Document

NOVEMBER (Novem- (9), BrEast Radiation), A Phase II Trial of a 9 Day Course of Whole Breast Radiotherapy for Early Stage Breast Cancer.

BACKGROUND

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

Once you know about the study, you will make a decision about whether to take part. If you decide to take part, you'll be asked to sign this form. Your decision to take part in this study is voluntary which means you are free to decide to join this study or not to join this study.

Why is this study being done?

You are being asked to take part in this study because you have had breast conserving surgery (lumpectomy) for breast cancer. Studies have shown that giving radiation therapy to the breast after lumpectomy helps keep cancer from coming back in the breast. Conventional radiation therapy is typically given daily for 5 to 7 weeks. However, recent studies have also shown that the chance of cancer returning in the breast can be the same with a higher daily dose of radiation given to the whole breast in a fewer number of treatments, reducing the number of weeks required for therapy.

In this study, you will be given radiation therapy at a higher daily dose than what would be given for conventional radiation therapy, and it will be given for a shorter period of time.

Shortening the treatment length to two weeks could be more convenient and save time and money. It is not known, but it is hoped, that the higher daily dose of radiation to the breast has the same chance or better of preventing the breast cancer returning, be cost effective, and have the same or better patient satisfaction and cosmetic results compared to standard daily doses of radiation. This study will also help researchers learn about how the study treatment affects your quality of life and the feelings you have about how your breast looks after radiation therapy. Quality of life is your physical and emotional well-being; you will be given a questionnaire to assess your quality of life.

The study is being conducted by Dr. Matthew Poppe at Huntsman Cancer Institute of the University of Utah.

NUMBER OF PARTICIPANTS

Approximately 102 patients are expected to be enrolled in this study from the Huntsman Cancer Institute/University of Utah.

STUDY TREATMENTS

Once it is decided that you are able to enroll into this study, you will begin study treatment. Within 12 weeks after your last breast conserving surgery (lumpectomy), you will receive radiation therapy to the breast and the area of the lumpectomy. Radiation therapy treatment will be given for 9 days over a two-week period.

STUDY PROCEDURES

If you decide you will take part in the study and you sign this informed consent form, you will have some screening tests and procedures done to make sure you are eligible to enroll.

Screening Period

- Medical history and physical exam, including breast exam
- An evaluation of your ability to perform everyday activities (performance status)
- If you are female with the potential of becoming pregnant, you will have a pregnancy test

Treatment Period

If the exams, tests and procedures show that you can be in the study and you choose to take part you will be enrolled and start radiation therapy. This radiation is considered standard of care and would be done even if you were not participating in this study.

Before you begin radiation, you will have the following procedures done:

- You will complete questionnaires that ask you some questions about your quality of life and about your breasts and your cancer treatments.
- Photographic cosmetic assessment. The study doctors want to know how the radiation treatment affects the physical appearance of the breast. This will be done by taking photographs of both breasts before you begin treatment and again 24 months after treatment. The photographs will be taken from the neck down and will not include your face.
- You will have a CT (Computerized Tomography) scan of the breast that had the cancer to help plan the radiation therapy. This scan is considered standard of care and would be done even if not participating in this study.

Once you begin radiation therapy on study, you will do the following every week:

- Physical exam if necessary
- An evaluation of your ability to perform everyday activities (performance status)
- Evaluation of any side effects
- You will also be asked to complete a diary about your health care expenses. This is optional.

Follow-up

- 2-8 weeks after completing radiation therapy:
    - Physical exam if necessary
    - Evaluations of your ability to perform everyday activities (performance status)
    - Evaluation of any side effects
    - You will complete a questionnaire (Health Care Expense Survey) that asks you some questions about your work status and costs of treatment (to help determine cost effectiveness).
    - You will complete questionnaires that ask you some questions about your quality of life and about your breasts and your cancer treatments.
- 6 months after completing radiation therapy:
    - Physical exam if necessary
    - Evaluations of your ability to perform everyday activities (performance status)
    - Evaluation of any side effects
    - Quality of life and breast questionnaire
- Then at years 1, 2 and 3:
    - Physical exam if necessary
    - Evaluations of your ability to perform everyday activities (performance status)
    - Evaluation of any side effects
    - Quality of life and breast questionnaire (year 2 only)
    - Photographic cosmetic assessment (year 2 only)

How long will I be in the study?

You will be in the study for up to 5 years. The radiation therapy will take approximately 2 weeks to complete. Follow-up visits will be scheduled around 1 month, then 6 months, and then yearly from the end of radiation therapy. After 3 years, you will have completed the study visits; however, the study doctor will continue to review your medical record to check the status of your disease for up to 5 years.

RISKS

Risks and side effects related to radiation therapy:

Likely

These side effects occur in 10% or more of patients:

- Reddening of the skin during treatment and for several weeks following treatment
- Tanning of the skin lasting months and may be permanent
- Slightly smaller breast size or change in the way the breast looks
- Mild thickening or firming of the breast on touch
- Tiredness and weakness during treatment and for several weeks following treatment
- Swelling of breast
- Peeling of the skin in the area treated with radiation

- Mild pain at the site of radiation treatment requiring over the counter pain relievers

Less likely
These side effects occur in 3–9% patients:

- Soreness or tightness in muscles of the chest wall under the treated breast
- Severe pain at the site of radiation treatment requiring prescription pain relievers
- Prominent thickening or firming of the breast on touch

Rare but serious
These side effects are rare but serious, occurring in less than 3% of patients:

- Cough
- Difficulty breathing
- Inflammation of the heart muscle
- Increased risk for heart disease for patients with cancer in the left breast
- Rib fracture
- Risk of developing another cancer

REPRODUCTIVE RISKS
Women who are pregnant or nursing may not take part in this study. Check with your study doctor about what kind of birth control methods to use. Some methods might not be approved for use in this study. If you suspect that you have become pregnant during the trial, you must notify the study doctor immediately.

Examples of medically acceptable birth control include oral or injectable hormonal contraceptives, medically prescribed IUDs, and double barrier methods, e.g., condom in combination with spermicide.

If you become pregnant, you will be withdrawn from the study and your pregnancy may be followed.

Other Risks and Inconveniences
There are also non-physical risks associated with taking part in this study, such as the risks associated with a breach of privacy or confidentiality. The risks of such improper disclosure are very small because Huntsman Cancer Institute has adopted strict privacy and confidentiality procedures for this research.

UNFORESEEABLE RISKS
In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS
There may not be any benefit to you from your being in the study. The information gained in this study will aid in the understanding of cancer and help in the development of new approaches to its treatment in the future.

ALTERNATIVE PROCEDURES
You may choose not to take part in this study and discuss other treatment options and their related benefits and risks with your study doctor.

Some other things you might do are:

- Use other approved radiation regimens.
- Use other investigational treatments.
- Get supportive care.
- Choose to have no further treatment.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, you can contact Dr. Poppe at 801-585-0255. If you think you may have been injured from being in this study, please call Dr. Poppe at 801-585-0255. The University Hospital Operator can be reached at this number: 801-581-2121 available 24-hours a day. Please ask for the oncologist on call.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY
If you are injured from being in this study, medical care is available to you at the University of Utah, as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. You may decide not to take part or you may leave the study at any time. Refusal to take part or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled.

Tell the study doctor if you are thinking about stopping or decide to stop, as it may be necessary to do certain tests in order to ensure your safety. If you choose not to return for an assessment, we may ask for medical records from your current general practitioner in order to continue to monitor your health.

If you decide not to continue in the study at any time, your study doctor will arrange for you to receive alternative treatment and any necessary assessments or procedures according to standard of care.

RIGHT OF INVESTIGATOR TO WITHDRAW

Your study doctor may decide to take you off this study at any time without your consent for any of the following reasons:

- if your disease becomes worse and is not responding to the study treatment,
- if he or she believes it is in your best interest,
- if you do not follow the study rules,
- if you miss study visits and/or procedures,
- if you have serious side effects,
- if you become pregnant

There is also the possibility that the investigator, may close the study before your participation is complete and without prior warning. If any of these events were to happen, your study doctor would assist with arrangements for your continued care as appropriate.

COSTS AND COMPENSATION TO PARTICIPANTS

Some of the procedures and treatments you'll have while you are on the study are considered "standard of care" for your type of illness. Even though you will be a part of the study, these types of procedures and treatments will be billed to you and/or your insurance company just like regular medical care. Some procedures and treatments you'll have while you are on the study are considered "study related" and are not billed to you and your insurance company. You should ask your study coordinator and treating physician for details about the specific procedures you or your insurance company will be financially responsible for.

You may be eligible to receive assistance for costs associated with travel. Please speak with your study coordinator or physician for details. If eligible, you may be asked to provide receipts in order to receive reimbursement. It will be necessary for us to collect your Social Security Number for your reimbursement. You will need to provide this information on a Federal W-9 Form that is filed with our accounts payable department. No other information (e.g. the name of this study) will be provided to that office. This amount may be reported to the Internal Revenue Service (IRS).

NEW INFORMATION
You will be given any new information about the study drugs that may affect your willingness to start or continue in the study as it becomes available.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and other working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like your name, address, telephone number, and email address.
- Related medical information about you like family medical history, allergies, current and past medications or therapies, information from physical examinations such as blood pressure readings, heart rate, temperature, and lab results.
- All tests and procedures that will be done in the study

How we will protect and share your information:
We will do everything we can to keep you information private, but we cannot guarantee this. The research records will be kept in a secured manner and computer records will be password protected. We may need to disclose information about you as required by law.

Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital.

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.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

- Members of the research team and University of Utah Health Sciences Center
- The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
- Government agencies responsible to confirm research accuracy such as the United States Food and Drug Administration (FDA), and the National Cancer Institute (NCI) which is a part of the National Institute of Health (NIH)

If we share your identifying information with groups outside of the University of Utah Health Sciences Center, the groups may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

During your screening visit and following radiation therapy, photographs (digital images) will be taken of your breasts to document the physical appearance of the breast. If you have a tattoo(s), your tattoo(s) may be included and visible in the photographs (digital images). Tattoos may be considered unique and identifiable, so the photographs (digital images) of your tattoo(s) may identify you in pictures. However, the photographs will be taken from the neck down and will not include your face.

What if I Decide Not to Take part After I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____ _____
Participant's Signature Date Time

_____
Name of Person Obtaining Authorization and Consent

_____ _____ _____
Signature of Person Obtaining Authorization and Consent Date Time

LANGUAGE INTERPRETER STATEMENT (if applicable):

I confirm that I was present as an interpreter for the duration of the consent process for this research study. I confirm that I am qualified/have the necessary skills to provide interpretation between [insert target language] _____ and English. By signing this form, I confirm that I provided a full and complete interpretation of the exchange between the research staff member named above and the patient named above, to the best of my ability.

Name of Interpreter_____ Employer/Vendor (if applicable) _____

_____ _____ _____
Signature of Interpreter Date/Time Target Language

Information requested for federal grant reporting purposes *(optional)*

Sex/Gender

- ❑ **Male**
- ❑ **Female**

Ethnicity

Do you consider yourself to be Hispanic or Latino? (see definition below)

Hispanic or Latino. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race.

Select one:

- ❑ **Hispanic or Latino**
- ❑ **Not Hispanic or Latino**

Race

What race do you consider yourself to be?
SELECT ONE OR MORE OF THE FOLLOWING:

- ❑ **American Indian or Alaska Native.** A person having origins in any of the original peoples of North America (including, Central or South America) who maintains cultural identification through tribal affiliation or community recognition.
- ❑ **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- ❑ **Black or African American.** A person having origins in any of the black racial groups of Africa.
- ❑ **Native Hawaiian or other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- ❑ **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
- ❑ **Unknown.**

❑ **Check here if you do not wish to provide some or all of the above information.**