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CONSENT FORM

CIRB NSABP B-43: PRE-ENTRY: 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

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NSABP B-43 CONSENT FORM FOR PRE-ENTRY CENTRAL HER2 TESTING

NSABP PROTOCOL 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

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.

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 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.

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 your study doctor about any questions or concerns you have about this testing. Contact your study doctor at the number listed on the cover page.

For questions about your rights while taking part in this HER2 testing, call the MultiCare Health System Institutional Review Board (a group of people who review the research to protect your rights) at 253-403-3877.

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) or TTY: 1-800-332-8615

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

I have been given a copy of all five 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.

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

Patient's name (printed or typed) Patient's Signature Date

Physician name (printed or typed) Physician Signature Date

Signature of person conducting the Informed consent discussion Date

**Authorization (Permission) to Use or Disclose (Release) Identifiable
Health Information for Research**

HER2 TESTING TO DETERMINE ELIGIBILITY FOR NSABP B-43

**NSABP B-43: PRE ENTRY: 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.**

Patient's Name: _____ Birth Date: _____

1. What is the purpose of this form?

The NSABP is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter an NSABP research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, such as laboratory test results; pathology results; and reports of physical exams, diagnostic tests, x-rays, and tumor measurements;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

You may request a blank copy of the NSABP data forms from the study doctor or his/her research staff to learn what information will be shared.

3. *Why do the researchers want my personal health information?*

The Northwest CCOP will collect your health information and share it with the NSABP Biostatistical Center and the NSABP Operations Center if you enter a cooperative group research study. The NSABP centers will use your information in their cancer research study. You are being asked to take part in a study known as NSABP B-43 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. You are being asked to take part in this study because you have had a lumpectomy to remove the DCIS, and you will be having breast radiation therapy.

This study is being done to compare the effects, good and/or bad, of adding the drug trastuzumab (also called Herceptin®) to breast radiation therapy. Radiation therapy is the standard treatment for patients with DCIS.

- This study will find out if adding trastuzumab to breast radiation therapy is more effective than radiation therapy without trastuzumab in preventing occurrence of breast cancer in the same breast, in the other breast, or in other parts of the body in patients with HER2-positive DCIS.
- The only research data on how trastuzumab affects the ovaries in women who have not yet gone through menopause are from studies of trastuzumab given with chemotherapy or after chemotherapy. This study will learn if trastuzumab given without chemotherapy affects the ovaries in women who have not yet gone through menopause.
- If you join the study, we will do special research tests on tumor tissue that was removed at the time of your lumpectomy. The results of these tests should provide NSABP researchers with information about how genes in the cancer cells may affect the way HER2-positive DCIS responds to treatment.

4. *Who will be able to use my personal health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. The Northwest CCOP may also permit these groups to come in to review your original records that are kept by the Northwest CCOP so that they can monitor their research study.

- the NSABP Operations Center;
- the NSABP Biostatistical Center;
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute that supports the research of the NSABP;
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;

- other people or organizations assisting with NSABP research efforts (including other groups who review the research to protect the rights and ensure the safety of patients);
- Genentech, Inc. (the company providing support for the study); and
- central laboratories, central review centers, and central reviewers. The central laboratories, centers, and review agencies may also give your health information to those groups listed above.

5. *How will information about me be kept private?*

The NSABP will keep all patient information private to the extent possible, even though the NSABP is not required to follow the federal privacy laws. Only researchers working together with the NSABP will have access to your information. The information will only be shared in a manner that will protect your identity. The NSABP will not release personal health information about you to others except as authorized or required by law. 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.

6. *What happens if I do not sign this permission form?*

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. *What happens if I want to withdraw my permission?*

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

Karyn Hart, RHIT, CCRP
Program Coordinator
Northwest CCOP
315 Martin Luther King Jr., Way
M/S 315-L2-CCO
Tacoma, WA 98405
(253) 403-1461

8. *How long will this permission last?*

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

9. *What are my rights regarding access to my personal health information?*

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by the Northwest CCOP. You do not have the right to review and/or copy records kept by the NSABP or other researchers associated with the research study.

Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient
or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Permission: _____ Date: _____

Printed Name of Person Obtaining Permission: _____