

Northwest Community Clinical Oncology Program (NWCCOP)

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CONSENT FORM

SWOG 0622: Phase II Studies of Two Different Schedules of Dasatinib (NSC-732517) in Bone-Metastasis Predominant Metastatic Breast Cancer.

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SWOG 0622: Phase II Studies of Two Different Schedules of Dasatinib (NSC-732517) in Bone-Metastasis Predominant Metastatic Breast Cancer.

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 study because you have breast cancer that has spread to other parts of your body.

Who is doing this study?

The Southwest Oncology Group (SWOG) is sponsoring this trial. SWOG is an adult cancer clinical trials organization, supported by United States taxpayers through the National Cancer Institute. Your study doctor is one of 4,000 physicians who participate in SWOG trials.

Why is this study being done?

Dasatinib is a drug that has been used to treat leukemia, however we would like to find out if the drug is able to slow the growth of your breast cancer and prevent your breast cancer from spreading to and breaking down bones any further.

This study is investigational and is being done to find out if taking the drug dasatinib by mouth by either of two different dosing schedules will help control your cancer and whether it will affect your bones.

In addition to the usual CT scan and bone scan monitoring of your cancer, your doctor will send blood to a central laboratory to help monitor your response to treatment and a second blood test to monitor for circulating tumor cells in your blood. Information about storing any leftover blood specimens to be used for future research studies is attached at the end of this consent form.

How many people will take part in the study?

About 80 people will take part in this study.

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

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.

- Medical History and Physical Exam
- Weight and Performance Status
- Electrocardiogram (EKG) to monitor your heart function. If you are on trastuzumab (Herceptin[®]) while on protocol treatment, you will also need a MUGA scan or echocardiogram. These tests provide a graphic outline of the heart's movement and are used to determine if any heart disease is present.
- Disease Assessment including CT scans, bone scans, and x-rays.
- Routine laboratory blood tests (to measure your blood counts and your kidney and liver function)
- A tumor marker test (CA 15-3 or CA27-29)

If you are currently on a bone-strengthening agent, such as zoledronic acid (Zometa[®]) it will have to be stopped at least 3 weeks prior to your enrollment in this study. This may be associated with a slight increased risk (about 10%) of having a problem with your bones related to your bone metastases, such as needing radiation treatment or having a bone fracture in an area of metastasis. Although the study drug dasatinib could have similar effects in preventing bone problems related to metastases, this has not yet been tested in patients.

During the study ...

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

- Complete blood count (CBC) (A test to check the number of red blood cells, white blood cells, and platelets in a sample of blood.) and routine laboratory blood tests: At Weeks 4, 8, 12, 16, 20, and 24.
- Medical History and Physical Exam: At Weeks 4, 8, 16, and 24, and then every 3 months as long as your cancer is not progressing.
- Weight and Performance Status: At Weeks 4, 8, 16, and 24, and then every 3 months as long as your cancer is not progressing.
- Electrocardiogram (EKG) to monitor your heart function: At Weeks 8, 16, and 24; if you are on trastuzumab (Herceptin[®]) while on protocol treatment, you will need a repeat MUGA or echocardiogram testing every 12 weeks.
- Disease Assessment (including CT scans, bone scans, and x-rays): At Weeks 8, 16 and 24, and then every 8 weeks as long as your cancer is not progressing.

The experimental procedures that will be done in this study are the following:

- You will be "randomized" into one of the two study groups described below. This means that you are put into a group by chance. It is like flipping a coin. Which group you are put into is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group.
- You will receive the drug dasatinib. If you are in Arm 1 of the study, you will receive dasatinib in the form of two 50 mg pills (for a total of 100 mg) to be taken by mouth once daily (100 mg total daily dose). If you are in Arm 2 of the study, you will receive dasatinib in the form of one 50 mg pill and one 20 mg pill (for a total of 70 mg) to be taken by mouth twice daily (140 mg total daily dose). This treatment will be repeated continuously as long as your cancer is not increasing in size or begins to spread to other parts of your body. The dose may be reduced if you experience side effects. If your disease or symptoms get worse, you will stop treatment on this study and be offered other treatment by your study doctor.
- Each "arm" will be closed to new patient entry after the first 40 patients are registered to that "arm". An "arm" will not be re-opened until a response is seen in that "arm". Depending on the time you enter the study, how many patients have been entered before you, whether any patients have responded to treatment, or other reason, one or both of the "arms" may be open at the time your treatment is assigned.
- Your study doctor will send blood (about 30 mL or 6-9 teaspoons) on Weeks, 1, 4, 8, 16, and 24 to a central laboratory for testing of tumor markers, circulating tumor cells, and bone markers. The results of these blood tests will not be available to you as their use in monitoring response to this type of treatment is experimental. These tests will not be billed to you or your insurance.
- Prior to beginning your treatment and then at Weeks 8, 16, and 24, you will be asked to complete one questionnaire. The questionnaire will take approximately 5 minutes to complete. The questionnaire will ask about how much pain you are experiencing, how pain affects your day to day activities, and your rating of your overall quality of life.
- With your permission on the attached "Consent Form for the Use of Specimens for Research" leftover blood will be sent to a bank for future studies. If you decide to participate, the leftover blood from the tests to monitor your response to the protocol treatment will be submitted. This testing is an optional part of the study. You can still take part in the treatment even if you decide not to allow any of your blood to be sent for future testing. Your decision will not affect your care in any way. The results of the testing on your blood will not be given to you or your doctor. Although the results will not affect your treatment, research using your blood may help future patients. Reports about research done with your blood will not be put in your health records. Results from these studies may be published, but you will not be identified in these publications.

How long will I be in the study?

Following the completion of treatment in this experimental study, your doctor will continue to follow your health status for this study every 3 months until your cancer increases in size or begins to spread to other parts of your body. After the cancer has increased in size, your doctor will continue to follow your health status for this study every 6 months. These visits will continue for a maximum of 2 years from the time you entered the study. The follow-up evaluation tests that are standard to cancer care will include a medical history, physical examination, performance status, and x-rays or scans to see whether your cancer has become worse.

The study doctor may decide to take you off this study if your disease gets worse despite the treatment; if the side effects of the treatment are too dangerous for you; or if 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 funding.

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 stopping early can be discussed with you by your study doctor. Another reason to tell your 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?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, 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 the completion of this experimental chemotherapy combination. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study. This is very important to do, even if the side effects are occurring in between your visits with the study doctor, because if you are having side effects your chemotherapy dose may be held of adjusted.

Risks and side effects known to be related to the dasatinib treatment include the following:

Likely (these risks occurred in > 20% of patients taking dasatinib)

- Lack of red blood cells (anemia)
- Decreased number of a type of white blood cell (neutrophil/granulocyte):
- Decreased number of a type of blood cell that helps to clot blood (platelet)
- Decreased red blood cell protein called “hemoglobin” that carries oxygen in the body
- Shortness of breath
- Skin rash with the presence of macules (flat discolored area) and papules (raised bumps)
- Diarrhea
- Nausea or the urge to vomit.
- Belly pain
- Infection
- Headache or head pain
- Build up of a large amount of fluid between the layers of the tissue that line the lungs and chest cavity
- Fatigue or tiredness

Less Likely (these risks occurred in ≤ 20% of patients taking dasatinib)

- Vomiting
- Loss of appetite
- Weight loss
- Weight gain
- Constipation
- Fever
- Infection
- Chills
- Fluid in the sac around the heart
- Decreased blood level in calcium
- Decreased blood level of phosphate
- Increased blood level of a liver enzymes (ALT/SGOT)
- Increased blood level of a liver enzyme (AST/SGOT)
- Decrease in the heart’s ability to pump blood during the “active” phase of the heartbeat (systole)
- Cough
- Swelling of soft tissues in more than one part of the body
- Swelling or feeling of fullness or tightness in the abdomen (belly)
- Irritation or sores in the lining of the anus
- Irritation or sores in the lining of the mouth
- Irritation or sores in the lining of the rectum
- Irritation or sores in the lining of the small bowel
- Chest pain not heart related
- Pain

- **Belly pain**
- **Joint pain**
- **Muscle pain**
- **Inflammation (swelling and redness) or degeneration of the peripheral nerves (those nerves outside of brain or spinal cord) causing numbness, tingling, burning**
- **Irritation or sores in the lining of the throat**
- **Irritation or sores in the lining of the voice box**
- **Irritation or sores in the lining of the windpipe**
- **Itching**
- **Sore (ulcer) somewhere in the digestive tract**
- **Bleeding in some organ(s) of the digestive tract**
- **Dizziness (or sensation of lightheadedness, unsteadiness, giddiness, spinning or rocking)**
- **Fever associated with dangerously low levels of a type of white blood cell (neutrophils)**

Rare, but Serious (occurring in < 3% of patients taking dasatinib)

- **Group of signs and symptoms due to rapid breakdown of tumor that can occur after treatment of cancer has started that causes increased levels of blood potassium, uric acid, and phosphate, decreased levels of blood calcium and kidney failure.**
- **Bleeding in the brain**
- **Collection of symptoms including headache, confusion, seizures, and vision loss associated with imaging findings (MRI, CT scan)**
- **Abnormal electrical conduction within the heart**
- **Progressive necrosis (tissue death) of a part (the white matter) of the brain without inflammation (swelling and redness)**

NOTE: Dasatinib in combination with other agents could cause any adverse events currently known to be caused by other agents to be severe, or the combination may result in events never previously associated with either agent. Due to interaction with dasatinib, you must not consume grapefruit juice or take St. John's Wort while receiving dasatinib. You should tell your study doctor about all medications (over the counter, herbal, and prescription) that you are taking as they may interact with your treatment.

Reproductive risks: Because the treatment in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study and for 3 months after completing protocol treatment. You 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.

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. While doctors hope this therapy will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We hope the information learned from this study will benefit future patients with breast cancer that has spread to the bones. 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?

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:

- The National Cancer Institute (NCI)
- The Food and Drug Administration (FDA)
- The Southwest Oncology Group
- Bristol Myers Squibb (makers of dasatinib)
- Veridex, LLC

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. These costs include the costs of the routine blood monitoring and x-rays or scans that are done during the 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 research blood work will be done free of charge. 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.

Bristol Myers Squibb (BMS), will provide you with the investigational agent (dasatinib) at no cost to you while you are participating on this study. If you should need to take dasatinib much longer than is usual, the free supply of dasatinib given through this study will continue to be provided to you; if this happens, your study doctor will discuss this option with you.

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 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 this 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. For questions about the study or a research-related injury, contact *the Northwest Community Clinical Oncology Program, 253-403-1461*. For questions about your rights as a research participant, call *MultiCare Health System Institutional Review Board at 253-403-3877*. The Institutional Review Board (IRB) is a group of people who review research studies to protect your rights.

The physician(s) involved with the medical care of the patient is available to answer **ANY** question(s) concerning the research/drug program. In case of a problem or an emergency, the physician should be contacted by telephone (see cover sheet).

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.

Future Contact

Occasionally, researchers working with the Southwest Oncology Group (SWOG) may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, we would need to contact participants in a particular study. You can agree or not agree to 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

Consent for use of excess blood for research purposes

We would also like to bank a serum specimen 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 an additional blood specimen for future research. If you agree, this specimen 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.

Your specimens will be kept at:

Southwest Oncology Group Solid Tumor Tissue Bank

University of Colorado HSC at Fitzsimons
Department of Pathology
RC-1 South, Room L18-5104
12801 East 17th Avenue
Aurora, Co 80010
Phone: 303/724-3086

Things to Think About

The choice to let us keep the additional specimen 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 specimen 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 on the specimens 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 specimen is used for this kind of research, the results will not be put in your health records.

Your specimen will be used only for research and will not be sold. The research done with your specimen 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 specimen from a Southwest Oncology Group Specimen Repository in the future, a written withdrawal of consent should be submitted through your treating physician 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/>

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

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.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

Specimen Consent Supplemental Sheets

How are Specimens Used for Research?

Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens 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 specimens from many patients. Many doctors across the country are helping in the same way.

Why do people do research with specimens?

Research with specimens 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 specimens 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 specimen?

Many different kinds of studies use specimens. 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 specimen may look for genetic causes and signs of disease.

How do researchers get the specimen?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. 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 specimen and information about you from your hospital, and sends the specimen 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 specimen?

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen 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 specimen, 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 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 specimen 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

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 Community Clinical Oncology Program (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).

S0622, "Phase II Studies of Two Different Schedules of Dasatinib (NSC-732517) in Bone-Metastasis Predominant Metastatic Breast Cancer"

Dasatinib is a drug that may be able to slow the growth of breast cancer, and it may be able to prevent breast cancer from spreading to and breaking down bones. This study is investigational and is being done to find out if taking the drug dasatinib by mouth by either of two different dosing schedules will help control your cancer and whether it will affect your bones.

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
- The Northwest CCOP
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute 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.
- 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 CCOOP. 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: _____