



**Heartland**  
Cancer Research

An NCI-Designated Community  
Clinical Oncology Program

Missouri Baptist Medical Center  
Institutional Review Board

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## INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

### Step 2

**TITLE OF STUDY: 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"**

**PRINCIPAL INVESTIGATOR: Alan P. Lyss, M.D.**

**PARTICIPANT NAME:** \_\_\_\_\_

This is a clinical trial, a type of research study. Your study doctor will explain the study to you. Clinical trials include only people who choose to take part. Please take your time to make your choice about taking part. You may discuss your choice 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 are a woman with hormone-responsive breast cancer with 1-3 positive lymph nodes and have a Recurrence Score of 25 or less. Your breast cancer has already been removed by surgery.

Recurrence Score: The Oncotype DX® 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 is, the more likely that the patient's breast cancer will come back after surgery.

### Why is this study being done?

The purpose of this study is to find out if the Oncotype DX® Recurrence Score can help decide whether patients should receive chemotherapy or not. This study is being done in patients with lower Recurrence Scores (25 or less).

Currently most women who have the kind of breast cancer you have are treated with endocrine therapy (treatment that works with hormones). Many women also receive chemotherapy. No one really knows which patients with lower Recurrence Scores need to get chemotherapy. Some women may be getting chemotherapy who do not need it. These women may be exposed to side effects of their treatment that are not a necessary risk in relation to the benefit they receive.

If the results of the study show that the benefit for getting chemotherapy is dependent on the Recurrence Score, the study should be able to identify a Recurrence Score level where chemotherapy should be considered (and a recurrence score level where chemotherapy may not be needed).

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

About 4,000 women will take part in this part of the study. We expect that about 8,800 women may be tested to see if they can take part, and that about 600 women may have already received the testing before they learn about this clinical trial.

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

Before you begin the study ...

You will need to have the following exams or tests to find out if you can be in the study. These exams or tests 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.

- Medical History and Physical Exam
- Weight and Performance Status
- A check of your cancer including CT scans, MRI scans, bone scan, PET scans and/or x-rays.
- Routine lab blood tests (to measure your blood counts and kidney and liver function)
- Pregnancy test (if determined to be appropriate by your study doctor)
- Required submission of blood and tissue specimens to a central laboratory for research purposes. The tissue will be taken from the tissue that was already removed as part of your surgery. The blood will be about 3-4 teaspoons and will be taken at the same time as your lab tests. You will not need an additional needle stick. These will be used for lab tests to look at how different aspects of your genetics and of your breast cancer may relate to choosing the best treatments for patients in the future. Additionally, at the end of this form you can also choose whether your specimens may be kept for use in similar kinds of lab studies in the future.
- MUGA/ECHO which are heart scans to see how your heart is functioning if your doctor thinks you need it.

During the study ...

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

- Medical history and physical exam at each follow-up visit
- Weight and performance status each follow-up visit
- A check for cancer including mammograms annually while you are receiving endocrine therapy and thereafter, following your doctor's direction
- A test of your heart's ability to pump may be done to decide the kind of chemotherapy you should get if you are randomized to get chemotherapy (and may be repeated as your study doctor chooses)
- Routine lab blood tests (to check for blood counts and kidney and liver function) at each follow-up visit if you receive chemotherapy

Follow-up visits occur every three months for the first year, then every 6 months for the next four years. After five years, you will make one follow-up visit per year. We would like you to remain in the study for at least 15 years, and you can continue to be followed after that if you are willing to visit the clinic each year.

You will receive endocrine therapy since your cancer has been shown to respond to such therapy. However, because we are not certain that chemotherapy is needed for women with low Recurrence Scores such as yours, then we "randomize" one-half of the patients to chemotherapy and one-half to not receive chemotherapy. This randomization makes sure the two groups are similar so we can compare results. While this randomization is done by a computer, it is similar to you pulling a card out of a hat that says whether you are part of the chemotherapy group or the no chemotherapy group. Before being randomized, please be certain that you can accept either choice. Once randomized to a particular group, neither you nor your doctor can change you to the other group if you want to stay in the study.

**If you are randomized to the endocrine therapy plus chemotherapy group, or Arm 1,** you will get one of the standard types of endocrine therapy (either tamoxifen or an aromatase inhibitor or both – given over a period of 5-10 years). You and your doctor must agree to one of the options outlined in the study. You will also get chemotherapy. The selection of the chemotherapy will be made based upon what is best for you and the treatment of your cancer. The study does not specify what treatment the doctor should choose, but does provide a list of options. You and your doctor must agree to one of the options outlined in the study. The doctor will monitor you using standard methods.

**If you are randomized to endocrine therapy alone, or Arm 2,** you will get one of the standard types of endocrine therapy (either tamoxifen, or an aromatase inhibitor, or both – given over a period of 5-10 years). You and your doctor must agree to one of the options outlined in the study. The doctor will monitor you using standard methods.

All of the drugs that are used as part of treatment on this study are commercially available, FDA approved and considered standard treatment for your kind of breast cancer.

### **How long will I be in the study?**

Your treatment on this study may continue for up to 10 years. Your treatment will end when you have completed standard endocrine therapy; or if your cancer returns. We would like to keep track of your health for 15 years after you start 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 that you can 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.

If you decide to withdraw from study participation we ask that written notification of withdraw be sent to the MBMC Cancer Research office, 3015 N. Ballas Rd., St. Louis, MO 63131.

### **What side effects or risks can I expect from being in the study?**

To find out more about the risks of the specific treatment you will get, or any other risks, 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 doctors hope that the Oncotype DX® test will improve the effectiveness of cancer treatment decision-making compared to the usual methods of deciding treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about the use of the Oncotype DX® test in relation to understanding the risk of breast cancer recurrence. 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 treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

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?**

Protected health information (PHI) is health information that identifies you. This information is protected by Federal law under the Health Insurance Portability and Accountability Act (HIPAA). Your rights regarding your health information will be explained further to you in a separate consent form.

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:

- Missouri Baptist Medical Center Staff
- Missouri Baptist Institutional Review Board (a group of people who review the research study to protect your rights)
- The National Cancer Institute (NCI)
- The Food and Drug Administration (FDA), involved in reviewing and inspecting the data and results of this clinical study, and in keeping research safe for participants in this study.
- 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 Safety and 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?**

The treatments received during this clinical trial are not experimental. They are considered standard. Both endocrine therapy alone and endocrine therapy combined with chemotherapy are typical treatments for this type of cancer. The costs of these treatments are not paid for by the study, and you and/or your health plan/ insurance company will need to pay for all of the costs of treating your cancer in this study. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

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 at his/her usual office if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call the usual clinic phone 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.

If you make the decision to withdraw from study we ask that written notification of your withdraw be mailed to:  
MBMC Research Office  
3015 N. Ballas Rd  
St. Louis, MO 63131  
Attention:S1007 data coordinator

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 new information or changes in the study that may affect your health or your willingness to continue in the 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 the usual clinic phone number.

For questions about your rights while taking part in this study, call the Missouri Baptist Medical Center Institutional Review Board (a group of people who review the research to protect your rights) at 314-996-5186.

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

**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** *(Please include the Quality of Life and Economic Analysis section in the Step 2 Consent Form only for patients who were not required to complete the Step 1 Consent Form, i.e. patients whose Oncotype DX® Recurrence Score is already known prior to initial registration.)*

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 prior to beginning treatment, one 6 months later, one 12 months later and the last one 36 months after you begin treatment. It takes about a half hour to fill out the questionnaire.

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

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 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

**Additionally, we would also like to bank any leftover tissue and blood specimens for future, unspecified scientific testing. An additional consent form and information is attached for this purpose.**

### **Consent Form for Use of Specimens for Research**

#### **About Using Specimens for Research**

We would like to keep leftover tissue and blood specimens for future research. If you agree, these specimens will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How are Specimens Used for Research" to learn more about specimen research.

The research that may be done with your specimens 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 specimens 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 specimens for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimens 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 specimens, then any specimens that remain will no longer be used for research.

In the future, people who do research may need to know more about your health. While the Southwest Oncology Group 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 specimens are used for genetic research (about diseases that are passed on in families). Even if your specimens are used for this kind of research, the results will not be put in your health records.

Your specimens will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future.

### **Benefits**

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

### **Risks**

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.

### **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, treat or cure cancer.**

Yes      No

- 2. My specimens may be kept for use in research about other health problems (for example: diabetes, Alzheimer's disease, or heart disease).**

Yes      No

- 3. Someone may contact me in the future to ask me to allow other uses of my specimens.**

Yes      No

If you decide to withdraw your specimens from a Southwest Oncology Group Specimen Repository in the future, a written withdrawal of consent should be submitted through your study doctor to the Southwest Oncology Group Operations Office. If you decide to withdraw your permission from the banking part of the study, then any remaining blood specimens will be destroyed.

**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/>

**This study has been reviewed by the Missouri Baptist Medical Center Institutional Review Board (IRB). The Missouri Baptist Medical Center IRB is a Federally recognized, administrative group established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted at Missouri Baptist Medical Center. If you have any questions or concerns regarding this study, or if any problems arise, you may call the Principal Investigator at 314-996-5569. You may also ask questions or state concerns regarding your rights as a research subject to Dr. David Striker, Chairman of the Institutional Review Board, Telephone: (314) 996-5186.**

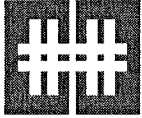
**I have read this consent form and have been given the opportunity to ask questions. I will also be given a signed copy of this consent form for my records. I hereby consent to my participation in the research described above.**

\_\_\_\_\_  
**Participant's Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Investigator's Signature**

\_\_\_\_\_  
**Date**



# Heartland Cancer Research

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## **Authorization to Use and Disclose Personal Health Information for Study:**

### **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"**

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Authorization explains how your personal health information will be used and who it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing this Authorization form, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Authorization. If you do not want to allow these uses and disclosures, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor and staff (also known as the research team) will use your medical records and information created or collected during the study to conduct the study.
- The research team will send your study-related health information ("study data") to the sponsor of the study and its representatives ("sponsor"). If the sponsor conducts business related to clinical research in multiple countries around the world, this may involve sending your study data outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will respect the terms of this Authorization in all countries.

- The study data sent by the research team to the sponsor generally does not include your name, address, social security number, or other information that *directly* identifies you. Instead, the research team often assigns a code number to the study data, which may include your initials or other similar information. Some study data used or disclosed under this Authorization may contain other information that could be used (perhaps in combination with other information) to identify you (eg, date of birth). If you have questions about the specific health information that will be used or disclosed pursuant to this Authorization, you should ask the study doctor.
- The research team and sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs, devices or other products.
- The sponsor or research team may add your study data to data from other studies in research databases so that it can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.
- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, research teams at other institutions participating in the study, central study cooperative or monitoring groups, and the review board overseeing this study.
- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions or training.
- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the ethical review board overseeing this study, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law. Portions of your medical record may be stored by the research team in the research record, as well.
- The sponsor may work with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners agree to protect your study data in the same way as the sponsor.
- Your medical records and study data may be held and processed on computers.
- Your personal health information or study data may be used or disclosed in any other manner or to any other person or organization referenced in the Informed Consent document to which this Authorization is attached or related.

Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team to these other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you agree that you will not be able to access or review such study information until after the study has been completed, when your access rights will be re-stored.

You may cancel your authorization at any time by providing written notice to the study doctor. If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

If you cancel your authorization, the research team will no longer use or disclose your personal health information in connection with this study, unless the research team needs to use or disclose some of your personal health information to preserve the scientific integrity of the study or for other purposes for which the research team has relied upon your original authorization (e.g., to be paid for services). The sponsor, oversight boards and regulatory agencies may still use study data that was collected before you canceled your authorization for the original purpose(s) of those disclosures.

Your consent for the uses and disclosures described in this Authorization does not have an expiration date.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date (by Participant)

\_\_\_\_\_  
Participant Name (Print or Type)

\_\_\_\_\_  
Participant Initials and  
Number (if applicable):

Complete ONLY if Authorization is signed by a legal representative of the Participant

\_\_\_\_\_  
Signature of Legal Representative

\_\_\_\_\_  
Date (by Legal  
Representative)

\_\_\_\_\_  
Legal Representative Name (Print or Type)

\_\_\_\_\_  
If signed by Legal Representative, description of  
relationship to patient or other basis for legal authority