

CONSENT (PRE-ENTRY CENTRAL HER2 TESTING)

**Consent Form
for**

**HER2 Testing to Determine Eligibility for NSABP B-43 - A Phase III Clinical Trial
Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation
Therapy Alone for Women with HER2-Positive
Ductal Carcinoma In Situ Resected by Lumpectomy**

Sponsor: National Surgical Adjuvant Breast and Bowel Project
(NSABP)

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**CIRB
APPROVED**

Amend 4 8/5/11

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(386) 254-4213 (Business Hours)

Participant's Initials: _____

Liberty IRB Approved 3/18/10
Liberty IRB Approved 4/15/10, Rev. 1
Liberty IRB Approved 9/09/10, Rev. 2
Liberty IRB Approved 12/23/10, Rev. 3
Liberty IRB Approved 7/28/11, Rev. 4
Liberty IRB Approved 8/25/11, Rev. 5

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You are being asked to have a test on your breast cancer tumor to find out if it is a type of cancer called "HER2-positive." HER2-positive means that the cancer makes too much of a protein called HER2. Too much of this protein can cause normal cells to receive extra growth signals. This can turn a normal cell into a cancer cell and can make cancer cells grow faster. The purpose of this HER2 testing is to find out if you may be eligible to take part in a clinical research study called B-43. This testing includes only people who choose to take part. Please take your time to make your decision about having the testing done. 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 doctor for more explanation.

Who is conducting the HER2 testing?

The HER2 testing will be done by Rush University Medical Center on behalf of the NSABP. The National Surgical Adjuvant Breast and Bowel Project (NSABP) is conducting the B-43 treatment study.

Why is this HER2 testing being done?

You are being asked to have the HER2 testing done for the B-43 study because you have a very early stage of breast cancer called ductal carcinoma in situ (DCIS). DCIS is also known as intraductal or non-invasive breast cancer. DCIS means that the cancer cells are only in the milk ducts in the breast and have not spread to other breast tissue or to other parts of the body.

The B-43 treatment study is a clinical trial, which is a research study. The B-43 study is being done to find out if adding a drug called trastuzumab to breast radiation therapy, will be more effective than radiation therapy without trastuzumab in treating DCIS. Radiation therapy is the standard treatment for patients with DCIS. Trastuzumab is considered to be investigational (still being researched) because it has not been approved by the U.S. Food and Drug Administration or Health Canada for use in the treatment of DCIS.

Trastuzumab is only known to be effective in treating breast cancer that is HER2-positive. Therefore, your tumor must be tested to find out if it is HER2-positive before you can join the B-43 study using trastuzumab. You are being asked to allow testing of your tumor to determine if it is HER2-positive.

How many people will have HER2 testing done?

We do not know how many women will agree to take part in this HER2 testing. The number will be several thousand women from different cancer treatment centers. About 2000 women will take part in the B-43 treatment study.

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What will happen if I have HER2 testing done?

By signing this consent form, you are agreeing to allow your local hospital to send a sample of your tumor, which has already been removed, to Rush University Medical Center (RUMC) Department of Pathology. At RUMC, the pathology department staff will test the tumor tissue to find out if it is HER2-positive. Every woman who is considering joining the B-43 study will have her tumor tested at RUMC because the HER2 test is not part of regular cancer care for patients with DCIS. Testing all of the samples at RUMC will also make sure that the HER2 testing was done in the same way for everyone.

Your doctor will be given the results of your HER2 testing within 1-2 weeks after RUMC receives your tumor tissue. Your doctor will tell you the results. If the test shows that your DCIS is **not** HER2-positive, you will not be able to take part in the B-43 study. This is because trastuzumab is not expected to be effective in treating HER2-negative DCIS. Any tissue remaining after the HER2 testing will be returned to your local hospital.

If the test shows that your DCIS is HER2-positive and you meet all other study requirements, you can join the B-43 study. You will need to sign another consent form that explains the B-43 treatment study. If you join the treatment study, any tissue that is remaining after the HER2 testing will be stored at the NSABP Division of Pathology and will be used for the purpose of research tests for the B-43 study.

Can I stop HER2 testing from being done on my tissue sample?

Yes. You can withdraw permission for testing on your tissue sample. Tell the study doctor immediately if you are thinking about withdrawing permission for HER2 testing. If you withdraw your permission, you will not be able to join the B-43 treatment study. Because the HER2 testing is being done quickly, depending on when you withdraw permission, testing may have already been done on your tissue sample, and it is possible that there may be no remaining tissue to return. Even if the HER2 testing has been done, and the test showed your DCIS to be HER2-positive, you can choose not to take part in the B-43 treatment study. If you do not choose to take part in the B-43 study, any tissue remaining after the HER2 testing will be returned to your local hospital.

What risks can I expect from allowing HER2 testing?

The only risk from allowing the HER2 testing is the accidental release of private information about you. Every effort will be made to ensure this does not happen.

Are there benefits to having the HER2 testing done?

Taking part in this HER2 testing will not make your health better. Taking part in the B-43 study may or may not make your health better. While doctors hope that adding trastuzumab to radiation therapy will be more useful in the treatment of DCIS compared to radiation therapy

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without trastuzumab, there is no proof of this yet. We do know that the information from this study will help doctors learn more about trastuzumab given with radiation therapy as a treatment for HER2-positive DCIS. This information could help future breast cancer patients.

What other choices do I have if I do not have the HER2 testing?

You can proceed with getting treatment that is recommended by your doctor for your DCIS without having HER2 testing. If you decide not to have the HER2 testing, you will not be eligible to participate in the B-43 study. Talk to your doctor about your choices before you decide if you will allow the HER2 testing to be done.

Will my medical information be kept private?

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. Information from this HER2 testing may be published or presented at scientific meetings, but 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:

- the National Surgical Adjuvant Breast and Bowel Project (NSABP);
- Genentech, Inc., a company that is providing support for the B-43 trial;
- Rush University Medical Center Department (RUMC) of Pathology; and
- your local Institutional Review Board (IRB), a group of people who review the research study to protect your rights
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to clinical trials, and
- government agencies including the NCI or its authorized representatives, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and Health Canada.. These agencies may review the research to see that it is being done safely and correctly.

What are the costs of HER2 testing?

There will be no charge to you or your insurance company for the collection, shipping, HER2 testing, and storage of your tumor sample at RUMC to determine if your DCIS is HER2-positive.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://www.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.

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What are my rights if I allow the HER2 testing?

To have the HER2 testing done to determine if you may be eligible for the B-43 treatment study is your choice. You may choose either to have it done or not. ***If you decide to have the testing done, you do not have to join the B-43 treatment study.*** No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Not having the HER2 testing done will not affect your medical care. You can still get your medical care from our institution.

Who can answer my questions about the HER2 testing?

You can talk to Dr. Deveras, the Principal Investigator overseeing the study at Halifax, your study doctor or the study coordinator about any questions or concerns you have about this testing. You can contact them at:

Halifax Health
Center for Oncology
303 N. Clyde Morris Blvd.
Daytona Beach, Florida 32114
(386) 254-4212 (24 Hour Number)

For questions about your rights while taking part in this HER2 testing, please contact:

Liberty IRB, Inc.
1450 S. Woodland Blvd. Suite 300A
DeLand, Florida 32720
(386) 740-9278 (Business Hours)

The Liberty Institutional Review Board (IRB) is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner.

You may also call the Operations office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the Continental US only).

Where can I get more information?

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.

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

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

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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://cancer.gov/cancerinfo/>

You will receive a copy of this form. If you want more information about the HER2 testing, ask your study doctor.

Signatures

Signatures

I have been given a copy of all six pages of this form. I have read the consent form or it has been read to me. This information was explained to me and my questions were answered.

I agree to allow a sample of my tumor to be sent to RUMC for HER2 testing.

Participant's Printed Name

Participant's Signature

Date

Time

Printed Name of Person Conducting Informed Consent Discussion

**Signature of Person
Conducting Informed Consent Discussion**

Date

Time

Physician's Printed Name

Signature of Physician

Date

Time

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