

Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

**A Trial of Pembrolizumab in Combination with
Doxorubicin as Treatment for Patients with Advanced
Sarcomas**

[Short title: Doxorubicin + Pembrolizumab]

A trial for patients with advanced sarcoma.

Principal Investigator: Seth Pollack MD, University of Washington, Fred Hutchinson Cancer
Research Center. 206-667-6629

Study Coordinator: Jeff Gregory 206-667-5892
Sabrina McDonnell 206-667-1583

Emergency number (24 hours): 206-598-6190

Your doctors are inviting you to participate in a research study. The purpose of this research study is to test the safety and efficacy of the immunotherapeutic drug pembrolizumab in combination with a standard drug commonly used for sarcoma called doxorubicin.

If you agree to join the study, you will be treated using both of these drugs. Doxorubicin is one of the best established drugs for treating advanced sarcomas. Many sarcoma specialists use it first for the treatment of advanced disease. Pembrolizumab has been proven effective for the treatment of melanoma, non-small cell lung cancer and other cancers, but we do not know whether it will be effective for sarcoma patients. This trial will determine whether the combination of doxorubicin and pembrolizumab is safe and effective. Pembrolizumab, also known as Keytruda[®], will be provided by Merck.

While we do not know if pembrolizumab will help treat sarcoma, we do expect that some patients will have side effects. This consent form includes most of the side effects that we can predict might happen.

You do not have to join this study. You could choose to receive standard methods to treat your advanced sarcoma including doxorubicin alone, often considered the “standard of care” for many patients. 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.

The 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 advanced sarcoma. Up to 47 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 examine the safety and efficacy of doxorubicin and pembrolizumab. Pembrolizumab is a new drug that we hope will be effective for sarcoma patients. Doxorubicin is an established, standard drug for sarcoma. We hope that the two drugs will be safe when used together but there is no way to know for certain without performing a clinical trial. While there is a scientific rationale to

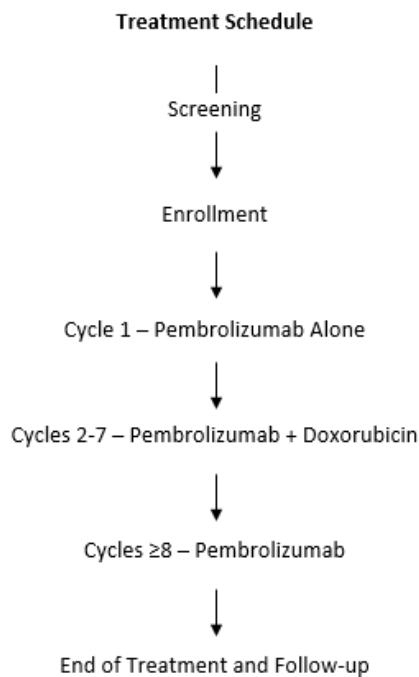
expect that the drugs together are more effective than either alone, we do not know whether this will really work well in sarcoma patients, and we are therefore doing a trial to test this theory.

Although doxorubicin is a very old treatment that has been used safely with many other drugs and pembrolizumab is also generally safe, these two drugs have never been used together and it is possible there will be side effects that we do not expect or predict.

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

There are two phases in this trial, a Phase I portion, and a Phase II portion. You will be notified by the study physician which phase you will be participating in. There are some differences in the procedures for each phase, which will be noted below. If you are one of the first 3-6 patients on this trial, you will receive a lower dose of doxorubicin than is typically given as standard of care, 45mg/m² vs 75mg/m².

In general, the treatment schedule for patients on this trial is similar to what you would receive if you were getting “standard” doxorubicin. Patients receiving standard doxorubicin get treatment every 21 days on a cycle. You will receive 1 cycle of pembrolizumab prior to starting doxorubicin. Below is a schematic outlining the treatment schedule. For the most part, you will be treated as you would if you were received standard treatment with doxorubicin.



Tests will be done during a screening visit at the study clinic to make sure that this study is appropriate for you. Some of the tests will be completed within 28 days and other within 14 days of the first treatment on Treatment Cycle 1.

During this study it is important that you check with your study doctor before starting any new medications. Taking other drugs (vaccines, prescription medications, over-the-counter medications, herbal remedies, or nutritional supplements) may cause additional side effects or even life-threatening reactions when combined with the drug(s) being used in this study. Specifically, any **live vaccines are prohibited within 30 days of starting study treatment and while on study**. Examples of live vaccines are measles, mumps, rubella varicella/zoster, yellow fever, rabies, BCG, and typhoid vaccine.

After you review and sign this informed consent form, these tests and procedures will be done:

- Physical exam and vital signs
- Blood sample collection for
 - Routine safety tests such as a complete blood count, comprehensive metabolic panel, and a coagulation panel
 - Thyroid function tests
 - 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
- Urine pregnancy test (or blood test) if you are a female of childbearing potential
- Electrocardiogram – tracing of the electrical activity of your heart
- Echocardiogram or multigated acquisition scan (MUGA) to test if your heart function is normal for any patients receiving doxorubicin.
- Computed tomography (CT) scans or 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. These tests can be done within 28 days of the first treatment on Treatment Cycle 1.
- If available, study staff will obtain tissue from extra tumor taken during your prior surgery or biopsies to be used 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 on to the

study. While on study, these tests and procedures will be done:

On Day 1 of Each Cycle:

- Physical exam and vital signs
- Blood sample collection for
 - Routine safety tests such as a complete blood count and comprehensive metabolic panel
 - Thyroid function tests
 - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drugs
 - These research samples will be collected on Cycles 1, 2, 5, 8, 12 and then every 4 cycles while you are on study treatment, and at end of treatment.
- Urine pregnancy test (or blood test) if you are a female of childbearing potential
- Electrocardiogram – During Phase I, EKGs will be done on day 1 of Cycles 2, 3, 4, 5, 6, 7, end of treatment and at the 30-day follow-up. During Phase II, EKGs will be done on day 1 of Cycles 2, 5, end of treatment and at the 30-day follow-up.
- Echocardiogram or multigated acquisition scan (MUGA) to test if your heart function is normal for any patients receiving doxorubicin. – Done on day 1 of cycle 4 on the Phase I portion of the trial.
- CT or MRI – Done on day 1 of Cycles 4, 8, and then every 12 weeks while on treatment.
- Study treatment. For cycle 1, you will receive pembrolizumab alone. For cycles 2-7, you will receive pembrolizumab and doxorubicin together. For cycles 8 and higher, you will continue to receive pembrolizumab as long as you are receiving clinical benefit for up to 2 years and no more than 35 cycles.

On Day 14 of cycles 2-7

- Routine safety tests such as a complete blood count and comprehensive metabolic panel

If your cancer gets worse, or you choose to stop treatment, you would have two additional visits, one on the day you end treatment, and one 30 days from the date of your last treatment. The following procedures will be done:

- Physical exam and vital signs
- Blood sample collection for
 - Routine safety tests such as a complete blood count and comprehensive metabolic panel
 - Thyroid function tests
 - Research blood tests
- Urine pregnancy test (or blood test) if you are a female of childbearing potential
- Electrocardiogram

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.

If you have a complete response, meaning all of your disease disappears completely, you will continue being treated until you have been treated for 24 weeks and have had the complete response for at least 2 cycles of pembrolizumab. After this, we will stop pembrolizumab but will continue to watch you closely. Should any disease recur, you could go back on pembrolizumab for up to one year.

If your disease is under control on the study for 2 years, we will stop pembrolizumab but continue to watch you closely. If your disease progresses within 12 weeks of stopping pembrolizumab, we would restart pembrolizumab for up to one year.

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.

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 doxorubicin and pembrolizumab 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 doxorubicin or pembrolizumab. In some cases, side effects can last a long time or never go away. There also is a risk of death.

Risks of Doxorubicin:

Doxorubicin is a traditional chemotherapy that is part of the standard of care for soft-tissue sarcoma.

The first group of patients participating in the study will get a lower dose of doxorubicin than is normally given in order to reduce the risk of adverse events. Your doctor will tell you if you will be receiving the lower dose of doxorubicin. As a single agent, this lower dose is less effective at controlling sarcoma than the higher dose.

It is very 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. Most people lose their hair while being treated with doxorubicin.

Doxorubicin is also likely to 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 doxorubicin infusion, you should seek medical attention immediately. It can also lower your blood counts and occasionally people even need a blood transfusion.

Doxorubicin can often causes heart problems when used at high doses but even at the doses used in this trial, serious heart problems can rarely occur, this is why we require an Echocardiogram or MUGA scan prior to study entry.

The following are known side effects of doxorubicin:

Likely side effects of doxorubicin are:

- fatigue
- hair loss
- nausea
- loss of appetite
- anemia (low red blood cells)
- immunosuppression (low white blood cells)

- sores in mouth
- low blood counts
- skin and nail discoloration
- urine discoloration
- light sensitivity

Rare but serious side effects at these doses of doxorubicin are:

- acute or chronic heart problems including congestive heart failure and cardiac arrhythmias
- liver problems
- radiation “recall” (bringing back or making worse side effects from radiation)
- acute leukemia

Risks of Pembrolizumab

Pembrolizumab works by helping your immune system fight cancer.

Pembrolizumab is generally well tolerated for a majority of patients but it can cause side effects which in some cases can be very serious. It can cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (such as causing hospitalization or be life-threatening), may result in death, or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

VERY COMMON (seen in 20% of people)

Out of 100 people who receive pembrolizumab, 20 or more people may have the following:

- Itching of the skin
- Loose or watery stools
- Cough

COMMON (5% but less than 20% of people):

Out of 100 people who receive pembrolizumab, at least 5 but less than 20 people may have the following:

- Joint pain
- Rash
- Fever
- Back pain
- Pain in your belly
- Loss of skin color (vitiligo)

- Not enough thyroid hormone so you may feel tired, gain weight, feel cold, or have infrequent or hard stools (hypothyroidism)
- Low levels of salt in the blood that may cause you to feel tired, feel confused, have a headache, have muscle cramps, or feel sick to your stomach (hyponatremia)

UNCOMMON (1% but less than 5% of people):

Out of 100 people who receive pembrolizumab, at least 1 but less than 5 people may have the following:

- Inflammation of the lungs so you may feel short of breath and cough (pneumonitis)
- Too much thyroid hormone so you may feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools (hyperthyroidism)
- Infusion reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure at the time of receiving your infusion (IV) or just after, or have pain at the site of infusion
- Inflammation of the bowels/gut, which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stool with blood or mucus (colitis)
- Inflammation of the skin so you may have peeling of the skin, itchiness, or skin redness. The skin inflammation (peeling, itching, redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and may cause the top layer of your skin to peel from all over your body which can cause severe infection (severe skin reactions, including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis)

RARE (less than 1% of people)

Out of 100 people who receive pembrolizumab, less than 1 person may have the following:

- Inflammation of the nerves that may cause pain, weakness, or tingling in your hands and feet, and may spread to your legs, arms and upper body, leading to severe muscle weakness and possible temporary paralysis (Guillain-Barré syndrome)
- Inflammation of the muscles so you may feel weak or have pain in your muscles (myositis)
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels) so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and have vomiting that gets worse when you eat (pancreatitis)
- Inflammation of the eye so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters or have headaches (uveitis)
- Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, a pain in the right side of your belly, yellow eyes and skin, and dark urine (hepatitis)

- Inflammation of the pituitary gland (a gland in your head), which may cause you to feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness, or fainting (hypophysitis)
- Adrenal glands (glands on the top of the kidneys) that may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, having joint, muscle, and belly aches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan (adrenal insufficiency)
- Type 1 Diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination and weight loss., You are likely to need regular insulin shots
- Inflammation of the kidney (nephritis) so you may pass less urine or have cloudy or bloody urine, swelling, and low back pain
- Inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath, and swelling of the legs (myocarditis). You may experience a fast or irregular heartbeat that may cause dizziness or fainting
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy (thyroiditis)
- A condition that may make you feel weak and tired and may cause drooping of the eyelid, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia gravis including exacerbation)
- The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin or lungs (sarcoidosis)
- Inflammation of the brain with confusion and fever (encephalitis). This may also include: disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, weakness or loss of movement in some parts of your body, and loss of consciousness
- Inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation (myelitis)
- Vision loss

Additionally, since pembrolizumab was approved in September 2014, the following side effects have been reported to people receiving pembrolizumab. These side effects were voluntarily reported from a group of people of unknown size. It is not possible to estimate the frequency of this side effect:

- Inflammation of the joints which may include joint pain, stiffness, and swelling (arthritis)
- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. This may include

fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma (haemophagocytic lymphohistiocytosis [HLH]).

- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)

Hyperprogressive disease has been observed with the study drug pembrolizumab. When used with people with other types of cancer, this drug has made some tumors grow faster.

If you have had an allogenic stem cell transplant (a procedure in which a person receives blood-forming stem cells from a donor), you may experience graft versus host disease (GvHD), which may include diarrhea, skin rashes, and liver damage, **after receiving pembrolizumab**. Sometimes this condition can lead to death.

If you have had a solid organ transplant (for example, if you have received a kidney or heart transplant), you may experience rejection of the transplanted organ. Your doctor will monitor you and should tell you what signs and symptoms you should report depending on the type of organ transplant that you have had.

Risks of Pembrolizumab and Doxorubicin in Combination:

There has been a case of a patient who was treated on this study that experienced multiple pneumothoraces as a result of the combination of pembrolizumab and doxorubicin. A pneumothorax is a collapsed lung and happens when air leaks into the space between your lung and chest wall. The air pushes on the outside of your lung and makes it collapse. You may experience this while on trial if some of your disease is located in your lung.

Reproductive risks

Doxorubicin and pembrolizumab 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.

For Females of Childbearing Potential:

Taking pembrolizumab may involve unknown risks to an embryo fetus (unborn baby) or nursing infant. Therefore, you could not join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study, you would have to use two effective methods of birth control from the time this form is signed until at least 120 days after the last dose of pembrolizumab. If you are already using a method of birth control, you would have to

check with the study doctor or a member of the study staff to make sure it is acceptable.

If you became pregnant after joining this study, you would have to notify the study doctor immediately. Participation in this study would end, and you would receive counseling and follow up throughout the pregnancy and for about 6 months after the child is born.

For Males

The effects of fathering a child are also unknown. Men who join this study must also agree to use one or more forms of effective and acceptable birth control from the time this form is signed until at least 120 days after the last dose of pembrolizumab.

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 amount of radiation exposure is similar to what you would receive in a CT Scan.

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 chest: 7 mSv
- CT abdomen: 8 mSv

- CT 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 the combination of doxorubicin and pembrolizumab would help treat advanced sarcoma. We hope the information we learn will help people with sarcoma in the future. The combination is still investigational and we are testing it to determine if it is safe.

We do not know if this study would help you. You might get better if you receive this study treatment, but your condition could stay the same or even get worse. We hope the information from this study will help other people with advanced 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.

Other choices include: "standard" doxorubicin alone, another chemotherapy, possibly another type of treatment such as pazopanib, another research study, and no treatment (possibly including hospice or comfort care).

Enrollment in this study may exclude you from other research studies, particularly those using drugs similar to pembrolizumab.

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:

- Researchers involved with this study.
- Merck (providing pembrolizumab for this study) and their agents.
- 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, 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 your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If you authorize others to see your 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. Imaging tests, such as CT and/or MRI scans will be billed to you or your insurance company while on this study.

You would **not** be billed for:

- The study drug, pembrolizumab.
- 1 MUGA during the Phase 1 portion of the study
- EKGs for Cycles 3, 4, 6, and 7 of the Phase 1 portion of the study
- Pregnancy Tests
- Research tests performed on your samples.

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 your doctor or the Principal Investigator, Dr. Seth Pollack, at 206-667-6629 so that you can be referred 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.

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.
- Before you leave the study, the doctor might ask you to sign a separate consent form to continue in the follow-up part of the study.

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.
- Takes 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: This study (including complaints and requests for information)	Call: 206-667-6629 (Dr. Seth Pollack)
If you get sick or hurt in this study	206-667-6629 (Dr. 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 number (24 hours): 206-598-6190

UWMC paging operator - ask the operator to page the oncology fellow on call.

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

Do you agree to being contacted if and when you stop the study treatment, also called long-term follow-up? This means we would contact you by phone every 12 weeks to check on how you are doing, to receive information about your cancer status, and about your current cancer therapy. We would also ask your doctor to send a copy of your medical records.

(circle one and initial next to choice)

YES _____ NO _____

Signatures

If you have read this form (or had it read to you), asked any questions, and agree to participate, please sign:

Participant / Printed Name, Signature, and Date

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.

Witness or Interpreter / Printed Name, Signature, and Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature / Printed Name, Signature, and Date

Protocol: FH9624
Current Consent version date: V10 dated 20 March 2020
Previous Consent version date: V9 dated 01 November 2019
Copies to: Health Information Management, Patient Chart

FHCRC IRB Approval
04/30/2020
Document Released Date