**NRG ONCOLOGY**
**Radiation Therapy Oncology Group**

**RTOG 1005**

***(ClinicalTrials.gov NCT #:* 01349322*)***

# A PHASE III TRIAL OF ACCELERATED WHOLE BREAST IRRADIATION WITH HYPOFRACTIONATION PLUS CONCURRENT BOOST VERSUS STANDARD WHOLE BREAST IRRADIATION PLUS SEQUENTIAL BOOST FOR EARLY-STAGE BREAST CANCER

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Sample consent form version: July 31, 2014
To be attached to protocol version: December 16, 2021

# RTOG 1005

## Informed Consent Template for Cancer Treatment Trials
## (English Language)

## A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation Plus Concurrent Boost Versus Standard Whole Breast Irradiation Plus Sequential Boost for Early-Stage Breast Cancer

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have breast cancer and underwent a lumpectomy to remove the cancer and have been recommended by your doctor to have radiation therapy to the breast.

## Why is this study being done?

Studies have shown that giving radiation therapy to the breast after lumpectomy helps keep cancer from coming back in the breast. However, this radiation therapy is commonly given to the entire breast on a Monday through Friday basis for 5 weeks. In addition, studies have shown that for many women giving a higher dose of radiation to the area of the lumpectomy, also known as a “boost”, helps further lower the risk of cancer coming back in the breast. However, this adds another 1 to 1 ½ weeks of treatment so that the total time needed for radiation treatment commonly requires up to six to seven weeks for a women to complete.

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 over only three weeks. This has the potential for shortening the number of days a woman is required to undergo radiation. These studies did not determine whether a boost may also be given at the same time at this more accelerated radiation schedule.

The purpose of this study is to compare radiation therapy given with a higher daily dose over 3 weeks with a boost given each day of radiation therapy compared with standard whole breast radiation followed by a boost given on separate days which extends over 6 to 6 ½ weeks. It is not expected that there would be a difference in survival by changing the number of daily treatments and shortening the length of time needed for treatment. However, shortening treatment length 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 compared to standard daily doses of radiation.

In this study, you will get either a standard daily dose of radiation therapy to the whole breast followed by additional radiation to only the area of the surgical cavity (boost) using the same standard daily dose of radiation OR a higher daily dose to the whole breast and to the boost on the same days but in a shorter overall number of daily treatments. You will not get both.

## How many people will take part in the study?

About 2312 people will take part in this study

## What will happen if I take part in this research study?

Within 9 weeks after your last breast conserving surgery or chemotherapy, you will receive radiation therapy to the breast and the area of the lumpectomy alone on a Monday through Friday basis. A daily radiation therapy treatment will take approximately 10 – 15 minutes. The total length of time for which you will receive radiation therapy will depend upon which arm you are placed into. You should be able to do most or all of your daily activities between treatments. Radiation does not stay in your body between treatments or after the final treatment.

## Before you begin the study … (5/6/13)

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.

- History and physical exam that includes a breast exam and record of your weight
- Blood tests (a few teaspoons)
- Pregnancy test (blood or urine) for women of childbearing potential
- Bone scan, bone x-rays, or other bone tests as indicated by your study doctor
- CT scan of your chest, abdomen and pelvis or PET/CT as indicated by your study doctor
- Mammogram
- Lumpectomy
- Surgery on the axillary lymph nodes if indicated by your doctor
- CT scan of the breast that had the cancer to help plan the radiation therapy
- Chemotherapy if your doctor decides it is necessary to treat your breast cancer. Chemotherapy if needed will be given either before or after surgery, or before radiation as determined by your team of doctors. Chemotherapy will not be given during radiation.
- Hormonal therapy if your doctor decides it is necessary to treat your breast cancer. Hormonal therapy may be given before, during or after radiation.

## During the study … (5/11/12)

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

- A weekly visit with your study doctor. This visit includes a breast assessment, a history and physical. It also includes an evaluation of any side effects from treatment you may have to determine how you are tolerating the treatment and what side effects you are having.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

*If you are in group 1 (often called "Arm A")* you will have radiation therapy once a day to the whole breast. This can be given over a period of 3-5 weeks as determined by your doctor. Then you will have radiation therapy to the area of the lumpectomy alone for an additional 1 to 1 ½ weeks as determined by your doctor. This is a total of 4 to 6 ½ weeks.

*If you are in group 2 (often called "Arm B")* you will have a higher daily dose of radiation therapy once a day to the whole breast, and a higher daily dose of radiation to the area of the lumpectomy during the same daily treatment, over a period of 3 weeks.

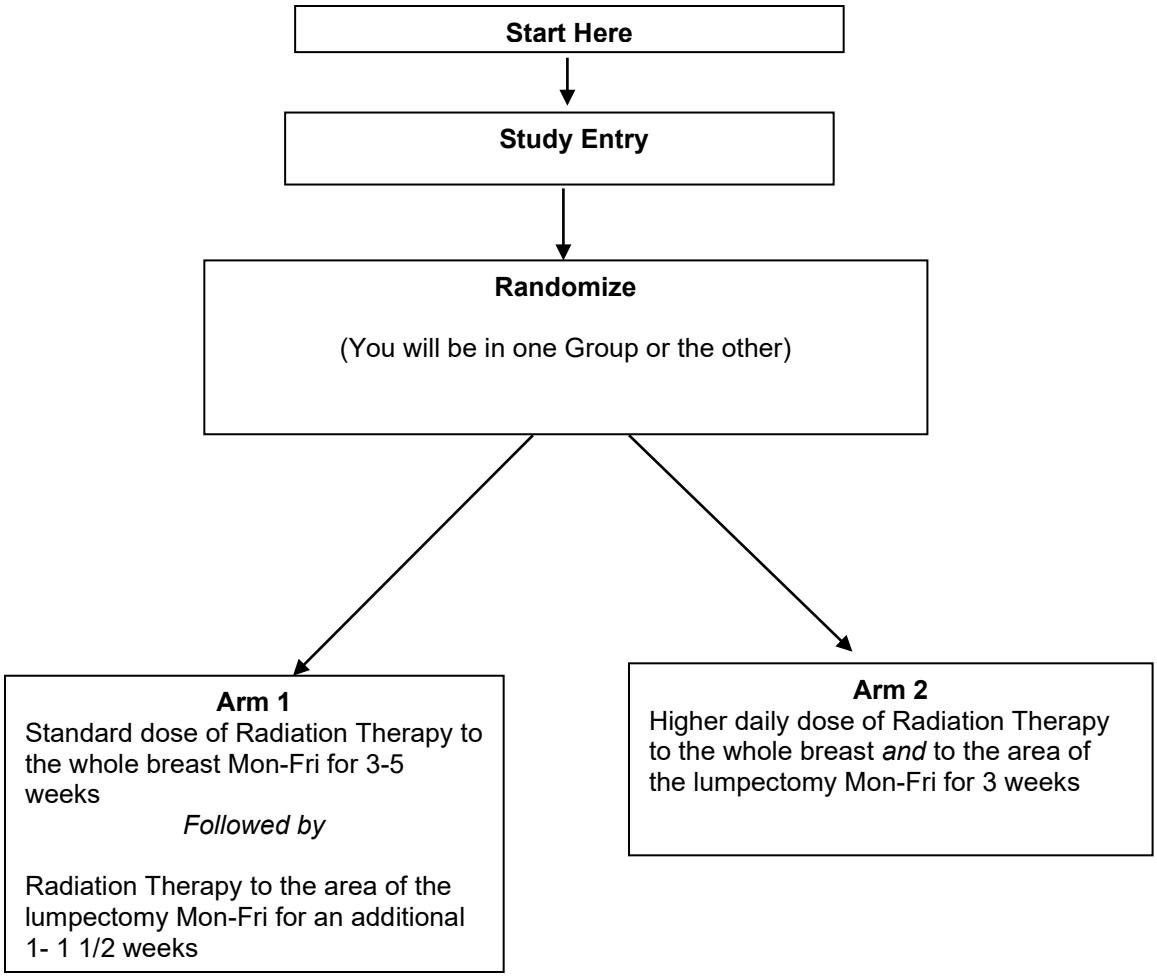
## During Follow up…

When you are finished receiving all treatment, you will have the following tests and procedures. Most are a part of regular cancer care unless otherwise indicated.

- A visit with your study doctor. This visit will be scheduled approximately 1 month, 6 months, and then every year from the end of radiation. This visit includes a history, physical and breast exam and evaluation of any side effects from treatment you may be having. Blood tests, CT scans, and X-rays may be ordered if indicated by your study doctor.
- Mammogram. This will be scheduled approximately 6 months, 1 year, and then every year from the end of radiation

## 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.



## How long will I be in the study?

The radiation therapy will take approximately 3 weeks to 6 ½ weeks to complete depending upon which group you are placed into. Follow-up visits will be scheduled at 1 month, then 6 months and then yearly from the end of radiation therapy. You should continue yearly mammograms for the rest of your life. We would like to keep track of your medical condition for the rest of your life. Keeping in touch with you and checking on your condition yearly helps us to look at the long-term effects of the study.

## Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the treatment can be evaluated by him/her. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

## What side effects or risks can I expect from being in 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 you stop radiation**.** 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.**

**Risks and side effects related with Radiation Therapy to the Breast:**

**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
- Tiredness and weakness during treatment and for several weeks following treatment
- Swelling of the 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%** of patients):*

- Soreness or tightness in muscles of the chest wall under the treated breast
- Severe pain at the site of radiation requiring prescription pain relievers

**Rare but serious** (*these side effects occur in less than **3%** of patients):*

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

Reproductive risks: You should not become pregnant while on this study because the radiation therapy in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. If you are a woman able to have children and have not been surgically sterilized (tubal ligation or hysterectomy), you should have a pregnancy test before enrolling in this study. You should not become pregnant 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. If you should become pregnant while you are on this study, you must tell your study doctor immediately. Ask about counseling and more information about preventing pregnancy.

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

## Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While researchers hope that this method of administering radiation therapy over 3 weeks will be as useful against cancer compared to the usual treatment given over a longer period of time, there is no proof of this yet. We do know that the information from this study will help researchers learn more about using larger daily doses of radiation therapy for fewer treatments in a shorter period of time as a treatment for cancer. This information could help future cancer patients.

## What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting radiation therapy treatment for your cancer without being in a study
- Taking part in another study
- Getting no treatment

**Talk to your study doctor about your choices before you decide if you will take part in this study.**

Will my medical information be kept private? (4/4/14)

Data are housed at NRG Oncology Statistics and Data Management Center in a password-protected database. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Your Institutional Review Board (IRB), a group of people who review the research study to protect your rights
- NRG Oncology
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials

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.

*[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local institutional policy.]*

## What are the costs of taking part in this study? (5/6/13)

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.

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

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

It is important that you tell your study doctor, _____ *[investigator's name(s)],* if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him/her at _____ *[telephone number].*

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this 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 regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

A Data Monitoring Committee (DMC) will be regularly meeting to monitor safety and other data related to this study. The Committee 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.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

## Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* at _____ *[telephone number].*

For questions about your rights while taking part in this study, call the _____ *[name of center]* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *(telephone number). [Note to Local Investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*

***You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).** *[*Only applies to sites using the CIRB.]*

**Please note: This section of the informed consent form is about additional research that is being done with people who are taking part in the main study. You may take part in this additional research if you want to. You can still be a part of the main study even if you say 'no' to taking part in this additional research.**

**You can say "yes" or "no" to each of the following studies. Below, please mark your choice [for each study].**

## Cosmesis/Quality of Life Study (1/9/14)

***NOTE**: Non-chemotherapy Cosmesis subset closed to accrual 3/8/13; chemotherapy Cosmesis subset closed to accrual 1/9/14*

We want to know your opinion about the cosmetic outcome following the treatment of your breast and your view of how your life has been affected by cancer and its treatment. This study will allow us to gather information from you and your study doctors about how your breast looks and feels after treatment, how satisfied you are with the appearance of your breast after your surgery and radiation therapy, and how you are able to carry out your day-to-day activities.

You will be asked to complete a questionnaire which includes a series of 22 questions and will take about 15-20 minutes to fill out at 7 study visits: once after your surgery but before you begin radiation therapy, once at the end of radiation therapy, one 1 month later, one 6 months later, and then one every year for 3 years.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, your study doctor will also fill out questionnaires that ask for a medical opinion of the appearance of your breasts before and after completion of your therapy. They will be completed at 3 study visits: once after your surgery but before you begin radiation therapy, once 1 year after the end of your radiation therapy, and once 3 years after the end of your radiation therapy. Also, photographs of your breasts will be taken during these same visits. 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 the doctors in charge of this study. The study doctors' opinions about the appearance of your breast will be compared to your opinion.

This information will help doctors better understand how patients feel during treatments 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.

Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please circle your answer.

I choose to take part in the Cosmesis/Quality of Life Study. I agree to fill out the seven Cosmesis/Quality of Life Questionnaires.

YES NO

## Consent Form for Use of Tissue for Research

## About Using Tissue and Blood for Research (5/11/12)

You have had surgery for the treatment of your cancer. Your doctor has removed some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue that is left over for future research. In addition, we would like to collect 3 teaspoons of blood for research before you start treatment. If you agree, your tissue and blood will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research. This information sheet is available at: http://cdp.cancer.gov/humanSpecimens/ethical_collection/patient.htm
Your tissue and blood may be helpful for research whether you do or do not have cancer. The research that may be done with your tissue is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your tissue and blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

## Things to Think About

The choice to let us keep the tissue and blood for future research is up to you. No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

If you decide now that your tissue and blood can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue and blood. Then any tissue and blood that remains will no longer be used for research and will be returned to the institution that submitted it.

In the future, people who do research may need to know more about your health. While the doctor or institution may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes tissue and blood is used for genetic research (about diseases that are passed on in families). Even if your tissue and blood is used for this kind of research, the results will not be put in your health records.
Your tissue and blood will be used only for research and will not be sold. The research done with your tissue and blood may help to develop new treatments for cancer in the future.

## Benefits

The benefits of research using tissue and blood include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

## Risks (4/4/14)

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included. The samples are given a code to protect your privacy before they are used. Any related information given to researchers will also be coded. Researchers will receive the code instead of any information that might directly identify you.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives.

Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information.

Many states have laws to protect against genetic discrimination [*list appropriate state information if your state has such laws]*. Additionally, a new federal law called the Genetic Information Non-Discrimination Act, or GINA is in effect. This law prohibits health insurer or employer discrimination. The law does not include other types of misuse by life insurance, disability, or long term care insurance. To learn more about the GINA Law, please ask *[Note to local investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*

## Making Your Choice

*Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at _____ [IRB's phone number].*

*No matter what you decide to do, it will not affect your care.*

1. *My specimens may be kept for use in research to learn about, prevent, or treat cancer, as follows:*
   - *Tissue ☐Yes ☐ No*
   - *Blood ☐Yes ☐ No*

2. *My specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease), as follows:*
   - *Tissue ☐Yes ☐ No*
   - *Blood ☐Yes ☐ No*

3. *Someone may contact me in the future to ask me to take part in more research.*
   *☐Yes ☐ No*

## Where can I get more information?

**You may call the National Cancer Institute's Cancer Information Service at:**

**1-800-4-CANCER (1-800-422-6237)**

**You may also visit the NCI Web site at http://cancer.gov/**

- **For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/**
- **For NCI's general information about cancer, go to http://www.cancer.gov/cancertopics/**

**You will get a copy of this form. If you want more information about this study, ask your study doctor.**

## Signature

**I have been given a copy of all _____** *[insert total of number of pages]* **pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.**

**Participant _____**

**Date _____**