Fred Hutchinson Cancer Research Center
Seattle Cancer Care Alliance
University of Washington

Consent to take part in a research study:

A Phase 2 Study of Apalutamide in Active Surveillance Patients

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University of Washington; Seattle Cancer Care Alliance; Fred Hutchinson Cancer Research Center

Funding and medication support: Janssen Scientific Affairs, LLC

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

Request the on-call Oncology Fellow

Your doctors are inviting you to participate in a research study. The purpose of this research is to determine if apalutamide has an effect on prostate cancer in men enrolled on active surveillance.

If you agree to join the study, you will be required to take apalutamide once daily for 90 days. Following this 90-day period, you will undergo a prostate biopsy.

We do not know if treating you with apalutamide will change the course of your disease. Apalutamide could cause side effects.

You do not have to join this study. You could choose to receive standard methods to treat prostate cancer. 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 prostate cancer and are currently enrolled on active surveillance. Up to 33 people will join this study at University of Washington and Johns Hopkins. This study will last for about 5 years.

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?

This research is being done to test whether a short course (90 days) of apalutamide will have an effect on prostate cancer in men enrolled on active surveillance. We think that this drug will be able to eliminate all evidence of prostate cancer, and that no detectable cancer will be left on repeat biopsy following the treatment. In theory, this could increase the chances that a man on active surveillance will be able to avoid having their prostate removed surgically (a prostatectomy) or require prostate radiation therapy.

We also hope to learn if there are ways we can predict which active surveillance patients will respond best to apalutamide and who may be at the highest risk of disease progression on active surveillance. To accomplish this goal, we will be collecting biospecimens, which include: blood, and tumor tissue. If you elect to join this study you must also agree to provide these biospecimens. This work will be exploratory in nature and these biospecimens will be stored for future use. This type of research is known as "biomarker research".

Eligible men must have prostate cancer that is no more than low-intermediate risk and have opted to enroll in active surveillance. Patients must not be receiving active treatment for their prostate cancer.

Apalutamide is a prostate cancer drug that works by blocking testosterone. This trial is based on prior clinical work showing that apalutamide has an anti-prostate cancer effect. Apalutamide is FDA approved only for the treatment of prostate cancer that has not spread (non-metastatic), but that continues to grow despite treatment with hormone therapy (castration-resistant). Treatment with apalutamide is still considered investigational in this trial setting, as it has not been FDA approved for use in patients enrolled in active surveillance.

In this study, we want to learn what effects, good or bad, apalutamide has on people with prostate cancer. If you join this study, we would give you apalutamide and watch carefully for any side effects.

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

If you join this study, we would do these tests and procedures:

STUDY PROCEDURES

Screening Visit

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If you agree to take part in the study, your study doctor will have up to 30 days to complete screening tests to see if you qualify for the study. Your study doctor will be collecting specific information regarding your previous and current treatments you may have had. That information will be used, along with other information about your cancer and general health, to determine whether you are eligible. The following tests will be done at the beginning of the study, during the screening period. Your doctor can give you more details about these tests.

- A complete medical history will be collected including information on your general health, past surgeries, 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 should not have taken another trial product in the 30 days before you begin this study. You will be asked to give as complete and accurate answers as you can. Giving false, incomplete, or misleading information could put your health at risk.

- A physical assessment including vital signs (blood pressure, heart rate and temperature), height, and weight, EKG and assessment of your ability to perform activities of daily living will be completed by either your doctor or a research nurse. Confirm you have had a prostate biopsy (ultrasound guided or MRI guided) no more than 12 months prior to this screening visit, and that you qualify for active surveillance.

- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function, Thyroid stimulating hormone (TSH), testosterone, PSA and hematology.

Screening tests may require more than 1 visit to the clinic. Your study doctor will review the test results and tell you whether or not you qualify to be in the study and that it is reasonably safe for you to join. These tests are also used to make sure things do not change too much while you are in the study.

Study Drug Administration Period

If you are enrolled into the study, you will start the study medication (apalutamide). You will take four 60 mg tablets (240 mg per day) of apalutamide by mouth once daily for a total of 90 days. It is important to stay on this schedule. A 30-day supply will be provided at the beginning of each month of the trial. As the study allows for a study visit window of +/- 7 days the study may dispense up to 7 additional days of study medication to compensate for this window if needed. 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 apalutamide. You need to tell your study doctor of all medications and supplements (e.g., herbs, vitamins) you take.

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

Apalutamide must be stored at room temperature at all times (between 15°C to 30°C, or 59°F to 86°F) with the cap on tightly and desiccant in the bottle. While you are taking the study medications, please do not take: St. John's Wort, drink grapefruit juice or eat grapefruit. If you miss a dose of study drug, do not try to make it up. It should be omitted.

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.

Treatment phase (Day 1)

- At this visit your study doctor/nurse will ask you questions to assess your current state of health, to determine if there has been a change in your health or if there has been any unexpected events since your last visit.
- A physical assessment, including vital signs (blood pressure, heart rate and temperature), weight, and assessment of your ability to perform activities of daily living will be completed by either your doctor or a research nurse. Review of medications you are currently taking and have taken in the past including herbal medications.
- You will be provided with the study medication (apalutamide) as well as a diary to keep track of when you take this medication. Apalutamide will be provided in tablet form. This medication should both be taken once every day by mouth for a total of 90 days. You will begin taking these medications at this visit.
- You will have a blood sample collected (less than 1 tablespoons of blood for research purposes).
- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function and hematology.
- A blood sample will be drawn to measure prostate-specific antigen (PSA).
- A blood sample will be drawn to measure serum testosterone and luteinizing hormone.

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- You will be asked to complete two questionnaires that will ask you how you have been feeling. The questionnaire will be completed while at the doctor's office and will take about 5-8 minutes to complete.

Treatment Phase (Day 30) [+/-7 days]

- At this visit your study doctor/research nurse will ask you questions to assess your current state of health, how you are tolerating the drugs, and if there have been any unexpected events since your last visit.

- A physical assessment, including vital signs (blood pressure, heart rate and temperature), height and weight, and assessment of your ability to perform activities of daily living will be completed by either your doctor or a research nurse.

- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function and hematology.

- A blood sample will be drawn to measure serum testosterone and luteinizing hormone.

- A blood sample will be drawn to measure thyroid stimulating hormone (TSH).

- You will have a blood sample collected (less than 1 tablespoons of blood for research purposes).

- Collect/dispense study drugs.

Treatment Phase (Day 60) [+/-7 days]

- At this visit your study doctor/research nurse will ask you questions to assess your current state of health, how you are tolerating the drugs, and if there have been any unexpected events since your last visit.

- A physical assessment, including vital signs (blood pressure, heart rate and temperature), and weight, and assessment of your ability to perform

activities of daily living will be completed by either your doctor or a research nurse.

- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function and hematology.
- A blood sample will be drawn to measure serum testosterone and luteinizing hormone.
- A blood sample will be drawn to measure thyroid stimulating hormone (TSH).
- Collect/dispense study drugs.

End of Study (Day 91) [+/-7 days]

- At this visit your study doctor/research nurse will ask you questions to assess your current state of health, how you are tolerating the drugs, and if there have been any unexpected events since your last visit.
- A physical assessment, including vital signs (blood pressure, heart rate and temperature), and weight, and assessment of your ability to perform

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activities of daily living will be completed by either your doctor or a research nurse.

- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests which measure your blood chemistry, including kidney and liver function and hematology.
- A blood sample will be drawn to measure prostate-specific antigen (PSA).
- A blood sample will be drawn to measure serum testosterone and Luteinizing hormone.
- You will have a blood sample collected (less than 1 tablespoons of blood for research purposes).
- You will undergo a repeat ultrasound guided biopsy of your prostate.
- If you previously had an MRI guided prostate biopsy you will undergo a repeat prostate MRI followed by repeat MRI guided biopsy. This biopsy will occur at the same time as the ultrasound guided biopsy.
- Collect study drugs.
- You will be asked to complete two questionnaires that will ask you how you have been feeling. The questionnaire will be completed while at the doctor's office. They will take about 5-8 minutes to complete.

Long-Term Follow-up (Day 180) [+/-30 days]

At this visit your study doctor/research nurse will:

- Ask you questions to assess your current state of health and if there have been any unexpected events since your last visit.
- You will have a blood sample collected for PSA measurement (less than 1 teaspoon of blood drawn as part of the standard management for men on active surveillance).
- You will be asked to complete two questionnaires that will ask you how you have been feeling. The questionnaire will be completed while at the doctor's office. These will take about 5-8 minutes to complete.

Long-Term Follow-up (Day 365) [+/-30 days]

At this visit your study doctor/research nurse will:

- Ask you questions to assess your current state of health and if there have been any unexpected events since your last visit.

- You will have a blood sample collected for PSA measurement (less than 1 teaspoon of blood drawn as part of the standard management for men on active surveillance).

- You will be asked to complete two questionnaires that will ask you how you have been feeling. The questionnaire will be completed while at the doctor's office. These will take about 5-8 minutes to complete.

- You will need to have an ultrasound guided prostate biopsy. This is a standard part of management for men on active surveillance.

Long-Term Follow-up (Day 545) [+/-30 days]

At this visit your study doctor/research nurse will:

- Ask you questions to assess your current state of health and if there have been any unexpected events since your last visit.

- You will have a blood sample collected for PSA measurement (less than 1 teaspoon of blood drawn as part of the standard management for men on active surveillance).

- You will be asked to complete two questionnaires that will ask you how you have been feeling. The questionnaire will be completed while at the doctor's office. These will take about 5-8 minutes to complete.

Long-Term Follow-up (Day 730) [+/-30 days]

At this visit your study doctor/research nurse will:

- Ask you questions to assess your current state of health and if there have been any unexpected events since your last visit.

- You will have a blood sample collected for PSA measurement (less than 1 teaspoon of blood drawn as part of the standard management for men on active surveillance).

- You will be asked to complete two questionnaires that will ask you how you have been feeling. The questionnaire will be completed while at the doctor's office. These will take about 5-8 minutes to complete.

- You will need to have an ultrasound guided prostate biopsy. This is a standard part of management for men on active surveillance.

- You will then be done with the study.

Long-Term Record Review (Years 3, 4 and 5) [+/-90 days]

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- Your medical record will be reviewed to collect data on your most recent PSA, biopsy results and to determine if any local treatment has been received (e.g. radiation, surgery).

MRI Exam Information:

As part of your participation in this research study, you may have an MRI exam. An MRI will only be done if you had an MRI guided biopsy prior to enrolling on the study. The MRI exam will take approximately 30 minutes. Prior to your exam, you will be asked to complete a standard questionnaire. The purpose of this questionnaire is to ensure that you are able to safely enter the MRI area. If you have a history of metal in your head or eyes, you will need an x-ray examination of your skull in order to find out if the MRI exam is safe for you.

To start your MRI test, you will lie on a padded table. A soft padded coil will be placed at the area where the pictures will be taken. The coil is necessary to help the MRI machine take pictures. The table on which you are lying will be moved to the center of an MRI magnet, which looks like a long narrow tube. Even though the tube is open, some people feel confined in small places. If this bothers you, please notify the MRI staff. You may end your participation in this study at any time by telling the MRI staff. When MRI pictures are taken radio-signals and magnetic fields are used. When this happens, it is normal for the MRI machine to make loud, banging, and clicking noises. You will be asked to wear earplugs or headphones for your comfort during the exam.

During the exam, the MRI staff is able to see and hear you. You will be able to hear the MRI staff. The MRI staff will be talking to you throughout your MRI exam and may issue simple instructions regarding holding your breath, maintaining position, etc. You will generally be requested to lie perfectly still throughout the exam.

At some point during your MRI exam the MRI staff will interrupt the scanning procedure in order to give a contrast agent. The agent is given through a needle placed (an IV) in your arm. The IV will be placed using standard hospital techniques.

What you will need to do:

All changes in the state of your health during the study must be reported to your doctor or a member of the study team, whether or not you think that the changes are related to the study. During the whole study, you will be monitored for new symptoms, new diseases, side effects, and use of other medications, and you will be asked to follow the appointment schedule.

While you are taking part in the study, you are not allowed to use any medication that interferes with the evaluation of the study drug, including any other investigational new drug or device. You will also be asked to maintain the current doses and schedule of medications you are currently taking.

Sometimes during a research study, new information that may affect a participant's health, welfare, or willingness to stay in this study may become known. If this

happens, your doctor will tell you about it, and will discuss with you if you want to stay in the study. If you decide not to stay in the study, your doctor will make arrangements for your care to continue and for you to receive appropriate treatment, including study follow up procedures.

Also, on receiving new information your doctor might consider it to be in your best interest to withdraw you from the study. He/she will explain the reasons for this and will arrange for your care to continue.

How long would you stay in this study?

If you join this study, you would stay in this study about 2 years. After the first two years of follow-up, we will continue to review your medical records for an additional 3 years (up until year 5) to gather additional information about your clinical course.

You would receive apalutamide for 90 days. After that, you would have follow-up exams in the office or clinic twice: once immediately after this 90 day period and again 21 months later.

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 stop taking apalutamide early (that is, less than 90 days), we would still plan to complete the study items listed under the "End of Study" and "Long-term Follow-up" sections (Pages 5-7). 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. Apalutamide 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.

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

Risks of Apalutamide

Doctors don't yet know all of the side effects that could happen when taking apalutamide. You will be watched carefully during this study for any side effects.

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Though most side effects are not serious, some may be serious and may require treatment or additional testing. This section describes common side effects from apalutamide.

There may be risks with apalutamide that are not yet known. You will be monitored carefully for side effects. During the study, the sponsor or study doctor may learn new facts about apalutamide. Your study doctor will inform you of any important new information about apalutamide. It is possible that this new information might make you change your mind about being in the study. Side effects may be mild, moderate, serious or even life-threatening. If you experience any side effects, your doctor may give you medicines to help lessen the side effects. Some side effects may go away soon after you stop taking the study medicine. Other side effects can be serious or long lasting.

If you experience a side effect, your doctor may temporarily hold the study drug or change the dose of the study drug to help manage the side effect. If severe side effects develop, you and your doctor may decide that it is in your best interest to stop taking the study drug. In addition, you will be provided with the telephone numbers for people who can answer any questions about the study, your rights as a study participant and for you to report any side effects.

Risks and side effects that are related to apalutamide include:

Very Common (>10%)	**Common (1 - <10%)**	**Uncommon (< 1%)**
Fatigue	Itching	Seizure
Skin rash	Changes in thyroid function (Hypothyroidism)	
Joint pain (Arthralgia) or muscle spasms	Increase in cholesterol	
Weight loss	Increase in triglycerides	
Fall	Change in experience of taste (Dysgeusia)	
Fracture	Reduced or blocked blood flow to the heart, including heart attack (Ischemic Heart Disease, including Myocardial Infarction)	
Increased blood pressure (Hypertension)		
Hot flush		
Diarrhea		

Seizures have been observed very rarely in patients taking part in apalutamide studies. Your doctor will confirm that you have no history of seizures and will check throughout the study that you are not taking other medications that can increase your risk of seizures. Please inform your doctor of all medications you are taking and any changes in medications. If you think you might have had a seizure, or convulsion, or have lost consciousness (passed out), let your doctor know right away.

More than 1 in 10 patients have developed a rash. Some rashes may need medical attention. The rash may be confined to one area of your body or may spread across your body. Contact your doctor at the first sign of rash or any symptoms of rash (like itching) during the study. Rashes that are painful, blisters on or near the lips, eyes or genitals may need immediate evaluation by your doctor. You may be given medicines to apply to your skin or take by mouth to help the signs and symptoms of rash. Also the study medication may be temporarily held.

Risks of MRI with contrast

MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA, like the x-rays used CT scans).

There are no known harmful side-effects associated with temporary exposure to the strong magnetic field used by MRI scanners. However, there are important safety concerns to consider before performing or undergoing an MRI scan:

- The magnet may cause pacemakers, artificial limbs, and other implanted medical devices that contain metal to malfunction or heat up during the exam.
- Any loose metal object may cause damage or injury if it gets pulled toward the magnet.
- If a contrast agent is used, there is a slight risk of an allergic reaction. MRI contrast agents can cause problems in patients with decreased levels of kidney function.
- Dyes from tattoos or tattooed eyeliner can cause skin or eye irritation.
- Medication patches can cause a skin burn.
- The wire leads used to monitor an electrocardiogram (ECG) trace or respiration during a scan must be placed carefully to avoid causing a skin burn.
- Prolonged exposure to radio waves during the scan could lead to slight warming of the body.

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.

Reproductive risks

The effect of the study drug on your semen is unknown. To avoid risk of drug exposure to your partner through the semen (even in men with vasectomies (tubes

that carry semen from the testicles have been cut), patients must use a condom during sexual activity while on study drug and for 3 months following the last dose of study drug.

Apalutamide may cause harm to the unborn child From when you start taking the study drug until 3 months after your last dose of study drug, you must use a condom and another effective method of birth control when you have sex with a woman of child-bearing potential. The type of birth control you use must be discussed with, and approved by, the study doctor before you begin the study. This is done to prevent pregnancy. If your partner becomes pregnant in the time between when you start taking the study drug until 3 months after your last dose of drug, you must tell the study doctor immediately.

Donation of sperm is not allowed during the study and for 3 months following the last dose of study drug.

You should advise your study doctor if you father a child while participating in the research project. The doctor will advise you on any appropriate medical attention for your partner should this be necessary. The study doctor may ask you and your partner to allow him/her to collect information about her pregnancy and the health of the baby.

Additional Information:

The apalutamide medication bottle will also include a small sachet, called a desiccant. You should not eat or remove this sachet. It has been placed in the bottle to protect the study medication. You should store your study medication in the study bottle and not place your pills in a separate container, such as a pill container. If you have any questions your study doctor will answer them. You must store your study medication in its original packaging with the desiccant. You cannot remove or eat the sachet that is in your bottle of study medication. You should not store your study medication in a separate pill container.

Non-physical risks

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

- 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.
- There may be psychological, emotional, financial, social, and legal risks that might result. These risks include change in emotional state, anxiety, or depression associated with taking the study drugs. There may be financial risks related to reimbursement for study procedures.

What are the benefits?

There may or may not be a direct benefit to you from taking part in this study. We are testing apalutamide to see its effects on people with prostate cancer. You might get better if you receive apalutamide, 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: continuing on actives surveillance alone, other research studies, prostatectomy, or prostate radiation therapy.

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:

- Researchers involved with this study.
- University of Washington (the sponsor of the 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.
- Janssen Scientific Affairs, LLC

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 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 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 stored for up to five years following the completion of this study. Samples will be stored at University of Washington and/or Johns Hopkins for research purposes only. These samples may also be sent to our research partners participating in this study, including Janssen Scientific Affairs, LLC. University of Washington and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort. Researchers will not report their results to you or your doctor. Your samples may be used in future studies of prostate cancer, including genetic studies. 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 Johns Hopkins. The use of these specimens will be supervised by the primary investigators at University of Washington (Michael T. Schweizer, MD) and/or Johns Hopkins (Mark Markowski, MD) and their designees.

Would we pay you if you join this study?

There is no payment for being in this study.

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It is possible that this research could lead to discoveries that could be licensed or patented. You will not benefit financially from products developed through this study.

Would you have extra costs if you join this study?

Taking part in this research study might lead to added costs to you or your insurance company.

You will not be charged for the medications that are being given solely for research purposes.

You or your insurance company will be charged for portions of your care during this research study that is considered standard care. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

Check with your insurer before you join this study.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

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

University of Washington Medical Center and Seattle Cancer Care Alliance do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at University of Washington Medical Center and/or Seattle Cancer Care Alliance is open to you as it is to all sick or injured people.

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 study doctor, Dr. Michael Schweizer, at (206) 606-6252 (business hours) or (206) 598-6190 (after hours). 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.

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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.
- 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 apalutamide. 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.

Conflicts of Interest

Dr. Evan Yu, Sub-Investigator for this study, has a financial or other relationship with the funding company Janssen Scientific Affairs, LLC. The University of Washington developed a Conflict Management Plan to reduce the possible effects of this relationship on your safety or welfare.

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.

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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) 606-6252 (Dr. Michael Schweizer) (206) 598-6190 (Oncology Fellow on-call 24 Hour)
If you get sick or hurt in this study	(206) 606-6252 (Dr. Schweizer)
Your rights as a research participant	206-667-4867 (Karen Hansen, 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	206-598-8260 (UWMC Patient Financial Services) 206-606-1091 (SCCA Patient Financial Clearance)

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

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

- I agree to provide pre-treatment and post-treatment biospecimens including blood and tumor tissue

_____

Participant 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: 9582
Current version date: 04/16/2019
Previous version date: 03/20/2018
Copies to: Researcher's file
Subject
Subject's medical record (if applicable)