

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: **S1007**, "A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER-2 Negative Breast Cancer with Recurrence Score (RS) of 25 or Less" – Step 1

(**S1007** Recurrence Score Specimen Submission Consent Form)

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This consent form gives you detailed information about the research study which the doctor will discuss with you. The purpose of this study includes evaluation of the safety as well as the effectiveness of the investigational therapy.

You are being asked to take part in this study because you are a woman with hormone-responsive breast cancer with 1-3 positive lymph nodes. Your breast cancer has already been removed by surgery.

Recurrence Score: The Oncotype DX® breast cancer test is a test that looks at multiple genes related to breast cancer. The combination of the test results produces a score that is useful in guiding treatment choices for patients with node-negative breast cancer. The higher the score, the more likely that the patient's breast cancer will come back after surgery.

Version Date: 1/15/2011
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Why is this study being done?

The Oncotype DX® test is a commercially available test that is already being used to assess the risk that breast cancer will come back after surgery. The performance of the test is not part of the research question in this study.

The purpose of this part of this experimental study is to send your breast cancer tissue for Oncotype DX® recurrence score testing to find out if you may be eligible to participate in the next part of the study.

How many people will take part in the study?

We expect that about 8,800 women may be tested to see if they can participate in the clinical trial. We expect that about 600 women may have already received the testing before they learn about this clinical trial.

Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. For this study, a tissue sample from your breast cancer will be collected and sent for Oncotype DX® testing. This tissue was already removed as part of your surgery.

Why is this test being done?

We are using the Oncotype DX® to determine whether patients are eligible to continue to the treatment part of this clinical trial. We are asking that you give permission for your breast cancer tissue to be tested.

If your recurrence score is higher than 25, the risk that your cancer may come back is higher than the limit we will be testing in the treatment part of this study. In this case, we ask that you discuss other treatment studies with your study doctor.

If your recurrence score is 25 or lower, we ask that you discuss participation in this study with your study doctor and consider joining the study. If you choose not to join the study, we will also ask you to let us know what kind of treatment you have chosen.

How does the specimen get to the laboratory for testing?

Your study doctor sends the specimen samples to the laboratory performing the test.

Will I find out the results of the test using my specimen?

Yes, you will know the results of the test before you decide whether to join the treatment part of the study. The result of the test will be included in your health record.

How long will I be in the study?

This part of the study is just about the Oncotype DX® test. You will be finished with this part of the study when your specimen is submitted for testing and the result is received. Then, if you are eligible to continue on the study, you will be asked to sign another consent form for the study treatment.

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.

How could the records be used in ways that might be harmful to me?

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members. Check with your study doctor to find out what kinds of privacy protections are available to you.

Where will my specimens be sent?

Your specimens will be sent to the laboratory of Genomic Health for testing. Any remaining tissue will be returned to the hospital/clinic that submitted it.

Are there benefits to taking part in the study?

Taking part in this part of the study will not have any impact on your health. We do know that the information from this part of the study will help doctors learn more about the use of Oncotype DX® testing. 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 tested locally for approaches to treating your cancer without being in a study
- Taking part in another study
- Being treated for cancer without using testing like Oncotype DX®

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

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. 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:

- Local Institutional Review Board (IRB)
- The National Cancer Institute (NCI) and other government agencies like the Food and Drug Administration (FDA) involved in keeping research safe for people
- The Southwest Oncology Group
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.
- Genomic Health: the laboratory and company responsible for the Oncotype DX® test and its performance
- CancerGen: a research group that studies the cost-effectiveness of cancer genomic technology
- A Data and Safety Monitoring Committee (DSMC), an independent group of experts will be reviewing the data from this research throughout the study.

What are the costs of taking part in this study?

Taking part in this study may or may not cost your insurance company more than the cost of not being in the study.

The Oncotype DX® test that is being used in this trial is commercially available and the Genomic Health laboratory is certified by federal and state agencies (CLIA) in the United States to perform this test. Your insurance company will be billed for the cost of the test. Representatives

from Genomic Health are available to answer any questions that you or your insurance company may have about the cost of the test or reimbursement for the test (1-866-662-6897).

If your insurance company denies payment of the test, Genomic Health will appeal this denial. It is likely that you will be receiving statements, or Explanation of Benefits forms (EOB), from your insurer. These are not bills.

We would like to assure you that, as a participant in this trial, should GHI be unsuccessful in receiving reimbursement for all or some of the cost of this assay after appeal, you will have no financial responsibility for the *Oncotype DX*® test. Patients will not be responsible for a co-pay or a deductible for cost of this test.

Genomic Health might ask your doctor to provide medical information in order to assist them in processing insurance claims, in a way very similar to the process used to cover other costs of their care.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://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 happens if I am injured because I took part in this study?

It is important that you tell your study doctor, _____, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____.

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.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about important new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

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 _____ at _____ .

For questions about your rights while taking part in this study, call the Marquette General Hospital Patient Advocate at 1-906-225-3183 or 1-800-562-9753, extension 3183.

NOTE: Use the following types of format only when the "additional studies" are optional for the patient. When mandatory, the description should be imbedded as a part of the study description in the main consent.

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

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

Quality of Life and Economic Analysis Study

We want to know your view of how your life has been affected by cancer and its treatment. We also want to compare the costs of the treatments in this study. This "Quality of life and Economic Analysis" 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. We also want to find out differences in health care costs related to treatment decisions based on having this test. So we are also asking permission to collect information on your Medicare and/or insurance coverage and on health coverage decisions and costs related to your breast cancer treatment. This information will be collected directly from your insurance and medical record. Information will be collected for about three years.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. The cost information will help doctors and patients better understand the short term and long term costs involved in different treatments. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

The Quality of Life portion of the study is in English and is available only to patients who read and speak English.

You will be asked to complete a questionnaire: one on your first visit and one after you find out the results of your Oncotype DX® testing. It takes about a half hour to fill out the questionnaire.

If you continue on to the treatment portion of the study you will also be asked to complete a questionnaire prior to beginning treatment, one 6 months later, one 12 months later and the last one 36 months after you begin treatment.

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 part of the study, the only thing you will be asked to do is fill out the questionnaires. You may change your mind about completing the questionnaires at any time.

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 Quality of Life and Economic Analysis Study. I agree to fill out the Quality of Life Questionnaires and to allow information about my health insurance claims to be sent to researchers.

Yes No

Future Contact

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes No

Signature

I have been given a copy of all 8 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 _____