

**Northwest Community Clinical Oncology Program (NWCCOP)**  
**MultiCare Health Research Institute**  
**315 Martin Luther King Jr. Way**  
**Tacoma, WA 98405**  
**Phone: (253) 403-1461 Fax: (253) 403-1615**  
Sponsored and Funded by the National Cancer Institute

### CONSENT FORM

**CIRB S0221: Phase III Trial of Continuous Schedule AC + G Vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node-Negative Breast Cancer.**

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**CIRB S0221: Phase III Trial of Continuous Schedule AC + G Vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node-Negative Breast Cancer.**

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your family and friends.

You are being asked to take part in this study because you have breast cancer that is considered high-risk.

**WHY IS THIS STUDY BEING DONE?**

**The main purpose of this study is to compare the effects (good and bad) of two different treatments (or “regimens”) for breast cancer. These two treatments include essentially the same drugs given in different ways and on different schedules. All of the treatments use standard, commercially available medicines that are known to be effective for treating breast cancer. The chance that your cancer will return or spread depends on a number of factors. You should discuss with your health care provider and/or the study doctor what the chance for return or spread is in your particular case both with and without various treatments.**

**The researchers would also like to learn whether there is any link between DNA or protein patterns from racial/ethnic groups and how your body metabolizes drugs and hormones. By analyzing your DNA or protein, researchers may be able to predict whether racial/ethnic groups with breast cancer will respond to specific drug therapies and whether this information can predict breast cancer survival. If you agree to submit to blood samples for this purpose, small amounts of your blood will be sent to a central laboratory where the DNA or protein will be extracted and analyzed. The studies done on your blood may lead to discoveries that may help future patients with breast cancer.**

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

About 3,250 people will take part in this study.



way to all patients. The paclitaxel is given differently in Arms 5 and 6. The numbers of the arms start at 5 because the study has been changed, and arms 1-4 are no longer being studied.

If you are assigned to Arm 5, you will receive the chemotherapy drugs doxorubicin and cyclophosphamide through a needle in your vein on Day 1 and pegfilgrastim as a shot under the skin on Day 2 every 14 days for four cycles (with each cycle being a 14-day timeframe). Two weeks after completing your last doxorubicin/ cyclophosphamide treatment, you will begin to receive the drug paclitaxel through a needle in your vein for 3 hours on Day 1 and on Day 2 pegfilgrastim is given as a shot under the skin every 14 days for six cycles.

If you are assigned to Arm 6, you will receive the chemotherapy drugs doxorubicin and cyclophosphamide through a needle in your vein on Day 1 and pegfilgrastim as a shot under the skin on Day 2 every 14 days for four cycles (with each cycle being a 14-day timeframe). Two weeks after completing your last doxorubicin/ cyclophosphamide treatment, you will receive the drug paclitaxel through a needle in your vein for one hour on one day every week for 12 weeks.

Regardless of which study arm you are assigned, you should drink 8 - 10 glasses of water per day while you are on cyclophosphamide.

Hormonal therapy will be given to you if your tumor is estrogen receptor-positive or progesterone receptor-positive as defined in the treatment plan. Hormonal therapy will be given within 1-28 days of completing adjuvant chemotherapy or at the discretion of your physician, within 1-28 days of the completion of radiation therapy, if given.

If you have tumors that are estrogen receptor-negative and progesterone receptor-negative, you will receive no adjuvant hormonal therapy.

If your tumor is estrogen receptor-positive or progesterone receptor-positive and you are a pre-menopausal woman (you have had your period within one year prior to entering the study) you could receive the following hormone treatments:

- Tamoxifen 20 mg once a day for five years, or
- Tamoxifen 20 mg once a day for five years plus removal of your ovaries or receive medical treatment to stop your ovaries from functioning for five years
- An aromatase-inhibitor for five years plus removal of your ovaries or receive medical treatment to stop your ovaries from functioning for five years. Entry onto the Southwest Oncology Group **S0230** and the intergroup trials IBCSG 24-02 (SOFT) and IBCSG 25-02 (TEXT) are allowed

If your tumor is estrogen receptor-positive or progesterone receptor-positive and you are a post-menopausal woman (you have not had your period for at least one year before entering the study, but not because of pregnancy) you could receive the following hormone treatments:

- Tamoxifen 20mg a day for five years, or
- An aromatase-inhibitor (such as anastrozole, femera or aromasin) for five years, or
- Entered on the intergroup study MA.27, a randomized trial comparing two aromatase-inhibitors (anastrozole and exemestane) in post-menopausal patients with hormone receptor positive breast cancer. You might be able to be treated on both this trial and MA.27, if you and your doctor wish. You can talk to your doctor about this possibility.
- If you completed 5 years of hormonal therapy, you may receive an additional 5 years of therapy with an aromatase inhibitor at the discretion of your doctor.

If you are a male whose tumor is estrogen receptor positive or progesterone receptor positive you could receive tamoxifen 20 mg a day for five years as your hormone treatment.

If you have tumors that are HER-2 positive (HER-2, human epidermal growth factor receptor 2; protein involved in the growth of some cancer cells), you may receive trastuzumab (Herceptin) either concurrently with the paclitaxel phase of therapy on any of the arms or sequentially (within 3 months of the last dose of paclitaxel). If trastuzumab is administered, you will first receive an initial loading dose of the drug through a needle in your vein, then you will receive one (1) weekly dose of trastuzumab or a dose every three weeks (or a combination of these schedules), depending on the decision of your study doctor. Regardless of dosing schedule, you would be given trastuzumab for a total of 52 weeks. The addition of trastuzumab is considered optimal treatment for patients with HER-2 positive tumors. The drug is not a specific part of this study and will not be supplied through the study.

**If you agree to submit samples for DNA polymorphism and/or serum analysis the following will be done:**

A total of 17 mL of blood will be collected (one 10-mL tube for serum protein analysis and one 7 mL tube for DNA analysis). Blood samples will be submitted before you begin treatment. The samples will be sent to a central laboratory for testing. This is not mandatory. You can still take part in the treatment study if you do not submit specimens for this testing.

## HOW LONG WILL I BE IN THE STUDY?

We expect that your initial treatment will take about 20 weeks. Patients with estrogen receptor-positive or progesterone receptor-positive tumors will receive five years of hormonal therapy after their initial treatment.

After your initial treatment is done we would like to examine you every six months for the first 5 years and then once a year for a maximum of 15 years to see how you are doing.

The researcher may decide to take you off this study if your disease gets worse despite the treatment; the side effects of the treatment are too dangerous for you; new information about the treatment becomes available and this information suggests the treatment will be ineffective or unsafe for you. It is unlikely, but the study may be stopped early due to lack of drug supply or lack of funding.

## WHAT ARE THE RISKS OF THE STUDY?

**While on the study, you are at risk for these side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs may be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the drug therapies are stopped, but in some cases side effects can be serious or long-lasting or permanent.**

**Risks and side effects related to the doxorubicin, cyclophosphamide, and pegfilgrastim treatment include:**

**Likely: (doxorubicin, cyclophosphamide, pegfilgrastim)**

- Nausea and vomiting
- Loss of appetite
- Heartburn
- Hair loss
- Low white blood cell counts which may make you more susceptible to infection
- Low platelet counts which may make you bruise more easily and bleed longer if injured
- Low red blood cell counts which may cause tiredness, shortness of breath or fatigue

**Less Likely:**

- Sores in the mouth
- Hand-foot syndrome (tingling pain and redness of the hands and feet)
- Change in color of fingernails and toenails
- Loosening of fingernails and toenails
- Inflammation or damage to the skin and around the IV tubing.
- Bladder inflammation (prevent this by drinking 8 - 10 glasses of water each day and emptying your bladder frequently)
- Bone or joint pain
- Cramps in the legs or back

**Rare but Serious:**

- **Heart damage**
- **Increased risk of blood cancer or other secondary cancers**
- **Spleen Rupture (related to pegfilgrastin use):** Your spleen may become enlarged and can rupture while taking pegfilgrastin. A ruptured spleen can cause death. The spleen is located in the upper left section of your stomach area. This pain could mean your spleen is enlarged or ruptured.
- **Serious Allergic Reactions (related to pegfilgrastin use):** Pegfilgrastin can cause serious allergic reactions. These reactions can cause a rash over the whole body, shortness of breath, wheezing, dizziness, swelling around the mouth or eyes, fast pulse, and sweating.
- **A serious lung problem called acute respiratory distress syndrome (ARDS) resulting in shortness of breath, trouble breathing, or a fast rate of breathing have been reported in patients using pegfilgrastin.**

**Risks and side effects related to the paclitaxel treatment schedule:**

**Likely**

- **Low white blood cell counts which may make you more susceptible to infection**
- **Low platelet counts which may make you bruise more easily and bleed longer if injured**
- **Low red blood cell counts which may cause tiredness, shortness of breath or fatigue**
- **Mild to severe allergic reaction, which may be life threatening with hives**
- **Wheezing and low blood pressure**
- **Numbness and pain of the hands and feet that sometimes worsens with additional treatment and may not disappear after the drug is stopped. This may lead to difficulty walking, buttoning clothes, etc.**
- **Hair loss**
- **Muscle weakness and muscle loss**
- **Muscle and joint aches**

**Less likely:**

- **A slowing of the heart rate (a slow pulse is not harmful; however if you should develop any other changes in heart rate during treatment, tests may be required)**
- **Irregular heartbeats**
- **Heart attack**
- **Nausea and/or vomiting**
- **Diarrhea**
- **Sores in the mouth or throat**
- **Fatigue**

- **Lightheadedness**
- **Headaches**
- **Kidney damage**
- **An increase in blood lipid levels which could increase risk of hardening of the arteries**
- **Liver damage**
- **Confusion**
- **Mood changes**
- **Skin irritation and swelling if the drug leaks from the vein into which it is being injected into the surrounding skin**
- **Changes in taste**
- **Irritation of the skin at a site of previous radiation**
- **Rash**
- **Inflammation of the colon, pancreas or lungs**
- **Blurred vision or other changes in eyesight such as sensation of flashing lights or spots.**

**Rare but Serious:**

- **Liver failure**
- **Swelling of the brain**
- **Seizures**

**The following are risks that may or may not be associated with three different types of hormonal therapies (tamoxifen, anastrozole, and goserelin).**

**Tamoxifen**

**Likely:**

- **Hot flashes**
- **Nausea (vomiting is rare)**
- **Vaginal bleeding**
- **Vaginal discharge and dryness**
- **Menstrual irregularities**
- **Skin rash**

**Less Likely**

- **Increase in calcium in the body**
- **Swelling in the arms, legs, hands and feet**
- **Loss of appetite**
- **Distaste for food**
- **Genital itching**
- **Depression**

- **Dizziness**
- **Headache**
- **Leg cramps**
- **Lightheadedness**
- **Hair thinning or partial hair loss**
- **Confusion**
- **Tiredness**
- **Abdominal pain or cramping**

**Rare, but Serious**

- **Blood clots in areas such as the lungs, legs and eyes**
- **Cataracts**
- **Secondary malignancy such as endometrial cancer**

**Anastrozole**

**Likely**

- **nausea and/or vomiting**
- **sore throat**
- **Hot flushes**
- **Weakness**
- **Joint pain**
- **Depression**
- **Rash**
- **Tiredness**

**Less Likely**

- **Diarrhea**
- **Trouble breathing**
- **Back pain or bone pain**
- **Constipation**
- **Cough**
- **Chest Pain**
- **Dizziness**
- **Flu syndrome**
- **Fever**
- **Headache**
- **Loss of appetite**
- **Stomach pain**
- **Numbness and tingling in hands and feet**
- **Fluid retention**
- **Sweating**

- Urinary tract infections
- Muscle pain
- Increased blood pressure
- Abnormal liver function test
- Bone fractures
- Vaginal bleeding
- Decreased red blood cell count
- Difficulty sleeping
- Thinning hair
- Vaginal dryness
- Sleepiness
- Increased cholesterol
- Dry mouth

**Rare but Serious**

- Blood clots
- Skin reactions involving ulcers

**Goserelin**

**Likely:**

- Menstrual periods stop for a while
- Hot flashes
- Headache
- Mood change
- Loss of libido
- Change in breast size
- Vaginal dryness
- Sweating
- Loss of bone density

**Less Likely:**

- Menstrual periods stop often and for a long time
- The influence of goserelin on breast cancer recurrence risk is unknown.

**Risks and side effects related to the trastuzumab (for patients with HER-2 positive tumors) include the following:**

**Likely (occurring in > 20% of patients):**

**Less Likely** (occurring in  $\leq 20$  % of patients)

- **A condition in which the heart muscle is abnormally enlarged or thickened.**
- **Loss of appetite**
- **Diarrhea**
- **Fever associated with dangerously low levels of a type of white blood cell (neutrophils)**
- **Lack of enough red blood cells (anemia)**
- **The heart stops pumping blood**
- **Decrease in heart's ability to pump blood during the "active" phase of the heartbeat (systole)**
- **Fluid in the sac around the heart**
- **Inflammation (swelling and redness) of the sac around the heart)**
- **Fast heartbeat; regular rhythm**
- **Fast heartbeat usually originating in an area located above the ventricles**
- **Belly pain**
- **Irritation or sores in the lining of the mouth**
- **Nausea or the urge to vomit**
- **Vomiting**
- **Chills**
- **Fatigue or tiredness**
- **Fever**
- **Flu-type symptoms (including body aches, fever, chills, tiredness, loss of appetite, cough)**
- **Chest pain not heart-related**
- **Pain**
- **Reaction during the infusion of a drug which may be life-threatening and may result in low blood pressure, fever, chills, difficulty breathing and kidney damage**
- **Infection**
- **Increased blood level of a liver and bone enzyme (alkaline phosphatase)**
- **Increased blood level of a liver enzyme (AST/SGOT)**
- **Increased blood level of a heart muscle protein (troponin I) indicating damage to the heart muscle)**
- **Increased blood level of a liver enzyme (GGT)**
- **Decreased number of a type of white blood cell (neutrophil/granulocyte)**
- **Decrease in the total number of white blood cells (leukocytes)**
- **Joint pain**
- **Back pain**
- **Bone pain**
- **Muscle pain**
- **Pain in the area of the tumor**
- **Headache or head pain**

- **Inflammation (swelling and redness) or degeneration of the peripheral nerves (those nerves outside of brain and spinal cord) causing numbness, tingling, burning**
- **Severe potentially life-threatening damage to the lungs which can lead to fluid in the lungs**
- **Stuffy or runny nose, sneezing**
- **Sudden constriction of the muscles in the walls of the bronchioles (small airways of the lungs)**
- **Cough**
- **Shortness of breath**
- **Decrease in the oxygen supply to a tissue**
- **Build up of a large amount of fluid between the layers of tissue that line the lungs and chest cavity**
- **Inflammation (swelling and redness) of the lungs**
- **Acne**
- **Skin rash with the presence of macules (flat discolored area) and papules (raised bump)**
- **Hives**
- **High blood pressure**
- **Low blood pressure**

**Rare, But Serious (occurring in < 3% of patients)**

- **Abnormal reaction of the body to substances, called allergens, that are contacted through the skin, inhaled into the lungs, swallowed or injected (allergic reaction)**
- **Serious potentially life-threatening type of allergic reaction that may cause breathing difficulty, dizziness, low blood pressure and loss of consciousness**
- **Abnormal build up of fluid in the lungs**
- **Scarring of the lungs that can cause shortness of breath and interfere with breathing**

**Reproductive risks: Because the drugs in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. Women should not nurse a baby while on this study. Ask about counseling and more information about preventing pregnancy. Doxorubicin and cyclophosphamide may also damage reproductive cells (eggs) and if you are a menstruating woman may begin having irregular menstrual periods or stop menstruating altogether.**

**Very rarely, severe bleeding or infection may result from lowered blood counts, and could be fatal.**

**For more information about risks and side effects, ask the researcher at the number listed on the cover page.**

**Risks from venipuncture (needed for drawing blood samples for DNA polymorphism/serum analysis): The risk from venipuncture is very small. There may be some bruising or bleeding at the site the blood is drawn.**

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

**We cannot and do not guarantee that you will benefit if you take part in this study. The treatment you receive may even be harmful. Your doctors feel that your participation in this study will give you at least as good a chance as you might expect from other treatments. We hope the information learned from this study will benefit other patients with breast cancer in the future.**

**The possible benefits of taking part in the study are the same as receiving similar chemotherapy without being in the study.**

**There is no benefit to taking part in the DNA polymorphism/serum analysis portion of the protocol. There may be some benefit to patients with breast cancer in the future.**

## WHAT OTHER OPTIONS ARE THERE?

**Instead of being in this study, you have these options:**

**You may be able to receive the same treatment combinations in this study without being in the study. You may choose to receive other chemotherapy combinations commonly used for this type of breast cancer without being in a study. You may be eligible for other treatment studies. You may also choose to have no anti-cancer treatment at this time (with care to make you feel more comfortable).**

**There may be other ways (besides the DNA polymorphism/serum analysis used in this study) of determining breast cancer survival. The methods used in this study are comparable to others that may be available. You also have the option of not having this procedure done on your blood samples. Please talk to your doctor about these and other options.**

## WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: the National Cancer Institute or its authorized representatives, the Food and Drug Administration, Amgen Pharmaceutical Company and the Southwest Oncology Group.

If we publish the information we learn from this study in a medical journal, you will not be identified by name or in any other way.

## WHAT ARE THE COSTS?

Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge.

Funds have been set aside by the hospital to compensate you in the event of injury. Although no government or drug company funds have been set aside to compensate you for injury or illness, you do not give up any of your legal rights for compensation by signing this form.

-OR-

Although no funds have been set aside to compensate you for injury or illness, you do not give up any of your legal rights for compensation by signing this form.

You may find a National Cancer Institute guide: "Clinical Trials and Insurance Coverage - a Resource Guide" helpful in this regard. You may ask your doctor for a copy, or it is available on the world wide web at <http://cancer.gov/clinicaltrials/insurance>

You or your insurance company will be charged for continuing medical care and/or hospitalization.

Medicare should be considered a health insurance provider.

You will receive no payment for taking part in this study.

Administration of the drug will be (provided free of charge/charged in the usual way). The parts of the research consisting of keeping research records will be paid by those organizing and conducting the research. The research requires that you receive certain standard medical tests and examinations. These standard tests and examinations will be charged in the usual way.

Doxorubicin, cyclophosphamide, paclitaxel, trimethoprim sulfa, and pegfilgrastim are commercially available and must be paid by you or your insurance company.

Filgrastim will be provided by Amgen Pharmaceutical. Pegfilgrastim may be provided free of charge through Amgen's Clinical Trial Product Access Program. Additionally (if needed), tamoxifen, goserelin, anastrozole, and trastuzumab are commercially available, and must be paid by you or your insurance company.

In the case of injury from venipuncture blood draws for the DNA polymorphism/serum analysis: other than medical care that may be provided at the discretion of the treating institution, and any other payment specifically stated in this consent form, there is no other compensation available for your participation in this part of the study.

## WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

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.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher at the number listed on the cover page.

For questions about your rights as a research participant, contact the MultiCare Health System Institutional Review Board (which is a group of people who review the research to protect your rights) at 253-403-3877.

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

## WHERE CAN I GET MORE INFORMATION?

You may call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

Visit the NCI's Web site...

[www.cancer.gov](http://www.cancer.gov)

For comprehensive clinical trials information go to

<http://cancer.gov/clinicaltrials>

For accurate cancer information go to <http://cancer.gov/cancerinformation>

You will get a copy of this form. Upon request, you will also receive a copy of the protocol (full study plan).

**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 main study. You may take part in these additional studies if you want to. You can still be a part of the main 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.**

We are also interested in whether or not use of certain medications, vitamins and supplements and other lifestyle habits during chemotherapy has any effect on your health while you are receiving treatment and afterwards. Right now, there are no strong data to guide decisions about whether or not to take supplements during treatment. It is unknown whether supplements will affect how well the treatment kills cancer cells (if it hurts or helps it), or how many side effects you may experience. We would like your permission to call you on the telephone and to send you a questionnaire to complete in a stamped envelope we will provide. This questionnaire asks about your use of medications, vitamins and supplements during your treatment and other lifestyle habits. We will ask you to complete the questionnaire at the beginning of treatment, at the end of treatment, and annually (from your date of registration) for a maximum of 15 years.

We would also like to use your blood specimen (if you consented to DNA polymorphism testing) to look at common forms of genes that may affect how antioxidants work in relation to your chemotherapy. There are very common differences in how active these genes are (for example, 25% of Caucasians have a more active form of an antioxidant gene), and we would like to look at whether or not these common differences affect how taking supplements may interact with your treatment.

We do not know whether taking supplements has any affect on treatment outcomes. We do not know if taking vitamins or supplements will make your treatment work better or worse. Therefore, this study should not interfere with your normal habits, and we would like you to continue either using or not using supplements according to your and your doctors decisions.

Except for the information we receive to contact you, the samples and the information you give to us will not have your name or any other personal identifying information on them. They will have only an ID number that will be assigned to you. The information that links your name with the code number and the signed consent forms will be kept in a locked file the SWOG statistical center that only certified investigators will have access to.

We need to ask your permission to contact you regarding use of supplements during treatment, and to use your blood sample to look at how inherited differences may affect how supplements impact treatment outcomes.

**(Please initial 'yes' or 'no' for each question)**

1. Do you give permission for a researcher to telephone you for a short interview and to mail you a brief questionnaire regarding medications, vitamins, supplements, and lifestyle habits before you begin protocol treatment, following completion of protocol treatment, and annually for 15 years?

Yes \_\_\_\_\_ No \_\_\_\_\_ Initials: \_\_\_\_\_

Please provide your contact information below:

Name \_\_\_\_\_

Address \_\_\_\_\_

Telephone Number \_\_\_\_\_

Consent for submission of blood samples for DNA polymorphism and serum analysis: This is not mandatory. You can still take part in the treatment study if you do not submit specimens for this testing.

2. Do you agree to submit blood samples for DNA polymorphism and serum analysis which will analyze how your body metabolizes drugs and hormones? (See Page 9 for background.)

Yes \_\_\_\_\_ No \_\_\_\_\_ Initials: \_\_\_\_\_

3. Do you give permission for the samples to be used to examine whether differences in genes that affect antioxidants may affect treatment outcomes?

Yes \_\_\_\_\_ No \_\_\_\_\_ Initials: \_\_\_\_\_

## SIGNATURE

You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer to take part in this study, and that you have read and understood all the information on 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 Authorization: \_\_\_\_\_

Printed Name of  
Person Obtaining Authorization: \_\_\_\_\_

Southwest Oncology Group Serum Repository  
Roswell Park Cancer Institute  
Elm and Carlton Streets  
Buffalo, NY 14623  
Phone: 716/845-8165  
FAX: 716/845-1356

Southwest Oncology Group Solid Tumor Tissue Bank  
Department of Pathology  
University of Colorado HSC at Fitzsimons  
RC-1 South, Room L18-5400A  
12801 East 17<sup>th</sup> Avenue  
Aurora, CO 80045  
Phone: 303/724-3086

### **Consent Form for Use of Specimen For Research**

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

**You have had a biopsy (or surgery) as part of your treatment. Your doctor has removed some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care. You have also had blood taken for special testing on this study.**

We would like to keep some of the tissue and blood that is left over for future research. If you agree, this tissue and blood will be kept and may be used in research to learn more about cancer and other diseases. Please read the question and answer sheet (attached) called "How are Specimens Used for Research" to learn more about tissue research.

The research that may be done with your tissue and blood probably will not help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your tissue and blood 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 the left over tissue and blood 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 tissue and blood 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 tissue or blood. Then the tissue and blood will no longer be used for research.

In the future, people who do research may need to know more about your health. When the Southwest Oncology Group gives them reports about your health, it will not give them your name, address, or phone number.

Sometimes tissue and blood are used for genetic research (about diseases that are passed on in families). Even if your tissue or blood is used for this kind of research, the results will not be put in your health records.

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

**Benefits**

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

There are very few risks to you. The greatest risk is the release of information from your health records. The Southwest Oncology Group will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

Please read each sentence below and think about your choice. After reading each sentence, check "Yes" or "No." **No matter what you decide to do, it will not affect your care.** If you have any questions, please talk to your doctor or nurse. For questions about your rights as a research participant, contact the MultiCare Health System Institutional Review Board (which is a group of people who review the research to protect your rights) at 253-403-3877.

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**1. My tissue and blood may be kept for use in research to learn about, prevent, treat, or cure cancer.**

Yes, both tissue and blood \_\_\_\_\_

Blood only \_\_\_\_\_

Tissue only \_\_\_\_\_

No \_\_\_\_\_

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**2. My tissue and blood may be kept for research about other health problems (for example: causes of diabetes, Alzheimer's disease, and heart disease).**

Yes, both tissue and blood \_\_\_\_\_

Blood only \_\_\_\_\_

Tissue only \_\_\_\_\_

No \_\_\_\_\_

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**3. Someone from the Southwest Oncology Group may contact me in the future to ask me to take part in more research.**

Yes \_\_\_\_\_ No \_\_\_\_\_

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Please sign your name here after you check your answers.

Participant \_\_\_\_\_ Date \_\_\_\_\_

## **Tissue Consent Supplemental Sheet**

### **How is Tissue Used for Research?**

#### **Where does tissue come from?**

After a person has had a biopsy (or surgery) and all tests have been done, there may be some left over tissue. Sometimes, this tissue is thrown away because it is not needed for the patient's care. Instead, a patient can choose to have the tissue kept for future research. People who are trained to handle tissue and protect donors' rights make sure that the highest standards of quality control are followed by the Southwest Oncology Group. Your doctor does not work for the Southwest Oncology Group, but has agreed to help collect tissue from many patients. Many doctors across the country are helping in the same way. If you agree, only left over tissue will be saved for research. Your doctor will not take more tissue during surgery than needed for your care.

#### **Why do people do research with tissue?**

Research with tissue can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using tissue can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

#### **What type of research will be done with my tissue?**

Many different kinds of studies use tissue. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your tissue may look for genetic causes and signs of disease.

#### **How do researchers get the tissue?**

Researchers from universities, hospitals, and other health organizations conduct research using tissue. They contact the Southwest Oncology Group and request samples for their studies. The Southwest Oncology Group reviews the way that these studies will be done, and decides if any of the samples can be used. The Southwest Oncology Group gets the tissue and information about you from your hospital, and sends the tissue samples and some information about you to the researcher. The Southwest Oncology Group will not send your name, address, phone number, social security number or any other identifying information to the researcher.

#### **Will I find out the results of the research using my tissue?**

You will receive the results of your biopsy, but you will not receive the results of research done with your tissue. This is because research can take a long time and must use tissue samples from many people before results are known. Results from research using your tissue may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

#### **Why do you need information from my health records?**

In order to do research with your tissue, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to the Southwest Oncology Group. If more information is needed, the Southwest Oncology Group will send it to the researcher.

#### **Will my name be attached to the records that are given to the researcher?**

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

**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.

**How am I protected?**

The Southwest Oncology Group is in charge of making sure that information about you is kept private. The Southwest Oncology Group will take careful steps to prevent misuse of records. Your name, address, phone number and any 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 if I have more questions?**

If you have any questions, please talk to your doctor or nurse, or call our research review board at 253-403-3877.

## **Authorization to Use or Disclose (Release) Identifiable Health Information For Research**

Participant's Name: \_\_\_\_\_

Birthdate: \_\_\_\_\_

### ***1. What is the purpose of this form?***

The **Southwest Oncology Group** 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 identifiable health information, you must sign and date this form to give them your permission.

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

The researchers want to abstract and use the portions of your medical record that they will need for their research. If you enter a Southwest Oncology Group research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- the history and diagnosis of your disease
- specific information about treatments you received
- information about other medical conditions that may affect your treatment
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, 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
- tissue and/or blood samples, associated data related to the analysis of the samples

You may request a blank copy of the Southwest Oncology Group data forms from the Northwest CCOP to learn what information will be shared.

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

The Northwest CCOP will collect your health information and share it with the Southwest Oncology Group if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The Southwest Oncology Group researchers will use your information for the following cancer research study(ies). You are being asked to take part in a study known as SWOG 0221: Phase III trial of continuous schedule AC + G Vs. Q2 week schedule AC, followed by Paclitaxel given either every 2 weeks or weekly for 12 weeks as post-operative adjuvant therapy in node-positive or high-risk node-negative breast cancer.

**4. *Who will be able to use my 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 staff from these Groups to review your original records as required by law for audit purposes.

- the Southwest Oncology Group (SWOG)
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- public health agencies and other government agencies (including non-U.S.) as authorized or required by law
- other people or organizations assisting with Southwest Oncology Group research efforts and the Food and Drug Administration.
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above.

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

The Southwest Oncology Group will keep all identifiable health information confidential to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. The Southwest Oncology Group will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

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

If you do not sign this authorization form, you will not be able to take part in a 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 separate research consent form.

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

You can change your mind at any time and withdraw this authorization. This request for withdrawal must be made in writing. Beginning on the date you withdraw your authorization, no new identifiable 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 authorization, you will be removed from the research study at that time.

To withdraw your authorization, please contact the person below. She will make sure your written request to withdraw your authorization 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 authorization last?**

If you agree by signing this form that researchers can use your identifiable health information, this authorization 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 my identifiable health information?**

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

\*\*\*\*\*

**Signatures**

I agree that my identifiable health information may be used and disclosed for 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 Authorization: \_\_\_\_\_

Printed Name of Person Obtaining Authorization: \_\_\_\_\_