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

Consent to take part in a research study:

Erdafitinib plus Abiraterone Acetate or Enzalutamide in Double Negative Prostate Cancer

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

Drug and Funding Support: Janssen Research & Development

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 if erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone is effective in men with metastatic prostate cancer that has progressed on standard hormonal therapy.

People who agree to join the study will be asked to attend clinic approximately once every 3 weeks. You will receive erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone, and treatment will continue for up to two years as long as there is no evidence of cancer growth or serious side effects. Blood will be collected at least every 3 weeks to monitor the effects of the study drugs. If felt to be safe by the treating physician, a metastatic biopsy will be performed after stopping treatment.

We do not know if erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone would help treat prostate cancer, and it could even make your condition/disease worse. Erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone could cause side effects such as blood electrolyte abnormalities, diarrhea, dry mouth, mouth sores, decreased appetite, fatigue and abnormal liver function, as 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 of participating in this study. 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. 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 metastatic prostate cancer that has previously progressed on abiraterone acetate and/or enzalutamide. Up to 25 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 clinical effects of erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone in men with metastatic prostate cancer that has previously progressed on standard hormonal therapies. We want to know if these drugs will result in prostate cancer tumors shrinking on scans.

Abiraterone acetate plus prednisone and enzalutamide has an anti-prostate cancer effect and are currently approved to be used to treat metastatic prostate cancer. Erdafitinib is not approved for the treatment of any cancer and is currently an investigational drug. We think that combining erdafitinib with enzalutamide or abiraterone acetate plus prednisone will result in an even greater anti-prostate cancer effect than any one drug alone.

In this study, we want to learn what effects, good or bad, the study drugs (erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone) have on people with metastatic prostate cancer. If you join this study, we would give you erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone and watch carefully for any side effects.

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

Study Procedures

Screening Visit

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 study 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.
- 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.
- An eye exam will be performed at an ophthalmologist.
- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests that measure your blood PSA level, testosterone level, chemistries (including kidney and liver function), blood counts (including white blood cells, hemoglobin and platelets) and the ability of your blood to form clots.
- An electrocardiogram (EKG) will be performed.
- You will undergo a CT and bone scan if not recently performed.
- A biopsy is recommended prior to enrolling to ensure that you do not have 'small cell' prostate cancer – a type of prostate cancer best treated with chemotherapy. This biopsy will be reviewed at the time of screening.[HC1]

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.

Treatment Visits (approximately every 21 days)

If you are enrolled to the study, you will continue to take either enzalutamide or abiraterone acetate plus prednisone. Erdafitinib will be added to your treatment regimen. A 3-week supply of erdafitinib will be provided at the beginning of the Treatment Phase of the study and you will be given a new supply of erdafitinib at follow up visits every 3-weeks. You will be given a diary to record your study drug dosing. Study staff will instruct you on how to fill out your diary.

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

- At these visits 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 have been any unexpected events since your last visit.
- Review of medications you are currently taking.
- You will be provided with erdafitinib as well as a diary to keep track of when you take your study drugs.
- 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. This will be completed by either your doctor or a research nurse.
- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests that measure your blood chemistries (including kidney and liver function) and blood counts (including white blood cells, hemoglobin and

platelets) (note: an additional blood sample will also be collected 2 weeks after starting).
- A blood sample will be drawn to measure prostate-specific antigen (PSA) (approximately every 9 weeks).
- You will have a blood sample collected (about 2-3 tablespoon of blood for research purposes) (beginning of treatment and after 9 weeks only).
- You will undergo a CT and bone scan every 9 weeks.

End of Treatment Visit

- 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 have been any unexpected events since your last visit.
- Review of medications you are currently taking.
- Any unused erdafitinib will be collected at this time.
- 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. This will be completed by either your doctor or a research nurse.
- Routine blood samples will be drawn (about 2-3 teaspoons) for laboratory tests that measure your blood PSA level, testosterone level, chemistries (including kidney and liver function) and blood counts (including white blood cells, hemoglobin and platelets)
- You will have a blood sample collected (about 2-3 tablespoon of blood) for research purposes.
- You will undergo a CT and bone scan if not recently performed.
- If felt to be safe by your treating physician, you will undergo a research biopsy.

How long would you stay in this study?

If you join this study, you would stay in this study as long as there is no evidence of cancer growth or serious side effects while receiving the study drugs, or up to about two years of treatment administration. After that, you would have one additional follow-up exam in the office or clinic within 14 days of coming off the study.

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.

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. Erdafitinib in combination with either enzalutamide or

abiraterone acetate plus prednisone 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 erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone. In some cases, side effects can last a long time or never go away.

Risks of Erdafitinib

As of June 4, 2019, 562 subjects with different types of cancer have received treatment with erdafitinib monotherapy across 12 ongoing and completed clinical studies. Side effects seen in five (5) pooled studies, which enrolled a total of 501 subjects, are summarized below.

Risks and side effects that could be related to erdafitinib include:

Very Common (occurring in more than 35% of subjects)

- Higher than normal levels of phosphate in the blood
- Dry mouth
- Swelling, redness, pain, or ulcers of the mouth
- Diarrhea

Common (occurring in 10% to 35% of subjects)

- separation of the fingernail or toenail from the nail bed)
- Infection of the fingernail or toenail
- Weakness
- Constipation
- Distortion of the sense of taste
- Vomiting
- Nausea
- Abdominal pain
- Skin problems including dryness and cracking
- Dry eye
- Loss of hair
- Low number of red blood cells which may cause tiredness or shortness of breath
- Pain in joints
- Fatigue
- Back pain
- Fever
- Abnormal liver function tests
- Urinary tract infection
- Shortness of breath or trouble breathing

- Discomfort of the palms of the hands and soles of the feet that can range from a burning sensation or pain to peeling of the skin
- Decreased appetite
- Weight loss
- Cough
- Nose bleeds
- Reversible fluid accumulation and swelling of the retina (internal part of the eye) that may or may not be associated with visual symptoms such as blurred or diminished vision or loss of vision

Uncommon (occurring in 5% to less than 10% of subjects)

- Itchy skin
- Nail changes including brittleness, peeling, discoloration, ridging, and breakage
- Indigestion
- Difficulty or pain swallowing
- Dry nose
- Low sodium in the blood, which may cause weakness or confusion
- Low magnesium in blood which, may cause muscle cramps, weakness, tremors or irregular heartbeat
- High calcium in the blood, which may cause an increase in urination and thirst, bone pain, headaches, weakness and muscle cramps
- Pain in arms or legs
- Pain in muscles or bones
- Insomnia (inability to sleep)
- Blood in the urine
- Redness, irritation, and infection of the eye
- Increased tearing of the eye
- Decreased blood pressure
- Build-up of fluid in the body causing swelling
- Headache
- Increased level of a type of a-protein (alkaline phosphatase) in the blood
- Increased level of a chemical waste product creatinine in the blood
- Blurry vision

Most side effects experienced by subjects were mild to moderate in severity and most of the side effects were reversible when the study drug was stopped. In rare cases some subjects experienced serious side effects.

Not all of the possible side effects and risks related to erdafitinib are known at this time. Other currently unknown risks and discomforts could appear. The new side effects may be mild or severe and may or may not be reversible and could also result in death. You will be monitored very closely by your doctor and his/her team for any side effect that may be caused by the study drug. You will receive appropriate care if side effects occur. If you experience nail or skin side effects, your study doctor may ask to take a photograph so that your condition can be monitored and assessed.

Please tell your study doctor if you have any of the side effects described above or any other ones not listed. You will be told of any new findings that may affect your decision to continue in this study.

It is very important that any new health problem is quickly reported to the investigator, regardless of whether or not you think it has to do with the study.

Erdafitinib is cleared from the body by the liver and may interact with other drugs that are cleared in the liver. There are certain medications that should not be taken with erdafitinib. Therefore, it is important that you do not take any medication, food supplements, or herbal products unless it is discussed with and approved by your study doctor first.

The activity of erdafitinib may be significantly decreased when given in combination with enzalutamide. In addition, other drugs may also result in decreased activity of erdafitinib when given in combination. You should discuss the potential for these drug interactions with your treating physician before signing this consent form.

Reproductive Risks associated with Erdafitinib

The effect of erdafitinib on sperm is unknown. From when you start taking the study drug until 3 months after your last dose, you must use a condom with spermicide when you have sex and must not donate sperm. In addition, your partner must use a recognized form of contraception as described below unless they are surgically sterile. This is done to prevent pregnancy. If you have had a vasectomy (confirmed to be successful), you do not need to use a condom for birth control. If your partner becomes pregnant in the time between when you start taking the study drug until 3 months after your last dose, you must tell the study doctor immediately. The sponsor may ask you and your partner to allow them to collect information about her pregnancy and the health of the baby.

If your partner is able to have children [and you are sexually active], your partner must use highly effective birth control (contraception) during the study and until 3 months after taking the last dose of study drug. For women, birth control methods that can be used while their partner is on this study include hormonal prescription oral contraceptives, contraceptive injections, contraceptive patch, intrauterine device, surgical sterility, or true sexual abstinence. True sexual abstinence is also an acceptable method and is defined as refraining from heterosexual intercourse during the entire period of the study including up to 3 months after the last dose of drug is given. Periodic abstinence (calendar, symptothermal, post-ovulation methods) however is not considered acceptable. The type of birth control your partner utilizes must be discussed with the study doctor before you begin the study. The study doctor must approve the method you use before you can enter the study.

Risks of Abiraterone Acetate

At present, known side effects related to abiraterone acetate include:

Frequent (occurring in 20% or more subjects)

- Hypokalaemia (low blood potassium, a mineral that helps regulate heart rate/function, fluid balance in the body and is needed for adequate body function)
- Hypertension (high blood pressure)

Very Common (occurring in 10% to 20% of subjects)

- Edema peripheral (swelling of the legs as a result of the body keeping too much fluid)

Common (occurring in 5% to 10% of subjects)

- Dyspepsia (uncomfortable feeling in upper belly, indigestion)
- Hematuria (presence of blood in the urine)
- Alanine aminotransferase increased (an enzyme in the blood that measures the function of the liver)
- Urinary tract infection
- Fractures (a break in the bone)

Less Common (occurring in fewer than 5% of subjects)

- Hypertriglyceridemia (high levels of fats (triglycerides) in the blood)
- Angina pectoris (chest pain from the heart)
- Atrial fibrillation (a fast and irregular heartbeat)
- Tachycardia (rapid heartbeats)

Uncommon (occurring in fewer than 1% of subjects)

- Adrenal insufficiency (decreased function of adrenal glands that normally help maintain blood pressure, balance minerals and fluid in your body)
- Cardiac failure (heart failure, the heart is unable to supply enough blood flow to meet the body's needs.)
- Arrhythmia (changes in the rhythm of the heart)
- Abnormal ECG with QT prolongation (an abnormal finding on the ECG)
- Bone density decreased (loss of strength of bones)
- Myopathy (muscle weakness and/or muscle pain).

Unknown (frequency isn't determined since data was derived from post-marketing experience and there was no report from clinical studies

- Failure of the liver to function (called acute liver failure)
- Allergic alveolitis (swelling and irritation of the lung)
- Rhabdomyolysis (breakdown of muscle tissue)
- Torsades de Pointes (rapid or irregular heart rate associated with feeling faint or lightheaded)
- Anaphylactic reaction (severe allergic reaction that may include symptoms such as difficulty swallowing or breathing, swollen face, lips, mouth, tongue or throat, or an itchy rash

There is a small chance of severe allergic reaction to the drug which may be life-threatening.

Abiraterone acetate may cause harm to the liver. Approximately 13% of patients taking abiraterone acetate have had abnormal blood levels of liver enzymes. Rarely, failure of the liver to function may occur, which can lead to death. Interruption or discontinuation of the treatment with abiraterone acetate was sufficient to normalize the liver enzymes in majority of these cases. Your liver function will be monitored closely by blood tests every two weeks for the first 3 months of the study and monthly thereafter. If elevations in your liver function enzymes are observed, the dose of your study medication will be adjusted or discontinued.

Abiraterone acetate should be used with caution in patients with a history of heart disease. Before treatment with abiraterone acetate, high blood pressure must be controlled and low potassium must be corrected. Potassium is needed for proper function of your heart, and other essential body systems.

It is important that you contact your study doctor right away if you cannot come to your regularly scheduled visit or get your blood tests. This is because some patients have no symptoms when their blood potassium is low. Contact your study doctor immediately if:

- You feel weak; have constipation, muscle pain, or cramps. These symptoms may be caused by low blood potassium.
- Your appetite decreases, or if you develop diarrhea. Potassium may become low if you are not eating well or is lost through diarrhea.

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

If you have diabetes, your blood sugar may drop if you take Zytiga plus prednisone/prednisolone with some medicines for diabetes such as pioglitazone or repaglinide. Tell your healthcare provider if you monitor your blood sugar while taking a medicine for diabetes and notice a drop in your blood sugar.

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

Abiraterone acetate or placebo is provided as 250 mg tablets. You will take 4 tablets by mouth once daily on an empty stomach. No food should be eaten for at least 2 hours before taking the tablets and for at least one hour after taking the tablets. The tablets should be swallowed whole with water. It is important to stay on this schedule. How abiraterone acetate enters your body can be quite different depending on when you eat. This is why abiraterone acetate should not be taken with food.

Abiraterone acetate must be stored at room temperature (between 15ºC to 30ºC, or 59°F to 86°F) with the cap on tightly and should not be refrigerated. If you miss a dose of study drug, do not try to make it up. It should be omitted.

Reproductive Risks associated with Abiraterone Acetate

Abiraterone acetate should not be handled by pregnant women or women of child bearing potential unless protective gloves are worn.

Abiraterone acetate may cause harm to the unborn child and the effect of the study drug on your sperm is unknown.

Risks of Prednisone

Prednisone is given with abiraterone acetate to reduce or stop some of the side effects of abiraterone acetate, such as high blood pressure, low blood potassium, and swelling of the legs.

You should tell the study doctor if you have ever had a reaction to prednisone. You may ask your doctor for printed information about prednisone and the potential side effects (this is called a package insert).

Prednisone is a type of drug called a corticosteroid. Corticosteroids can weaken your body's ability to fight off infection and can make infections hard to diagnose or treat. If you develop fever, or suspect you have an infection, you should alert your study doctor right away.

Other side effects caused by corticosteroids are:

- Fluid retention
- Stomach bleeding
- Indigestion
- Seizures
- Swelling of the brain
- Emotional changes
- Mood swings or severe depression
- Eye problems such as cataracts or glaucoma
- Insomnia (sleeplessness, wakefulness)
- Elevated blood sugar (*for diabetics, this can make your glucose level more difficult to control)*
- Increased risk of glucocorticoid-induced bone loss (decreasing bone absorption and increasing excretion)

Possible risks associated with long term use of corticosteroids:

Cushing's syndrome: Taking corticosteroids over a long period of time can cause a condition called Cushing's syndrome. Symptoms of Cushing's syndrome include:

- Weight gain
- Muscle weakness
- A moon faced appearance
- Thin, fragile skin
- Brittle bones
- Purplish stripe marks on the skin

Adrenal insufficiency may occur due to long term use of steroid medicines taken orally. It can be life threatening at times of major illness and extreme physical stress. Symptoms of adrenal insufficiency include:

- Weakness and fatigue
- Low blood pressure
- Nausea
- Vomiting
- Diarrhea
- Irritability and/or restlessness

Prednisone should never be stopped suddenly. If you need to stop your doctor will advise on how to slowly cut down the dose and stop the drug. If you were to stop taking prednisone suddenly you could have:

- Weakness and tiredness
- Very low blood pressure
- Very low blood sugar
- Abnormal blood minerals

While these reactions are usually not severe, they are potentially fatal if not treated.

Risks of Enzalutamide

At present, known side effects related to enzalutamide include:

Likely Risks (occurring in >10% of subjects)
- Enlargement of breast tissue (Gynecomastia)
- Hot Flashes

Less Likely Risks (occurring in 1% to 10% of subjects)
- Fatigue
- Diarrhea
- Nausea
- Rash

Rare but Serious (occurring in less than <1% of subjects)
- Seizures

If you experience a side effect, your treating doctor may change your enzalutamide doses in an effort to decrease or stop any side effects. If severe side effects do develop, you and your doctor may decide that it is in your best interest to stop taking part in the study. If you choose, you always have the right to withdraw from the study. 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.

Reproductive Risks associated with Enzalutamide
Enzalutamide may be harmful to a developing fetus. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with enzalutamide. If their sexual partner may become pregnant, a condom and another form of birth control must be used during and for 3 months after treatment.

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 Risks
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 too low to be detectable and may be nonexistent.

- Abdomen CT: 8 mSv
- Chest CT: 7 mSv
- Pelvis CT: 6 mSv
- Bone Scan: 5.3

Non-physical risks

- 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 erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone to see its effects on people with prostate cancer. You might get better if you receive these study drugs, but your condition could stay the same or even get worse.

Patients may derive no benefit from the continuation of abiraterone acetate or enzalutamide with the addition of erdafitinib.

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: standard treatment, another research study, no treatment or comfort care.

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

Protecting Privacy as an Individual and the Confidentiality of Personal Information

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

- Researchers involved with this study.
- University of Washington (the study site) 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.
- 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 an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

Would we pay you if you join this study?

There is no payment for being in this study.

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?

If you join this study, you would have some extra costs. Your insurance company might pay these costs, but some insurance policies do not cover these costs. We could help find out whether your insurance company would cover these costs.

The extra costs are:

- Cost of tests that are given more often than usual.
- Cost of enzalutamide or abiraterone acetate plus prednisone.
- Cost of standard doctor visits and lab tests.
- Cost of any other medical care needed because of this study.

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

You would **not** be billed for:

- Erdafitinib
- Blood collected solely for research purposes
- Biopsy done solely for research purposes

You or your insurance company will be charged for portions of your care during this research study that are 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?

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 T. Schweizer, at (206) 606-6252 (business hours) or (206) 598-6190 (after hours).

If you have a physical injury as a direct result of being in this study, we will treat you or refer you for treatment. The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you

to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. 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.

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. There is no plan to share with you 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 would include any genetic changes (mutations) detected in your cancer, as detected by standard tests.

In addition, be aware that by agreeing to participate in this study, your information or tissue samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

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 might include genetic testing called whole genome sequencing. Whole genome sequencing looks at all the known genes 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 genetic information to identify you.

Future genetic research

Several genetic databases are available to help researchers understand different diseases. These databases contain DNA code and medical information from participants who have various diseases.

As part of this study, we might release DNA code and information about your medical condition into a genetic database in order to help future research. The genetic

database would not contain names, addresses, or other information that could be used to identify you.

The DNA code in a genetic database cannot be used by itself to identify any specific person. A researcher who already has DNA code about you could use information from a genetic database to learn more about you. Once we release information to a genetic database, we no longer have any control over the use of this information.

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.

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 Fred Hutchinson Cancer Research Center for research purposes only. These samples may also be sent to our research partners participating in this study. 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 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 Research Center. The use of these specimens will be supervised by the primary investigators at University of Washington (Michael T. Schweizer, MD) and their designees. These samples will not contain your name or other identifiable information. Analyses will be conducted at the University of Washington and/or Fred Hutchinson Cancer Research Center.

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 erdafitinib in combination with either enzalutamide or abiraterone acetate plus prednisone. You and the doctor could talk about the follow-up care and testing that would help the most.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your responsibilities

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

- Follow the schedule of study visits and procedures.
- 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:	**Call:**
This study (including complaints and requests for information)	(206) 606-6252 (Dr. Michael T. Schweizer) (206) 598-6190 (Oncology Fellow on-call 24 Hour)
If you get sick or hurt in this study	(206) 606-6252 (Dr. Michael T. Schweizer)
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	206-598-8260 (UWMC Patient Financial Services) 206-606-1091 (SCCA Patient Financial Clearance)

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

Request the on-call Oncology Fellow

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

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

Participant:

Printed Name	Signature	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.

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: 10288
Current version date: 07/15/2020
Previous version date: 08/12/2019
Copies to: Researcher's file
Subject
Subject's medical record (if applicable)