

MARQUETTE GENERAL HEALTH SYSTEM

Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: Patient Informed Consent Form for Central HER2 Testing to Determine Eligibility for the BETH Trial ("Bevacizumab with Trastuzumab Adjuvant Therapy in HER2+ Breast Cancer") CIRG (TRIO) 011/NSABP B-44-I/BO20906

INVESTIGATORS: Sheetal Acharya, MD
Mohammad Al-Nsour, MD
Jorge Frank, MD
Gustavo Morel, MD
Suresh Nukala, MD
Irina Sachelarie, MD
Aaron P. Scholnik, MD
1414 W. Fair Avenue
Marquette, MI 49855

You are being asked to allow a HER2 test to be done on your breast cancer tumor that was removed during your recent breast surgery. This HER2 test will be done at a central laboratory as part of a clinical trial (research study) that is being done for the treatment of invasive breast cancer that is HER2-positive. Invasive breast cancer means that the cancer has spread from where it started in the breast into surrounding tissue. 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 tumors grow faster.

After your breast cancer surgery, your local hospital may have already performed HER2 testing that indicated that your tumor is HER2-positive. The researchers for the BETH Trial want to perform a second HER2 test even if this testing was performed by your local hospital because there are different ways to perform HER2 testing and to report the results of the test.

Testing at a central laboratory means that the same methods will be used to test all of the tumor samples and to report all of the test results. If the central testing shows that your cancer is HER2-positive, you will be asked to sign another consent form to take part in a breast cancer treatment study called the BETH Trial. The information contained in this consent form is only for the HER2 testing at the central laboratory.

This testing only includes people who choose voluntarily 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.

Patient's Initials: _____

Who is conducting the HER2 testing?

Two research groups will be conducting the BETH Trial: the Cancer International Research Group (CIRG) and the National Surgical Adjuvant Breast and Bowel Project (NSABP). The central HER2 testing of your tumor will be done by the CIRG Central Laboratory. Marquette General Hospital is also conducting the trial locally.

Why is this HER2 testing being done?

You are being asked to allow a test on your breast cancer tumor to check if it is HER2-positive using the methods for the BETH Trial. The central test will be done in exactly the same way for all of the patients who would like to take part in the BETH Trial.

The BETH Trial is being done to find out if adding a drug called bevacizumab to standard therapy for invasive HER2-positive breast cancer is more effective than standard therapy without bevacizumab. Chemotherapy given with another drug called trastuzumab, which is a type of therapy called “targeted therapy”, is standard treatment in the United States for women with invasive HER2-positive breast cancer. Bevacizumab is also a type of treatment called “targeted therapy”. Bevacizumab is considered to be investigational (still being researched) because it has not been approved by the U.S. Food and Drug Administration for use in the treatment of HER2-positive breast cancer.

How many people will have HER2 testing done?

Central HER2 testing will have been performed for all women who would like to take part in the BETH Trial. We do not know the exact number of women who will have the central testing. At least 3,500 women from cancer treatment centers from all over the world will take part in the BETH Trial, but more women will have the HER2 testing performed.

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 that was removed when you had your breast surgery to the CIRG Central Laboratory. At the central lab, the staff will test your tumor sample to check if it is HER2-positive using the study methods.

Your doctor will be given the results of your HER2 testing within 1 week after the CIRG Central Laboratory receives your tumor sample. Your doctor will tell you the results. If the test shows that your breast cancer is **not** HER2-positive according to the central laboratory guidelines, you will not be able to take part in the BETH Trial. Your doctor will talk with you about these results and decide the course of action that will be best for you. Also, any tumor remaining after the HER2 testing will be returned to your local hospital.

If the central test shows that your breast cancer is HER2-positive according to the central laboratory guidelines and if you meet all other study requirements, you can join the BETH Trial.

Patient's Initials: _____

You will need to sign another consent form that explains the treatment in the BETH Trial. Also, remaining tumor after the required HER2 testing will be kept by the CIRG Central Laboratory if you agree to take part in the BETH Trial and if you agree to the additional research using your tumor sample. If not, the tumor sample will be returned to the local laboratory.

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

Yes. You can withdraw permission for the central testing on your tumor sample. Tell the study doctor immediately if you are thinking about withdrawing permission for the central HER2 testing. If you withdraw your permission, you will not be able to join the BETH Trial. Because the central HER2 testing will be done quickly, depending on when you withdraw permission, testing may have already been done on your tumor sample.

Even if the central HER2 testing has been done and the test showed that your breast cancer is HER2-positive, you can choose not to take part in the BETH Trial. If you do not choose to take part in the BETH Trial, any tumor remaining after the central HER2 testing will be returned to your local hospital.

What risks can I expect from allowing HER2 testing?

The only risk from allowing the central 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?

Finding out whether or not your tumor is HER2-positive is important for planning the best treatment for your breast cancer. This is true whether or not you join the BETH Trial.

Taking part in the BETH Trial may or may not make your health better. While doctors hope that adding bevacizumab to standard therapy will be more useful in the treatment of HER2-positive breast cancer, there is no proof of this yet. We do know that the information from this study will help doctors learn more about bevacizumab given with standard therapy for HER2-positive breast cancer. This information could help future breast cancer patients who may receive similar treatment.

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

If your local hospital has not performed HER2 testing, it may be possible for you to have the HER2 testing performed without taking part in the BETH Trial.

If you have already had the HER2 testing performed by your local hospital that indicates that your tumor is HER2-positive, you can receive therapy for HER2-positive breast cancer without taking part in the BETH Trial.

Patient's Initials: _____

Talk to your doctor about this before you decide if you will allow the central HER2 testing to be done.

Will my medical information be kept private?

All information obtained during the HER2 testing that concerns you will be treated as confidential and will not be made publicly available. You will be identified only by a unique code number and information about the code will be kept in a secure location and access limited to research study personnel. The data will be coded, stored, and protected.

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 central HER2 testing may be published or presented at scientific meetings, but your name and other personal information will not be used.

By agreeing to participate in this study, the following organizations may have confidential access to your medical records for research, quality assurance, and data analysis:

- the Cancer International Research Group (CIRG), including monitors and auditors;
- the National Surgical Adjuvant Breast and Bowel Project (NSABP), including auditors;
- F. Hoffmann-La Roche, Ltd. (including auditors), a company that is providing support for the BETH Trial;
- Genentech, Inc. (including auditors), a company that is providing support for the BETH Trial;
- Quintiles (including monitors and auditors), a company that will monitor the centers taking part in the BETH Trial;
- the CIRG Central Laboratory;
- the Marquette General Hospital Institutional Review Board (IRB), a local group of people who reviewed and approved the research study to protect your rights
- government agencies including the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP). 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 and shipping of the tumor sample and the central HER2 testing.

You will not be paid for participating in this HER2 testing.

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.

Patient's Initials: _____

What are my rights if I allow the HER2 testing?

Allowing the central HER2 testing to be done to determine if you are eligible for the BETH Trial is your choice. You may choose either to allow or not allow the central test. ***Even if you decide to allow the testing to be done, you do not have to join the BETH Trial.*** No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. If you decide to not have the central HER2 testing, this will not affect your medical care. You can still get your medical care from your center.

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 _____ [name(s)] at _____ [telephone number].

For questions about your rights while taking part in this HER2 testing, call Marquette General Hospital at 906-228-9440 and ask to speak with the Patient Advocate.

Where can I get more information?

You may call the National Cancer Institute's (NCI'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 the NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials>
- For the NCI's general information about cancer, go to: <http://cancer.gov/cancerinfo>

You may also visit the NSABP Web site at <http://www.nsabp.pitt.edu>

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

Patient's Initials: _____

Signatures

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

I consent to allow a sample of my tumor that was removed at the time of my surgery to be sent to the CIRG Central Laboratory for HER2 testing to determine if I am eligible for the BETH Trial.

Date

Patient's signature

Printed name of patient

Date

Signature of person conducting the
informed consent discussion

Printed name of person conducting the
informed consent discussion

Patient's Initials: _____