

Northwest Community Clinical Oncology Program (NWCCOP)

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CONSENT FORM

CIRB PACCT 1: Program for the Assessment of Clinical Cancer Tests (PACCT-1):

Trial Assigning Individualized Options for Treatment:

The *TAILORx* Trial

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**CIRB PACCT 1: Program for the Assessment of Clinical Cancer Tests (PACCT-1):
Trial Assigning Individualized Options for Treatment:
The *TAILORx* Trial**

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. 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 study doctor for more explanation.

You are being asked to take part in this trial because you have breast cancer that is estrogen receptor and/or progesterone receptor positive that has not spread to the axillary lymph nodes. Although you have received surgical treatment for your cancer, there is a chance that you may have a future recurrence of the cancer in the breast, chest wall, or other parts of your body. Based on our current knowledge about the treatment of breast cancer, your doctor believes that you are a candidate for chemotherapy in addition to hormonal therapy in order to reduce your risk of recurrence, a recommendation that is consistent with established guidelines for the treatment of your breast cancer. Chemotherapy is usually recommended if the risk of recurrence is at least 10% despite hormonal therapy. Approximately 80-85% of patients with your stage of disease are expected to be alive without evidence of recurrent breast cancer at 10 years with hormonal therapy alone. Because we are unable to precisely identify who benefits from chemotherapy, many patients receive chemotherapy unnecessarily.

This study involves the use of a new diagnostic test called the *Oncotype DX* (Genomic Health, Inc, Redwood, CA). This test involves analysis of cancer that has already been taken during your surgery and has been stored in the pathology laboratory affiliated with the facility where you had the surgery. Storage of the cancer in the pathology laboratory after surgery is a routine procedure. The analysis requires that several small slices of the tumor section be taken. The sections will be analyzed in a specialized laboratory that can measure the levels of a specific panel of genes in the tumor. The laboratory that performs this test (Genomic Health laboratory) has been certified by federal and state agencies in the United States to perform the test (*Oncotype DX*). The results of the test are computed into a score (called Recurrence Score). The results from initial studies indicate that tumors may be classified into the following groups:

- **Secondary Study Group-1 (Recurrence Score ≤ 10)**: This group has a 5% or less chance of having a relapse of breast cancer in other organs at 10 years if treated with hormonal therapy alone. In this group, chemotherapy has not been proven to reduce the risk of recurrence. Approximately 25% of patients have a tumor with a Recurrence Score of ≤ 10 .
- **Secondary Study Group-2 (Recurrence Score ≥ 26)**: This group has about a 30% chance of having a relapse of breast cancer in other organs at 10 years if treated with hormonal therapy. In this group, chemotherapy reduced the risk of recurrence by about 75%. In other words, adding chemotherapy increases the chance of being without disease recurrence at 10 years from about 70% to about 90% in this group. About 35% of patients have a tumor with a Recurrence Score of ≥ 26 .

- **Primary Study Group (Recurrence Score 11-25)**: This group has about a 10% chance of having a relapse of breast cancer in other organs at 10 years if treated with hormonal therapy. In this group, although the risk of recurrence is high enough to recommend consideration of chemotherapy, it is unknown whether chemotherapy reduces the risk of recurrence and whether the overall health benefits favor the use of chemotherapy. About 40% of patients have a tumor with a Recurrence Score of 11-25.

Why is this study being done?

This study is being done because chemotherapy would normally be recommended for the treatment of your disease to lower the risk of your breast cancer recurring. The purpose of this study is to determine whether patients who have a tumor with an *Oncotype* DX Recurrence Score of 11-25 benefit from chemotherapy, and to confirm that patients who have *Oncotype* DX Recurrence Score of ≤ 10 have a very low risk of recurrence with hormonal therapy alone (and do not need chemotherapy to reduce their risk of recurrence). Another objective is to create a tissue and blood specimen bank that includes specimens from all women who participate in this study, and to collect follow-up information regarding the health status of all women who participate in the study. This will allow researchers to evaluate new diagnostic tests in the future as they develop that may predict benefit or side effects from certain treatments.

How many people will take part in the study?

Approximately 11,000 women with breast cancer will take part in this study.

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

If you agree to participate in this study, the sequence of events is outlined in the attached study plan, and described below.

If you have not had the *Oncotype* DX test performed: In the “PREREGISTRATION PHASE”, a tumor specimen will be sent to Genomic Health for the *Oncotype* DX test. It will take about 10 –14 days to obtain the results of the test back from Genomic Health. The results will be sent to your study doctor. Your study doctor will fax the report to the ECOG Coordinating Center. One to three days after the report has been sent to the ECOG Coordinating Center, you will proceed to the “REGISTRATION PHASE” and specific treatments will be recommended:

- **Secondary Study Group-1 (Recurrence Score ≤ 10)**: You will receive hormonal therapy, but no chemotherapy (Arm A).
- **Secondary Study Group-2 (Recurrence Score ≥ 26)**: You will receive chemotherapy plus hormonal therapy (Arm D).
- **Primary Study Group (Recurrence Score 11-25)**: You will be randomly assigned by chance (like a coin flip) to treatment with either:
 - hormonal therapy alone (Arm B)
 - chemotherapy plus hormonal therapy (Arm C)

If you have already had the *Oncotype* DX test performed: You may be eligible for this trial if the Recurrence Score was 11-25. If this is the case, your study doctor will fax a copy of the Recurrence Score report to the ECOG Coordinating Center and then you will be enrolled on the "REGISTRATION PHASE". You will be randomly assigned by chance (like a coin flip) to receive either hormonal therapy, or chemotherapy followed by hormonal therapy. Also, a tumor specimen from a previous biopsy or surgery will be sent to central laboratories to be used for research studies.

Genomic Health will forward any left over tissue or other samples to the ECOG Pathology Coordinating Office to be used for research studies. Your study doctors may also forward tumor tissue to the ECOG Pathology Coordinating Office for research studies. The research studies performed using your tissue will be done to learn more about breast cancer. In addition, you will be asked to provide samples of blood and to allow left over tumor tissue to be stored in the ECOG Pathology Coordinating Office for possible use in future research. Your participation in this study will not be affected by your decision to provide or not provide the samples for future research.

If you would like to know the results of the *Oncotype* DX test, speak to your study doctor.

Before you begin the study ...

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

- History and physical examination
- Blood tests (including complete blood count and liver and kidney function tests)
- Mammogram
- Paper and pencil questionnaires for the Quality of Life study

During the study ...

A sample of your tumor will be sent to Genomic Health for the *Oncotype* DX test. You will be asked to provide a sample of your tumor and blood for banking and future research. Treatment will be assigned based upon the score of the *Oncotype* DX test, as described above under **What will happen if I take part in this research study?**

During and after the treatment...

When chemotherapy is given, it is usually administered over 3-6 months. Hormonal therapy is usually given for five years or longer, and begins after the completion of chemotherapy (if given). You will need the following tests and procedures during and after treatment in order to determine if there is a relapse of the breast cancer, or if another breast cancer develops. These procedures/tests are part of regular cancer care, and include the following:

- *History and physical exam every 3-6 months for the first five years, then yearly after year five*
- *Mammogram once yearly*

There are several different types of chemotherapy and hormonal therapy, which your study doctor will discuss with you. Chemotherapy usually consists of two or more drugs given intravenously for 4-8 treatments, and works by killing residual microscopic tumor cells. Hormonal therapy usually consists of an oral medication taken once daily, which may include either tamoxifen or drugs called aromatase inhibitors (e.g., anastrozole [Arimidex], letrozole [Femara], and exemestane [Aromasin]), all of which work by blocking the effects of the female hormone estrogen on residual microscopic breast cancer cells. These drugs are usually taken for at least five years, or longer. In addition to this trial, your study doctor may offer you participation in another clinical trial that is testing different types of chemotherapy and/or hormonal therapy and/or radiation therapy. Patients who have had a lumpectomy will also be treated with radiotherapy.

If you have been randomized or assigned to hormonal therapy alone, it will begin within 14 days of registration. If you have been randomized or assigned to chemotherapy, it will also begin within 14 days after registration; after chemotherapy is completed, hormonal therapy will begin within 4 weeks after the last dose of chemotherapy. Treatment with hormonal therapy will be given at the same time as radiation therapy. However, treatment with radiation therapy will be given only after chemotherapy has been completed.

Laboratory Research Studies

Some of your tissue from the breast cancer will be sent to the ECOG Pathology Coordinating Office. This tissue will be used for research studies to learn more about breast cancer; the results of these tests will not be sent to your study doctor and will not be placed in your medical record. They are for research purposes only.

Genomic Health will also send to the ECOG Coordinating Center detailed results outlining how they determined your Recurrence Score and additional information describing the tissue samples sent to them. This information will NOT be sent to you or your study doctor or your insurance company. It will not be placed in your medical record. It will only be used for research to help better understand your disease and how to treat it.

Blood samples will also be requested before you begin treatment. These samples will only be collected if you agree to allow the samples to be kept by ECOG for future research. If you do not agree, it will not affect your medical treatment or your participation in this study.

QUALITY OF LIFE (QOL) QUESTIONNAIRES

You will be asked to complete questionnaires to assess your well-being during and after the study. These questionnaires include questions about how you were affected by side effects associated with treatments you have received. By collecting information from study participants using paper and pencil questionnaires, we will learn more about how chemotherapy and hormonal treatments affect quality of life. The QOL forms for this study will be given to you by your doctor or nurse when you come in for your appointments. Your doctor or nurse may ask you the questions verbally and fill out the form for you or you may fill out the forms yourself, whichever you feel more comfortable with.

You will be asked to complete 6 different questionnaires at different timepoints throughout your treatment. Sometimes, you will only need to complete 5 questionnaires. Each questionnaire should take you 10 minutes or less to complete and all 6 questionnaires should take between 20 and 30 minutes.

Timing of Questionnaires

Questionnaires	Timepoints						Approximate time for you to complete
	Before your treatment	At 3 months	At 6 months	At 12 months	At 24 months	At 36 months	
FACT-Cog Version 3	X	X	X	X	X	X	10 minutes
FACT-Fatigue Subscale	X	X	X	X	X	X	3 minutes
PROMIS Fatigue 7-item Short Form	X	X	X	X	X	X	2 minutes
Assessment of Survivor Concerns	X	X	X	X	X	X	2 minutes
FACT-Endocrine Subscale	X	X	X	X	X	X	4 minutes
FACT-General	X			X		X	7 minutes

RISKS

Completing the questionnaires which are part of this study may remind you of unpleasant aspects of your condition and treatment, which may be upsetting. You may also refuse to answer any questions that make you feel uncomfortable. Refusing to participate in the QOL portion of this study will not affect your medical care.

How long will I be in the study?

You will be followed by your study doctors for up to 20 years after you enroll on this study. Your study doctor will monitor you periodically as described above to monitor you for recurrence of the cancer, which is part of routine medical care.

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 any risks from the chemotherapy and/or hormonal therapy can be evaluated by your study doctor. Another reason to tell your study doctor that you are thinking about stopping is to 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.

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

Commonly used chemotherapy regimens include doxorubicin (Adriamycin) and cyclophosphamide (called AC), AC followed by paclitaxel (called ACT), cyclophosphamide, methotrexate, and 5-fluorouracil (called CMF), cyclophosphamide, epirubicin, and 5-fluorouracil (FEC), and other regimens. The choice of the chemotherapy regimen used will be up to your study doctor and you. In addition to chemotherapy, treatment also always consists of at least 5 years of hormonal therapy, which usually begins within about 4 weeks after the completion of chemotherapy. Hormonal therapy consists of either tamoxifen or aromatase inhibitors. Several aromatase inhibitors are currently available and commonly used, including anastrozole (Arimidex), letrozole (Femara), and exemestane (Aromasin). The choice of hormonal therapy will be left to your study doctor and you. If you have had a lumpectomy, radiation to the breast is also usually recommended after the completion of chemotherapy, or after you have adequately healed from the surgery if you don't receive chemotherapy. The decision regarding whether to administer radiation, and the type of radiation, will be left to your study doctor and you.

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, study doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drugs. In some cases, side effects can be serious, long lasting, or may never go away.

Risks and side effects related to the chemotherapy are summarized below. Other side effects may be expected depending upon with the specific regimen recommended your treating physician. You should discuss the side effect profile of your treatment regimen with your study doctor. **You should talk to your study doctor about any side effects that you have while taking part in the study.** Some of the most common side effects of chemotherapy include:

Likely:

- Nausea and/or vomiting
- Hair loss
- Fatigue
- Anemia
- Lowering of the white blood cell count
- If not yet menopausal, premature menopause and sterility

Less Likely:

- Infection
- Mouth sores
- Numbness/tingling in the hands/feet (for paclitaxel)
- Allergic reactions
- Irritation of the bladder

Rare but serious (occur only with some types of chemotherapy that include doxorubicin or epirubicin):

- Leukemia
- Heart failure

Risks and side effects related to the hormone therapy are listed below. Some side effects occur with tamoxifen, some with aromatase inhibitors, and some with both drugs.

Likely:

- Hot flashes
- Osteoporosis – bone loss (aromatase inhibitors)
- Vaginal discharge and/or dryness

Less Likely:

- Bone fractures from osteoporosis (aromatase inhibitors)
- Joint pains (aromatase inhibitors)
- Shortness of breath (aromatase inhibitors)
- Diarrhea (aromatase inhibitors)
- Painful intercourse

Rare but serious:

- Blood clots (tamoxifen)
- Uterine cancer (tamoxifen)

Reproductive risks: You should not become pregnant while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. For more information about risks and side effects, 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. We expect that the information from this study will help doctors learn more about how to better select patients for treatment with chemotherapy. 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 for your cancer without being in a study
- Taking part in another study
- Getting no treatment
- Having the *Oncotype* DX test performed without participating in the study

Talk to your study doctor about your choices before you decide if you will take part in this study. If you take part in this study, you may also take part in other studies sponsored by the National Cancer Institute, as long as the treatment in those studies is consistent with the treatment assignment in this study (chemotherapy plus hormonal therapy vs. hormonal therapy alone).

Will my medical information be kept private?

The Eastern Cooperative Oncology Group (ECOG) is conducting this study. ECOG is a cancer group that conducts studies for the National Cancer Institute. Your study doctor is a member of ECOG or another group that is participating in this study. To help protect your privacy, ECOG has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS).

With this Certificate, ECOG cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about you or your involvement in this research. Note, however, that if an insurer or employer learns about your participation and obtains your consent to receive research information, then ECOG may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your privacy.

Finally, you should understand that your study doctor and ECOG are not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others and the Certificate does not prevent the review of your research records under some circumstances by certain organizations for an internal program audit or evaluation. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- Eastern Cooperative Oncology Group (ECOG)
- North Central Cancer Treatment Group (NCCTG)
- Southwest Oncology Group (SWOG)
- Cancer and Leukemia Group B (CALGB)
- American College of Surgeons Oncology Group (ACOSOG)
- National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)
- National Surgical Adjuvant Breast and Bowel Project (NSABP)
- The Breast Cancer Intergroup of North America (TBCI)
- National Cancer Institute (NCI)
- Food and Drug Administration (FDA)
- Other regulatory agencies and/or their designated representatives
- Central Laboratories
- Genomic Health, Inc.
- Cancer Trials Support Unit (CTSU). The CTSU is a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.

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). Sometimes tissue or blood is used to better understand inherited genetic defects (genetic changes that are passed on in families) that predispose some people to develop cancer. This is often called 'genetic testing'. The results of genetic research may not apply only to you, but to your family members. For diseases caused by gene changes, the information in your health record could also be used against you or your family members. For example, insurance companies may also deny a patient insurance or employers may not hire someone if they have had a genetic test which indicates that they may at greater risk for developing certain illness (such as cancer). If your tissue is used for genetic research, it will be done in such a way that the results cannot be related to you as an individual, and will not appear in your health records.

How am I protected?

The Eastern Cooperative Oncology Group and other federally funded research groups participating in this study will make sure that information about you is kept private. These groups will take careful steps to prevent misuse of records. Your name, address, phone number and other identifying information will be taken off anything associated with your tissue before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person, which will help to protect your privacy.

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

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 or your insurance company will not be charged for the laboratory research studies performed by designated central laboratories for this study.

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 study doctor in person or call him/her at 253-403-3877.

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.

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 doctor at the number listed on the cover page.

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

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

Consent Form for Use of Tissue and/or Blood for Research

About Using Tissue and/or Blood for Research

You have had a biopsy (or surgery) to diagnose your breast cancer. A sample of left over cancer tissue is routinely stored in the pathology laboratory of the hospital where you had your biopsy, which is part of standard medical practice. If you participate in this study, a sample of your breast cancer tissue will be sent to laboratories for research studies.

We would like to keep any tissue that is left over, and if available, extra tissue from the pathology laboratory of the hospital to be sent and stored for possible use in future research. You will also be asked to provide 4 tubes of blood (about 2-3 tablespoons) before you start any treatment. The tissue and/or blood samples will be stored in the Eastern Cooperative Oncology Group ("ECOG") Pathology Coordinating Office. These samples of tissue and blood are referred to as "specimens."

If you agree, the specimens will be kept and may be used in research to learn more about cancer and other diseases.

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 study 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 the left over 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 Eastern Cooperative 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 specimens 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 study 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. May we keep your tissue for use in future research to learn about, prevent, or treat cancer? I agree my tissue will be submitted for research.

Yes No

2. Do you give permission for samples of your blood to be drawn and sent to ECOG to be kept for use in future research to learn about, prevent, or treat cancer? I agree to provide additional blood for research.

Yes No

3. My specimens may be kept for research about other health problems (for example: causes of diabetes, Alzheimer's disease, or heart disease).

Yes No

4. Someone from this institution may contact me in the future to ask me to take part in more research.

Yes No

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 get a copy of this form. If you want more information about this study, ask your study doctor.

Signature

I have been given a copy of all 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.

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

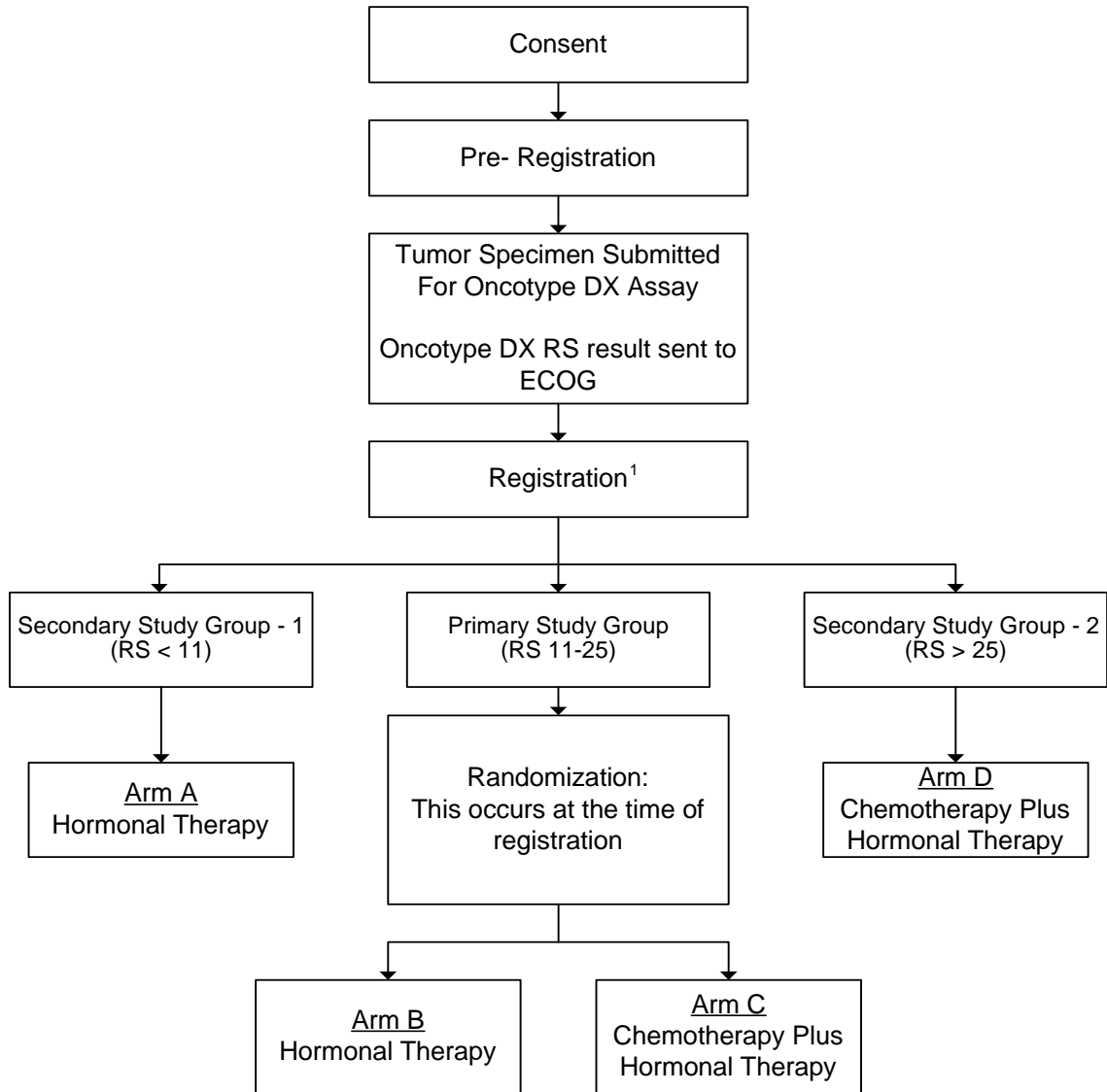
Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Permission: _____ Date: _____

Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



Patients who have had breast conservation surgery will also be treated with radiotherapy

Rev. 1/10 1. All patients who register will complete Quality of Life questionnaires at the time you enter the study and at 3 months, 6 months, 12 months, 24 months and 26 months.

**EASTERN COOPERATIVE ONCOLOGY GROUP (ECOG)
Authorization (Permission) to Use or Disclose (Release)
Identifiable Health Information for Research**

Participant's Name: _____

Birth Date: _____

1. What is the purpose of this form?

The Eastern Cooperative Oncology Group (ECOG), 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 ECOG 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, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- 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 ECOG 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 ECOG Biostatistical Center and the ECOG Operations Center if you enter a cooperative group research study. The ECOG centers will use your information in their cancer research study. Chemotherapy would normally be recommended for the treatment of your disease to lower the risk of your breast cancer recurring. The purpose of this study, PACCT-1, **Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial**, is to determine whether patients who have a tumor with an Oncotype DX Recurrence Score of 11-25 benefit from chemotherapy, and to confirm that most patients who have Oncotype DX Recurrence Score of ≤ 10 may be cured with hormonal therapy alone. [The Oncotype DX test (a test

performed by Genomic Health, Inc, Redwood, CA) involves analysis of cancer that has already been taken during your surgery.] Another objective is to create a tissue and blood specimen bank that includes specimens from all women who participate in this study, and to collect follow-up information regarding the health status of all women who participate in the study. This will allow researchers to evaluate new diagnostic tests in the future as they develop that may predict benefit or side effects from certain treatments.

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 the following 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 Eastern Cooperative Oncology Group (ECOG) Operations Center;
- The Eastern Cooperative Oncology Group (ECOG) Biostatistical Center;
- The Southwest Oncology Group (SWOG);
- The Cancer and Leukemia Group B (CALGB);
- The American College of Surgeons Oncology Group (ACOSOG);
- The National Cancer Institute of Canada Clinical Trials Group (NCIC CTG);
- The National Surgical Adjuvant Breast and Bowel Project (NSABP);
- The Breast Cancer Intergroup of North America (TBCI);
- The National Cancer Institute (NCI);
- The Food and Drug Administration (FDA);
- Genomic Health, Inc.;
- The Cancer Trials Support Unit (CTSU) or designees, a research group sponsored by the National Cancer Institute that supports the research of ECOG;
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- Other people or organizations assisting with ECOG research efforts. This may include drug manufacturers, drug companies that may provide partial support for the study, drug distributors, and/or their designees;
- Central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the bullets above.

5. How will information about me be kept private?

ECOG will keep all patient information private to the extent possible, even though ECOG is not required to follow this federal privacy rule. Only researchers working with ECOG or authorized by ECOG will have access to your information.

ECOG 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
Tacoma, WA 98405
(253) 403-1461

9. *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.

10. *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 ECOG 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: _____