Official Title:	**Olaparib in Prostate Cancer Patients with Evidence of Homologous Recombination Deficiency as Assessed Using an Integrated Genomic Signature**
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Fred Hutchinson Cancer Center
University of Washington

Consent to take part in a research study:

Olaparib in Prostate Cancer Patients with Evidence of Homologous Recombination Deficiency as Assessed Using an Integrated Genomic Signature

Principal Investigator: **Michael T. Schweizer, MD.**
University of Washington; Fred Hutchinson Cancer Center
206-606-6252

Funding Source: **AstraZeneca**

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

Request the on-call Oncology Fellow

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to determine the clinical effect of olaparib in men with metastatic prostate cancer that has become resistant to standard hormonal therapies (also known as castration-resistant prostate cancer) and whose tumors show genetic changes that we predict may respond well to olaparib.

People who agree to join the study will be required to take olaparib twice daily. You will also be asked to provide blood samples and undergo imaging procedures (bone scans and CAT scans) at regular intervals.

We do not know if olaparib will help treat this subtype of prostate cancer. Olaparib could cause side effects such as those described below in this form.

You do not have to join this study; you can choose to receive standard methods to treat prostate cancer instead. We will give you details about the purpose, 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 to make an informed decision about joining this study.

The following is a detailed description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will 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 prostate cancer that has become resistant to standard hormonal therapies (also known as castration-resistant prostate cancer)

and your tumor showed genetic changes that we predict may respond well to olaparib. Up to 30 men with castration-resistant prostate cancer who have these genetic changes 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 withdraw after joining. If you say "*no*," you will have no penalty or loss of benefits and your regular medical care will not change.

What is the purpose of this study?

We are doing this study to examine the clinical effects of olaparib in men with prostate cancer that has become resistant to hormonal therapies and has specific changes on tumor genetic sequencing. We want to know if men with prostate cancer who have these changes and whose cancer is getting worse after treatment with hormone therapy will experience a Prostate Specific Antigen (PSA) decline following treatment with olaparib.

In this study, we want to learn what effects, good or bad, olaparib has on men with prostate cancer with certain genetic changes in their cancer. If you join this study, we will give you olaparib and watch carefully for any side effects.

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

STUDY PROCEDURES

Screening Visit (Up to 30 days prior to starting study drugs)

If you decide to take part, your study doctor will first talk with you and give you a physical exam, to see if you are able to join the study. At this visit, your doctor will:

- Ask questions about your medical history, your current health, if you suffer from pain or other problems, and if you are taking any other medications or have recently been on any other research studies. You are asked to give as complete and accurate answers as possible.

- Record your vital signs such as temperature, blood pressure, pulse, height, and weight.

- Obtain an EKG (to check for any possible heart conditions).

- Collect a blood sample for standard tests (approximately 2 tablespoons of blood).

- CT scan of the chest, abdomen, and pelvis: a CT scan uses special x-ray equipment to take pictures of the body to identify and/or measure any tumors that may be present at the beginning of the study. This scan will be needed prior

to taking the study drug. Your first scan should be done within 8 weeks prior to starting the study drug. If you have already had a chest, abdomen and pelvis CT scan done according to the study requirements and the results can be used for this study, they do not need to be repeated. You will continue to have CT scans of your chest, abdomen and pelvis every three months throughout your participation in the study.

- Bone scan: a bone scan is done to identify abnormal processes involving the bone such as tumor, infection, or fracture. A bone scan uses bone-seeking radioactive material that is injected into a vein so that it travels through the bloodstream. The radiation is detected by a camera that slowly scans your body and takes pictures of how much the radioactive material collects in the bones. This scan will be needed prior to your receiving the study drugs. The first bone scan should be done within 8 weeks prior to starting the study drug. If you have already had a bone scan done according to the study requirements and the results can be used for this study, they do not need to be repeated. You will continue to have a bone scan every three months throughout your participation in the study.

- Biopsy: A bone or tissue biopsy will be taken from an area of your body where the cancer has spread. A biopsy is a procedure in which a small sample of tissue or bone is taken from the body.

  You may not have to undergo a biopsy if leftover tissue or bone is available from a past biopsy done as part of your cancer care. If the previous biopsy sample is available and appropriate for genetic testing, the researchers will use these samples instead of asking you to have a biopsy. Samples that are stored at another hospital from previous biopsies will be requested by the researchers if appropriate. You may be asked to undergo another biopsy if the first biopsy could not be used to evaluate the genetic profile of your cancer. You do not have to agree to another biopsy. Your decision to have or not have the biopsy will not affect your medical care and you will not lose any benefits to which you are entitled.

- Additional PET/CT or MRI scans may be used as initial screening assessments.

Treatment Period

If you are enrolled into the study, you will start the study medication, olaparib. You will take two 150mg tablets of olaparib (300mg total) twice daily. A 4-week supply of the oral drugs will be provided at the beginning of each month of the trial. You will be given a diary to record your study drug dosing. Study staff will instruct you on how to fill out your diary.

Certain drugs may interact with the olaparib. You need to tell your study doctor of all medications and supplements (e.g., herbs, vitamins) you take.

Olaparib must be taken only by you. It must also be kept out of the reach of children or persons of limited capacity to understand.

You will be evaluated for side effects and asked about all medications you are taking throughout the study. Below are time points and the tests and procedures that will be done during these time points. The study doctor may perform more tests and procedures if they feel it is necessary to monitor your safety and evaluate your cancer.

If you can join the study, at this visit your doctor/research nurse will:

Cycle 1 Study Visits

- **Day 1 visit**
    - A 28-day supply of olaparib will be provided.
    - Ask questions about your medical history, your current health, if you suffer from pain or other problems. Ask if you have recently started any new medications or supplements.
    - Record your vital signs such as temperature, blood pressure, pulse, and weight.
    - Give you a physical exam.
    - Blood will be collected for standard labs (less than 2 tablespoons).
    - Blood will be collected for research purposes (approximately 2 tablespoons).

Cycle 2 and 3 Visits

- **Day 1 visit**
    - A 28-day supply of olaparib will be provided.
    - Any unused olaparib from the prior 28 days will be collected.
    - Ask questions about your medical history, your current health, if you suffer from pain or other problems. Ask if you have recently started any new medications or supplements.
    - Record your vital signs such as temperature, blood pressure, pulse, and weight.
    - Give you a physical exam.
    - Blood will be collected for standard labs (less than 2 tablespoons).

Cycle 4 Study Visits

- **Day 1 visit**

- Any unused olaparib from the prior 28 days will be collected.
- Scans: Undergo a bone scan and CT scan of the chest, abdomen, and pelvis.
- A 28-day supply of olaparib will be provided as long as there is no evidence that your cancer is worsening.
- Ask questions about your medical history, your current health, if you suffer from pain or other problems. Ask if you have recently started any new medications or supplements.
- Record your vital signs such as temperature, blood pressure, pulse and weight.
- Give you a physical exam.
- Blood will be collected for standard labs (less than 2 tablespoons).
- Blood will be collected for research purposes (approximately 2 tablespoons).

Cycle 5 and on Study Visits

- **Day 1 visit**
  - Any unused from the prior 28 days will be collected.
  - Undergo bone, CT scan chest, abdomen, and pelvis scans every 3 cycles: Cycle 7, Cycle 10, Cycle 14, etc.
  - A 28-day supply of olaparib will be provided if there is no evidence that your cancer is worsening.
  - Record your vital signs such as temperature, blood pressure, pulse, and weight.
  - Give you a physical exam.
  - Blood will be collected for standard labs (less than 2 tablespoons).

End of Study Visit (Within 14 days of stopping all study drug)

Once your participation in the study is completed, you will have a final visit for the study. The following items must be completed within 30 days of stopping study drugs:

- Collect any unused olaparib from the prior 28 days.
- Ask questions about your medical history, your current health, if you suffer from pain or other problems. Ask if you have recently started any new medications or supplements.
- Record your vital signs such as temperature, blood pressure, pulse, and weight.
- Give you a physical exam.

- Blood will be collected for standard labs (less than 2 tablespoons).
- Blood will be collected for research purposes (approximately 2 tablespoons).
- Optional biopsy: This will be performed as described under the 'Screening visit' section above.

Long-term Follow-up (approximately every 6 months for up to 2 years)

- You will not have to come to clinic for these visits. A study coordinator or nurse will contact you via telephone, mail, or email to ask you questions about your prostate cancer. In the event of your passing, we will contact your next of kin.

How long would you stay in this study?

If you join this study, you will stay in this study as long as you appear to be benefitting from treatment. After stopping treatment, you will remain in the study for an additional 2-years.

You will receive olaparib as long you appear to be benefitting from treatment. After that, you would have follow-up exams in the office once within 14 days of stopping treatment. Additional follow up will be performed by phone, email or postal for up to 2-years after your last dose of study drugs.

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 are 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.

Long-term follow-up means keeping track of someone's medical condition for a long time. If you join this study, we will contact you approximately every 6 months by phone, email, or postal mail to see how you are doing. We will also ask your doctor to send a copy of your medical records. This information will help us learn about the long-term effects of olaparib.

You do not have to be in long-term follow-up. You can say "*yes*" or "*no*". Either way, you can still join this study. If you drop out of the study, you will be asked if we can contact you every 6 months by phone, email, or postal mail to see how you are doing.

If you choose not to join long-term follow-up, you will not be contacted regularly, and we will not ask your doctor to send medical records, but we might still need to contact you for some other reason.

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. Olaparib 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 will tell you if we discover new side effects that could affect you.

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 olaparib. In some cases, side effects can last a long time or never go away.

Risks of Olaparib:

Very common side effects (more than 10% of patients):

- Nausea
- Vomiting
- Tiredness/weakness/fatigue
- Indigestion/heartburn (dyspepsia)
- Difficulty breathing (Dyspnea)
- Loss of appetite
- Headache
- Change in taste of foods (dysgeusia)
- Dizziness
- Diarrhea. Your doctor may prescribe a medicine to treat this. If it gets severe, tell your doctor straight away.
- Cough
- Decrease in the number of red blood cells (anemia), which can be associated with symptoms of shortness of breath, fatigue, pale skin or fast heartbeat
- Decrease in the number of platelets in blood (thrombocytopenia) which can be associated with symptoms of bruising or bleeding for longer if injured
- Decrease in the total number of white blood cells (leukopenia) and in certain white blood cells (neutropenia) that protect from infection, which can be associated with symptoms of fever

Common side effects: (1 to 10% of patients)

- Sore mouth (stomatitis)
- Pain in the stomach area under the ribs (upper abdominal pain)
- Rash
- Decrease in the number of white blood cells that support the immune system (lymphopenia) which can be associated with increased susceptibility to infection
- Increase in blood creatinine seen from a laboratory test showing how your kidneys are working.

Uncommon (up to 1% of patients) side effects that may occur are:

- Increase in size of red blood cells: This will be monitored by the laboratory safety tests that will be done in this study because this doesn't normally have any symptoms.
- Allergic reactions (Hypersensitivity)
- Itchy rash on swollen, reddened skin (dermatitis)
- Swelling under the skin (Angioedema)
- Myelodysplastic syndrome: a pre-cancerous condition where the bone marrow isn't as good at producing blood cells as it was before (red blood cells and/or white blood cells and/or platelets). This condition has the potential to transform into acute myeloid leukemia.
- Acute myeloid leukemia: a cancer of the bone marrow where many abnormal and immature white blood cells (blast cells) are made while normal functioning blood cells are not made.

Driving and using machines
The study drug may affect your ability to drive or use machines. If you feel dizzy, weak, or tired while taking your study treatment, avoid when driving or using tools or machines.

Other potential risks of olaparib:
Other side effects have been seen in previous studies, but it is not yet known if these were related to olaparib, or if they were unrelated events possibly due to the patient's cancer or other cause. Assessing the full range of side effects of olaparib is an important part of this study.

Pneumonitis: (lung inflammation) has been reported in a small number of patients treated with olaparib in previous studies, and some patients have died. It is not known

if olaparib caused the pneumonitis in these patients as they had other possible causes such as lung cancer and/or metastases in the lungs, pre-existing lung disease, were smokers, or had been treated previously with chemotherapy or radiotherapy. Notify your study doctor as soon you experience worsening of symptoms of shortness of breath, cough and fever.

The Study Doctor may decide to interrupt, reduce or permanently stop your olaparib dose if you experience certain side effects. If your dose is reduced, you will be given a new bottle of tablets.

Risks of Blood Draw:

You may feel some discomfort when the needle is placed in your vein to draw blood for testing. Sometimes a bruise may develop where the blood was drawn or the needle was placed, and occasionally infection or bleeding may develop at the puncture site. Light-headedness and/or fainting may occur during blood collection.

Radiation Exposure:

While you are in this research study, CT scans, Bone Scans, and x-rays may be used to evaluate your disease and expose you to radiation. The frequency of these exams is no greater than what you would receive as standard care. 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 too low to be detectable and may be nonexistent.

- CT chest: 7 mSv
- CT abdomen: 8 mSv
- CT pelvis: 6 mSv
- Bone Scan: 6.3 mSv

In the long term, over many years, there is a very low risk of developing a new cancer because of the radiological evaluation and treatment for your cancer.

Risks Associated with Contrast Agents Used During Scans:

There is a small risk with using a contrast agent that is injected into a vein during the CT scan. The contrast agent is a special dye that highlights organs, blood vessels or tissue to make them more visible. Depending on the type of contrast agent that is used, it may cause decreased kidney function or worsen kidney function in people who already have decreased kidney function. Therefore, we will monitor your kidney function closely while you participate in this study. If there is any change in your kidney function, we may have to remove you from the study.

Rarely, some people have allergic reactions (such as hives and itching) to the contrast agent. Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare.

Reproductive risks:

If you join this study, you will have to use condoms from the time this form is signed until at least 3 months after the last dose of olaparib when having sexual intercourse with a female partner, even if they are pregnant. Your female partner must also use a suitable method of contraception either hormonal or non-hormonal.

Suitable methods of contraception for you and your female partner include:

- Total/True abstinence: When the patient refrains from any form of sexual intercourse and this is in line with their usual and/or preferred lifestyle; this must continue for the total duration of the trial and for at least 3 months after the last dose of study drug. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods, or declaration of abstinence solely for the duration of a trial) and withdrawal are not acceptable methods of contraception.

- Vasectomized participant PLUS male condom. With participant assurance that they received post-vasectomy confirmation of azoospermia.

- Tubal occlusion PLUS male condom

- IUD PLUS male condom. Provided coils are copper-banded.

- Normal and low dose combined oral pills PLUS male condom

- Cerazette (desogestrel) PLUS male condom. Cerazette is currently the only highly efficacious progesterone based pill.

- Hormonal shot or injection (e.g., Depo-Provera) PLUS male condom

- Etonogestrel implants (e.g., Implanon, Norplant) PLUS male condom

- Norelgestromin / EE transdermal system PLUS male condom

- Intrauterine system [IUS] device (e.g., levonorgestrel releasing IUS -Mirena®) PLUS male condom

- Intravaginal device (e.g., EE and etonogestrel) PLUS male condom

You must not donate sperm while taking study treatment and for 3 months after the last dose of study treatment. Tell your study doctor immediately if your partner becomes pregnant while taking study treatment or within 3 months of your last dose of study

treatment.

Non-physical risks:

In addition to the physical risks/discomforts associated with this study, there may be psychological, emotional, financial, social, and legal risks that might result. If you join this study, non-physical risks are:

- You may get tired or bored when we are asking you questions. You do not have to answer any question you do not want to answer.
- There is risk that information about you may become known to people outside this study.
- You might not be able to work.
- Results of 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 potential benefits?

We do not know if this study would help you. We are testing olaparib to see its effects on people with prostate cancer that has become resistant to hormonal treatments and whose tumors show genetic changes that we predict may respond well to olaparib. You might get better if you receive olaparib, but your condition could stay the same or even get worse. We hope the information from this study will help other people with prostate cancer 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: other hormonal therapies (Zytiga, Xtandi, ketoconazole) or chemotherapy (docetaxel, cabazitaxel), radiation (Xofigo), vaccine therapy (Provenge), other research studies or palliative care (treatment of symptoms such as pain when they occur, but no specific therapy for your cancer).

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:

- AstraZeneca (the manufacturers of olaparib) and their agents.

- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center, University of Washington.
- 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.

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 your medical record, they would see a copy of this consent form.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

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 prevents 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.

How long will my samples be stored?

Your samples will be used for the purposes of this study and may be stored for up to five years following the completion of this study. Samples will be stored at University of Washington and/or Fred Hutchinson Cancer Center for research purposes only. Your samples will be destroyed after use for the purposes of this study. Researchers will not report their results to you or your doctor. Your specimens will not be used for reasons unrelated to this research study. All specimens will be kept in locked research laboratories at University of Washington and/or Fred Hutchinson Cancer Center. The use of these specimens will be supervised by the primary investigators at University of Washington (Michael Schweizer, MD) and his designees. These samples will not contain your name or other identifiable information. Analyses will be conducted at the University of Washington, Fred Hutchinson Cancer Center and/or their research partners.

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 will have some extra costs. Your insurance company may pay these costs, but some insurance policies do not cover these costs. We can help you find out whether your insurance company would cover these costs.

The extra costs are:

- Cost of staff and equipment to give study drugs olaparib). There is no charge for the olaparib itself.
- Cost of standard doctor visits and lab tests.
- Cost of extra tests that are given outside of standard care.

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:

- Olaparib (study drug)

- Research bone marrow procedure or testing.

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 study staff via the 24-hour emergency number on the first page of this form . They will treat you or 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 will not lose any legal right to seek payment for treatment if you sign this form.

What will my information and/or tissue samples be used for?

Your information and tissue samples (such as blood and tumor cells) will be used for the purposes of this study.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. You will not receive any revenue generated from products developed using your tissue samples.

During this study, if the researchers learn new information that may be important to your general health or to your disease or condition, they will share that information with you. This study is not specifically designed to identify inherited genetic conditions that lead to risk of cancer. During this study, however, we may find information about genetic conditions you may have been born with and we will attempt to share these with you.

Your tissue contains DNA. DNA makes up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases such as cancer. There are many different types of genetic tests. The testing on your tissue samples will include genetic testing called whole genome sequencing. Whole genome sequencing looks at all the genetic information in your cells. This type of testing can provide useful information to researchers. It can also present risks if the test results became known to others, for example you could have problems with family members or insurance companies. There is also a risk that these test results could be combined with other information to identify you.

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 will tell you.
- If you join this study, you will not have to stay in it. You can 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 will want you to tell the study doctor. The doctor could tell you about the effects of stopping olaparib. You and the doctor could talk about the follow-up care and testing that would help the most
- Before you leave the study, the doctor might ask you to continue in the long-term 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 website at any time.

Your responsibilities

If you join this study, you will 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 can 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)	206-606-6252 (Dr. Michael Schweizer) 206-606-7486 (Zoya Bauer, research Manager)
If you get sick or hurt in this study	206-606-6252 (Dr. Michael Schweizer)

Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	206-598-8260 (UWMC Patient Financial Services) 206-606-1091 (Fred Hutchinson Cancer Center Patient Financial Clearance)

Optional Procedures:

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

Do you agree to undergo biopsy at the End of Study? (circle one) **YES** **NO**

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date

If you served as an interpreter or impartial witness during the consent process, sign below to indicate you attest to the accuracy of the presentation and the participant's apparent understanding of and willingness to participate in the research.

Impartial Witness or Interpreter:

Printed Name	Signature	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	Date

Protocol: Version 14.0
Current consent version date: 10/25/2021
Previous consent version date: N/A
Copies to: Patient, Sponsor and Regulatory Binder