CONSENT FORM

QUALITY OF LIFE STUDY

RTOG 0413

TITLE OF RESEARCH: A RANDOMIZED PHASE III STUDY OF CONVENTIONAL WHOLE BREAST IRRADIATION (WBI) VERSUS PARTIAL BREAST IRRADIATION (PBI) FOR WOMEN WITH STAGE 0, I, or II BREAST CANCER

SPONSOR: National Surgical Adjuvant Breast and Bowel Project (NSABP) & Radiation Therapy Oncology Group (RTOG)

INVESTIGATOR: Ruby F. Meredith, MD, PhD

CO-INVESTIGATORS: Sharon Spencer, Jennifer De Los Santos, MD; Helen Krontiras, MD

You may be asked to participate in a quality of life and cosmesis 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. In addition, it looks at cosmesis which is about how satisfied you are with the appearance of your breast after your surgery and radiation therapy. Your doctor will also fill out questionnaires that ask for a medical opinion of the appearance of your breasts after completion of your therapy. You will be asked to complete 7 questionnaires that will take about 15-20 minutes each to fill out: one before you join the study; the timing of the next 3 questionnaires will depend on whether or not you receive chemotherapy; and the last 3 will be at 1 year, 2 years, and at 3 years after completing your therapy. If any questions make you feel uncomfortable, you may skip those questions and not give an answer.
If you are a participant in the QOL and cosmesis study, your doctor will also fill out questionnaires that ask for a medical opinion of the appearance of your breasts after completion of your therapy. Also, photographs of your breasts will be taken when you start the study and 1 year and 3 years after you are done receiving your therapy. The photographs will only include your breasts. Your face will not be in the photos and your name and other personal information will not be given out. These photos will be checked only by doctors who are the doctors in charge of this study, and who are experts in radiation therapy. The photos will only be checked for the purposes of this study. The doctors’ opinions about the appearance of your breast after study therapy will be compared to your opinion.

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

You may change your mind about completing the questionnaires or having the photos taken of your breasts at any time. It will not affect your taking part in the main study.

**Please Initial by your answer.**

I choose to take part in the quality of life and cosmesis study. I agree to fill out the 7 quality of life questionnaires and to have 3 sets of photos taken of my breasts.

YES ______  NO ______

**LEGAL RIGHTS**

You are not waiving any of your legal rights by signing this consent form.

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SIGNATURES

You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer to take part in this study and that you have read or had read to you all the information on this form. You will be given a signed copy of this form.

Signature of Participant or Legally Authorized Representative

Date

Signature of Physician or Investigator

Date

Signature of Witness

Date

Signature of Person Obtaining Consent (If other than Principal Investigator)

Date

Amendment 1

Participant's Initials: ________
University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION
FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant name: ____________________________
Research Protocol: A Randomized Phase II Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer
UAB IRB Protocol Number: F050513003
Principal Investigator: Ruby F. Meredith, MD, PhD
Sponsor: Radiation Therapy Oncology Group

What health information do the researchers want to use? All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, The Children's Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: ____________________________ Date:__________
or participants’ legally authorized representative: ____________________________ Date:__________
Printed Name of participant’s representative: ____________________________
Relationship to the participant: ____________________________

Amendment 1