Fred Hutchinson Cancer Research Center
University of Washington School of Medicine

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

A Phase I/II Trial Combining Avelumab and Trabectedin for Advanced Liposarcoma and Leiomyosarcoma

PROTOCOL NO.: FH9717

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Emergency phone:

- Monday through Friday, 9 am to 5 pm: Seattle Cancer Care Alliance at **206-606-7400**
- 24 Hours: University of Washington Medical Center paging operator at **206-598-6190.** Ask the operator to page the oncology fellow on-call.

Important things to know about this study.

Your doctors are inviting you to participate in a research study. The purpose of this research is to test the safety and efficacy of combining a new drug called avelumab with standard trabectedin therapy.

If you agree to join the study, you will receive avelumab in combination with trabectedin.

We do not know if avelumab would help trabectedin work better and it could cause increased side effects.

You do not have to join this study. You could choose to receive standard methods to treat your sarcoma. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. Afterwards, you can ask questions that will help you decide whether to join the study. If you join this study, we would give you a signed copy of this form to keep for future reference.

We invite you to join this research study.

We invite you to join this research study because you have Liposarcoma or Leiomyosarcoma. About 34 people will join this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in the study. You are free to say “yes” or “no”, or to drop out after joining. If you say “no,” you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

We are doing this study to determine whether a new drug called avelumab can improve the activity of standard treatment using trabectedin (Yondelis). We want to know if this combination is safe and effective.

Although thousands of patients have been treated with avelumab either alone or in combination with other drugs, it has never before been combined with trabectedin.

In this study, we want to learn what effects, good or bad, the combination of avelumab and trabectedin has on people with liposarcoma and leiomyosarcoma. If you join this study, we would give you this combination and watch carefully for any side effects.

What research tests, procedures, and treatments are done in this study?

This study will include a Phase I and Phase II portion. In the Phase I portion, we will determine the appropriate dose of trabectedin to be given with avelumab. The Phase II portion will use the dose we found in Phase I to treat additional patients. Your physician will tell you which phase of the trial you are in.

Detailed below are the procedures that will be done during your visits for this trial.

Screening

Tests will be done during a screening visit at the study clinic to make sure that this study is appropriate for you. These tests will be completed within 28 days of the first treatment on Week 1. After you review and sign this informed consent form, these tests and procedures will be done:

- Physical exam and vital signs, including height and weight
- Blood sample collection for
    - Routine safety tests such as a complete blood count, comprehensive metabolic panel
    - Thyroid function tests
    - Creatine kinase (CK)/creatinine phosphokinase (CPK) test
    - Pregnancy test if you are a woman who is able to have children
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drugs
- Urine sample collection for routine safety tests
- Electrocardiogram – tracing of the electrical activity of your heart (Phase I Portion Only)
- Echocardiogram or multigated acquisition scan (MUGA) to test if your heart function is normal.
- Computed tomography (CT) scans to look at your tumor. You may also have magnetic resonance imaging (MRI) if you are unable to have a CT scan or if your doctor feels that this test is better to look at your disease.
- If available, study staff will obtain tissue from a prior surgery or biopsy of your tumor for research testing. If this tumor is not available, you may still participate in the trial and no additional biopsies are required.

When these tests and procedures are complete, the study doctor will review all of the information and make sure you can take part in the study. If your screening results qualify and if you agree to take part in the study, you will then be enrolled onto the study.

On-Study Visits

In general, the treatment schedule for patients on this trial is based on what you would receive if you were getting "standard" treatment. Trabectedin is usually given every 21 days while single agent avelumab is usually given every 14 days.

For this trial, you will receive trabectedin every three weeks (21 days, ±3 days) for the first six weeks. Avelumab will be given every two weeks (14 days, ±3 days). After the first six weeks, trabectedin will be given every 4 weeks to reduce the number of visits you need to make to Seattle Cancer Care Alliance.

Below is a table showing when you will receive the study drugs during the first 12 weeks, if you do not need a dose delay or modification:

	Week											
Drug	1	2	3	4	5	6	7	8	9	10	11	12*
Avelumab	●		●		●		●		●		●	
Trabectedin	●			●			●				●	

*Week 12 is when you will have your first CT or MRI scan for disease assessment.

The following procedures will be done at each treatment visit, unless otherwise specified:

- Physical exam and vital signs, including weight
- Blood sample collection for
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Thyroid function tests
    - CK/CPK test, only on days you receive trabectedin
    - Research blood tests – done to understand your immune system, sarcoma, and how your disease may respond to the study drugs. This will be done on treatment days until you have your first CT or MRI scan. Then we will collect this every 6 weeks on treatment days for the rest of the trial.
- Urine pregnancy test (or blood test) if you are a woman who is able to have children
- Echocardiogram or multigated acquisition scan (MUGA) to test if your heart function is normal. This will be done on Week 6, then every 12 weeks while you are receiving trabectedin.
- CT or MRI scan – done every 12 weeks while on treatment
- Study treatment as described in the diagram above

End of Treatment (EOT) Visit

If your cancer gets worse, or you choose to stop treatment, you would have three additional visits. One will be on the day you end treatment (EOT), a 30-day safety follow-up visit, and a 90-day safety follow-up visit . The following procedures will be

done at your EOT visit:

- Physical exam and vital signs, including weight
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Thyroid function tests
    - CK/CPK test
    - Research blood tests
- Urine pregnancy test (or blood test) if you are a woman who is able to have children
- Electrocardiogram, if you are in the Phase 1 portion of the trial
- Tumor imaging if not done within the 4 weeks of your last visit

30-day Safety Follow-up Visit

The following procedures will be done at your 30-day safety follow-up visit:

- Physical exam and vital signs, including weight
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Thyroid function tests
    - CK/CPK test
- Urine pregnancy test (or blood test) if you are a woman who is able to have children
- Electrocardiogram, if you are in the Phase 1 portion of the trial

We will also ask you if you have started a new anti-cancer treatment.

90-day Safety Follow-up Visit

This visit may be done either in-clinic or over the phone to check on how you are doing and to make sure you are not experiencing adverse events related to the study treatment. If this visit is done over the phone, we may request for you to come into the clinic if any concerns are noted.

Long-Term Follow-up

Every 12 weeks after your 90-day follow-up visit, we will contact you either by phone or review your medical record for up to two years, to check on how you are doing, to receive information about your cancer status, and about your current cancer therapy. After two years, this follow-up will change to every 6 months.

How long would you stay in this study?

If you join this study, you would stay in this study until your disease progresses. If your disease progresses, we may contact you by phone every 12 weeks to see how you are doing until the study closes.

Doctors could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

With some immunotherapy drugs, people's first set of scans after starting treatment show their disease getting worse (progressing), but the next scan might show the disease getting better. We will tell you if any scan shows that your disease is progressing. If your first scan shows progressive disease but you are doing well overall, you may be allowed to continue on the study until progression is confirmed on one additional scan. We do not know if the next scan would show that your disease is better, worse, or the same. Staying on the study would delay your opportunity to try another treatment. As always, you are allowed to leave the study at any time or ask your doctor to discuss other treatments that may be right for you.

What are the side effects (risks)?

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. The combination of trabectedin and avelumab could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

If you join this study, we would tell you if we discover new side effects that could affect you.

This form lists side effects of *individual* drugs. Other side effects could occur when we use these drugs *together*.

Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Many side effects go away soon after you stop taking trabectedin and avelumab. In some cases, side effects can last a long time or never go away. There also is a risk of death.

Risks of Trabectedin:

Trabectedin is an FDA-approved chemotherapy that is part of the standard of care for soft-tissue sarcoma. It is likely to make you feel tired and nauseated. We are generally able to keep the nausea from getting too bad using drugs to make you feel better.

Trabectedin can sometimes weaken your immune system and could make you susceptible to life-threatening infections. Because of this, if you have a fever during the weeks following your trabectedin infusion, you should seek medical attention immediately. It can also lower your blood counts and occasionally people even need a blood transfusion.

Although very rare, trabectedin can cause heart problems, this is why we require an Echocardiogram or MUGA scan prior to study entry.

There is a very rare, but very serious and potentially fatal, problem that trabectedin can cause called rhabdomyolysis. This is a problem of wide-spread muscle breakdown. If you have severe generalized muscle pain or feel very ill generally, seek immediate medical attention

Most Common (greater than or equal to 20% of subjects) side effects of trabectedin are:

- Fatigue
- Vomiting
- Nausea
- Constipation
- Loss of appetite
- Diarrhea
- Swelling of your hands, ankles, and feet
- Shortness of breath
- Headache
- Back pain and stomach pain

Less Common (greater than or equal to 5% of subjects) side effects of trabectedin are:

- Decreased red blood cell count (anemia), which may cause you to be tired
- Decreased platelet cell counts (thrombocytopenia), which may make it miore likely that you have bleeding
- Changes in liver and kidney function blood tests
- Decreased level of white blood cell counts, which can increase your risk for infection
- Increase in creatinine phosphokinase (CPK), an enzyme found in your heart, brain and skeletal muscles. High levels usually indicate some type of stress or injury to your heart or other muscles.

Rare But Serious (less than 2% of subjects) side effects at these doses of trabectedin are:

- Rhabdomyolysis (explained above)
- Liver failure

- Severe infection
- Heart muscle problems, including heart failure
- Acute kidney injury or failure
- Small bowel obstruction
- Capillary Leak Syndrome, a condition that causes fluid to leak out of blood vessels into different tissues. This can cause swelling, a sudden drop in blood pressure, and a drop in a blood protein called albumin. This can be fatal.
- Severe allergic infusion reactions, can be fatal
- Development of a blood cancer such as leukemia or myelodysplastic syndrome (MDS), can be fatal
- Damage to tissue or tissue death if trabectedin leaks outside of the IV during infusion.

There have also been rare cases of death related to trabectedin. This includes patients who have had multi-organ failure, kidney failure, liver failure, bleeding of the stomach or bowel, fluid in the lungs, blood clots in the lungs, and infections with low blood counts leading to septic shock (neutropenic sepsis).

Risks of Avelumab

Although Avelumab has been tested in prior clinical trials and has an established safety record, it is important to note that it is still an investigational therapy that has not yet been approved by the FDA. Avelumab is generally well tolerated for a majority of patients but it can cause side effects which in some cases can be very serious.

The likely (>10%) side effects of avelumab are:

- Anemia (low red blood cells)
- Diarrhea
- Constipation
- Nausea
- Vomiting
- Abdominal (stomach) pain
- Fatigue
- Fevers
- Edema (swelling)
- Infusion reactions
- Weight loss
- Decreased appetite
- Back and joint pain

- Cough
- Shortness of breath

The less common (1-10%) side effects of avelumab are:

- Problems with the thyroid gland which makes hormones including low thyroid function, too much thyroid hormone, inflamed thyroid and autoimmune thyroid destruction
- Chills
- Dizziness
- Headaches
- Inflammation of the lungs (pneumonitis)
- Rash or itching
- High blood pressure

Avelumab can rarely have very serious autoimmune effects which can even be fatal. The rare (<1%) side effects of avelumab are:

- Problems with the adrenal gland (adrenal insufficiency)
- Problems with the pituitary gland that makes hormones, which may cause headaches, stomachache, double vision, menstrual changes, weakness, skin darkening, rapid heartbeat (hypophysitis)
- Inflammation of the uvea in the eye (uveitis)
- Inflammation of the bowels and colon causing severe diarrhea (colitis)
- Liver problems ranging from abnormalities on routine lab tests to autoimmune hepatitis and liver failure
- Allergy to the medication including anaphylaxis
- Development of diabetes
- Inflammation of muscles may include weakness, aches, muscle tenderness, swelling, and pain (myositis)
- Inflammation of kidneys (nephritis)
- Kidney failure
- Inflammation of the heart which can cause chest pain, abnormal heartbeat, shortness of breath, and sudden death (myocarditis or pericarditis)
- Inflammation of the pancreas, which may include pain in the upper abdomen, nausea, vomiting, constipation, weight loss, or indigestion (pancreatitis)
- Small bowel obstruction
- Development of Myasthenia Gravis / Myasthenic Syndrome: a weakness and rapid fatigue of muscles your body uses for movement. Symptoms may include

weakness in the arm and leg muscles, difficulty with speech, swallowing or chewing, double vision, or an unsteady walk

Risks of Combination Therapy

One of most important reasons for doing this study is to confirm that the combination of trabectedin and avelumab is safe. We do not expect to see additional toxicities with the combination that are not seen with either drug alone, however this is possible. It is even possible those side effects could be serious or life threatening.

The combination of trabectedin and avelumab could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Many side effects go away soon after you stop taking trabectedin and avelumab. In some cases, side effects can last a long time or never go away. There also is a risk of death.

If you join this study, we would tell you if we discover new side effects that could affect you.

Port Inflammation and Clotting
Two side effects have been noted in subjects treated with avelumab and trabectedin in combination on this study. One is an increased risk of port inflammation and the other is clotting in the subject's ports.

5 subjects out of the 33 subjects (15.2%) treated on this trial have experienced port inflammation or irritation at their port site. You may notice redness or pain at your port site. If you experience this, please let the study team or your provider know. Your port may need to be replaced if this happens.

2 subjects out of the 33 subjects (6.1%) treated on this trial have experienced a blood clot within or near their port. These clots could require you to have your port removed and replaced and could even potentially cause more serious problems. We have made changes in the way the drugs are administered that we hope will prevent this problem in the future, however this remains a risk.

Although rates of inflammation and clotting are similar to what has been seen in published literature for trabectedin, there was one particularly severe clotting event for a subject on this trial that required surgical intervention. It is unclear if the addition of avelumab might have contributed in this case.

Reproductive risks

Trabectedin and avelumab treatments could cause sterility (unable to have children). For this reason, we recommend that males or females who are considering having children in the future consider either sperm banking or egg freezing. Discuss this with your doctor.

The risk of trabectedin and avelumab to an unborn child or nursing infant is unknown. Therefore, you cannot join this study if you are pregnant, if you are planning to become

pregnant, or if you are breast-feeding. You must agree to not become pregnant while you are in this study.

Women:

If you are able to have children and are sexually active, two effective methods of birth control must be used. This could include the following:

- Hormonal contraceptive
    - Oral pills
    - Intravaginal, such as the NuvaRing
    - Transdermal, such as a patch
    - Injectable, such as Depo-Provera
- Intrauterine device (IUD) or intrauterine hormone-releasing system (IUS)
- Double-barrier method
    - This includes the use of condoms, occlusive cap (diaphragm or cervical/vault caps) **with** spermicidal foam, cream, gel, film, or suppository.

Abstinence is an allowed method of birth control. If you are sexually active, you must agree to use 2 methods of birth control as explained above. These methods need to be discussed with your study doctor before you begin treatment. You will need to use birth control while you are on study through 5 months after your last dose.

If you get pregnant during the study, you must tell your study doctor immediately. You will have to stop taking trabectedin and avelumab. Your doctor will advise you about your medical care. We may ask you to allow us to follow your pregnancy for information about your health and that of your baby.

Men:

The effects of fathering a child while you are study treatment are also unknown. Men who join this study must also agree to use a condom or other form of effective and acceptable birth control while you are on study until at least 5 months after the last dose of trabectedin.

If your partner becomes pregnant while you are receiving treatment, you must tell your study doctor immediately. We may ask you to allow us to follow the pregnancy for information about your partner's health and that of your baby.

No sperm donations should be made from time of your first dose of study treatment until 5 months after the last dose of study drug.

Risks of Study Procedures

Blood draws: When you have your blood drawn you may feel some minor discomfort. Possible side effects include pain, redness, bruising or bleeding at the site of the needle

puncture. Some people feel lightheaded or faint when their blood is drawn. Rarely blood clots or an infection may occur.

CT Scans: You will be exposed to radiation at a level below the levels considered to cause harmful effects. If a contrast dye is used, there is a small risk of an allergic reaction. You may experience discomfort related to lying still in an enclosed space for a prolonged period of time.

MRI Scans: A loud banging noise will be produced. Earplugs or headphones will be available if needed. If a contrast dye is used, there is a small risk of an allergic reaction. You may experience discomfort related to lying still in an enclosed space for a prolonged period of time.

MUGA Scans: During the MUGA scan, a small amount of a radioactive substance or tracer (called a radionuclide) is put into your blood. The tracer attaches to your red blood cells. The amound of radiation exposure is similar to what you would receive in a CT Scan

Radiation: Some of the tests that you will have in this research study will expose you to radiation. Everyone receives a small amount of radiation every day called "background radiation". This radiation is natural and comes from space, air, water, soil, and the food you eat. Each year you are exposed to about 3 milliSieverts (mSv) of this background radiation. A milliSievert is a unit of radiation dose. For comparison, the estimated radiation dose from each of these tests is listed below. The risk to your health from this level of radiation exposure is likely zero.

- MUGA scan: 9.4 mSv
- CT scan of the chest: 7 mSv
- CT scan of the abdomen: 8 mSv
- CT scan of the pelvis: 6 mSv

Non-physical risks

If you join this study, non-physical risks are:

- You might not be able to work.
- You might have financial expenses caused by transportation to and from the doctor's office
- Results of research studies, including genetic tests, might be released by accident. This risk is very low, because we keep personal information private. If these results became known, you could have problems with family members or insurance.

What are the benefits?

We do not know if this study would help you. We are testing the addition of avelumab to trabectedin to see its effects on people with sarcoma. You might get better if you receive the combination of trabectedin and avelumab but your condition could stay the same or

even get worse. We hope the information from this study will help other people with sarcoma in the future.

You have other choices besides this study.

You do not have to join this study. You are free to say "yes" or "no". Your regular medical care would not change if you decide to say "no".

You have other choices for treatment. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

There may be other FDA-approved treatment choices for your disease that you have not received yet. This may include older chemotherapies such as doxorubicin or newer, FDA-approved drugs such as pazopanib or eribulin. Talk to your doctor about these other treatments as they may be good options for you.

Other choices include: trabectedin alone, another "standard" treatment like chemotherapy, another research study, no treatment, comfort care.

Enrollment in this study may exclude you from other research studies.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- The researchers involved in the study.
- EMD Serono (the maker of Avelumab) who is financially supporting the study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Research Center, University of Washington, Seattle Children's, and Seattle Cancer Care Alliance.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

Policies of the University of Washington (UW Medicine) and the Seattle Cancer Care Alliance (SCCA) require that certain information about participation in this research must be included in permanent medical records.

If you join this study but do not already have a medical record at UW Medicine or SCCA, we would create a record even if the only connection with UW Medicine or SCCA involves this research study.

The information in the permanent medical record would include:

- Name of the study.
- Name of the group or company that is paying for the research.
- The number the group or company assigned to this study.
- The name of the researcher.
- The name of the study coordinator.
- Contact phone number for the study.
- Contact email address for the study.
- Emergency phone number for the study.

If you join this study, information about research procedures and test results might also be put in your medical record. This information would include all scans and standard labs drawn as part of the study and may include non-standard research tests as well.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see the medical record, they would see a copy of this consent form.

How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevent health insurance companies or group health plans from

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

Would we pay you if you join this study?

There is no payment for being in this study.

Would you have extra costs if you join this study?

If you join this study, you or your insurance company would have to pay for the costs of standard treatment in this study.

You would **not** be billed for:

- Avelumab
- Correlative blood tests for research
- Tissue slides and curls from a previous biopsy
- 12-lead ECG done at screening and at the discontinuation of treatment
- Urine Pregnancy tests for women of child-bearing potential
- Thyroid tests, including TSH, Free T4, and Total T3

What if you get sick or hurt after you join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact one of the study coordinators, their numbers are below. They will refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

We invite you to donate tissue samples for other research.

After we do tests on tissue in this study, some tissue may be left over. We invite you to donate this leftover tissue for future research. This may include genetic research.

If you join this study, you would not have to donate tissue for research. You would be free to say “yes” or “no”. Regular medical care would not change if you say “no.”

If you donate tissue, it would be stored in a secure location. If we want to use your tissue for other research or share it with other scientists for research, an ethics review committee (IRB) would review the request. The IRB would decide if we need to ask you for permission to do the research.

Your donated tissue would be used only for research. This research could be done by for-profit companies. Researchers would not report their results to you or your doctors. The

research results would not be included in medical records. The results would not affect your medical care.

Research with tissue might help develop new products. If these products make money, there is no plan to share the money with the participants who donate the tissue.

If you donate tissue for research, you could withdraw the donation at any time by calling Roxanne Moore at 206-606-6425. You would have no penalty for withdrawing the donation, and regular medical care would not change. We could not return donated tissue, but we might be able to destroy the donated tissue. We could not destroy tissue if it is stored or shared without any label saying who donated it. In this case, it could still be used for research.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.
- If you decide to drop out, we would want you to tell the study doctor. The doctor could tell you about the effects of stopping avelumab and trabectedin. You and the doctor could talk about the follow-up care and testing that would help the most.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

For more information

If you have questions or concerns about this study, you could talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-667-6629 Dr. Seth Pollack 206-606-6425 Roxanne Moore (Assistant Director)
If you get sick or hurt in this study	206-667-6629 Dr. Seth Pollack
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	206-606-1113 (Seattle Cancer Care Alliance Patient Financial Services)

Emergency phone:

- Monday through Friday, 9 am to 5 pm: Seattle Cancer Care Alliance at **206-606-7400**
- 24 Hours: University of Washington Medical Center paging operator at **206-598-6190.** Ask the operator to page the oncology fellow on-call.

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to donate your tissue to study cancer? (circle one and initial next to choice) **YES** **NO**

Subject's Statement

I have read the information in this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to take part in this research study. If I sign this form I will not lose any of the legal rights that I would otherwise have as a subject in a research study.

CONSENT SIGNATURE:

_____
Subject Name (printed)

_____ _____
Signature of Subject (18 years and older) Date

Researcher's Statement

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____
Printed Name of Person Conducting the
Informed Consent Discussion

_____ _____
Signature of Person Conducting the Date
Informed Consent Discussion

Witness or Interpreter:

If you served as an interpreter or witness during the consent process, sign below to indicate you attest to the accuracy of the presentation to the participant and the apparent understanding of the research by the participant.

Printed Name	Signature	Date

Copies to: Researcher's file
Subject
Subjects medical record