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

Consent to take part in a research study:

OPEN-LABEL, PILOT STUDY OF OLAPARIB AS A NEOADJUVANT THERAPY FOR PATIENTS UNDERGOING PROSTECTOMY FOR LOCALIZED PROSTATE CANCER

Principal Investigator: Robert Bruce Montgomery, MD. University of Washington; Seattle Cancer Care Alliance. Telephone: (206) 598-0860

Emergency (24-hour) phone:
(206) 598-6190 Request the on-call Oncology Fellow

Or

Emergency (24-hour) pager:
(206) 559-5058 Robert Bruce Montgomery, MD

Important things to know about this research study.

We are inviting you to participate in a research study. Research studies only include those who choose to participate. A person who takes part in a research study is called a research subject, or research participant. As a research participant, you have the right to know about the procedures that will be used in this research study so that you can make an informed decision whether or not to participate.

The purpose of this research study is to determine if the study drug (olaparib) has an effect on prostate cancer in men planning to undergo prostatectomy (surgical removal of the prostate) as treatment for their prostate cancer. If you agree to join the study, you will be required to take olaparib twice daily for 90 days. Following the 90 days of taking olaparib, you will undergo your planned prostatectomy. You will also be required to come in for a follow-up visit approximately 30 days after the last dose of olaparib.

We do not know if olaparib will help treat prostate cancer. There could also be side effects from taking olaparib. These side effects are described below in this form.

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You do not have to join this study. You could choose to receive standard methods to treat prostate cancer instead of participating in this study. We will give you details about the purpose, procedures, risks and possible benefits related to this study. We will also explain other treatment options to you. We will give you any other information that you need in order to make an informed decision about whether or not you would like to participate in this study.

The 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 decide to join this study, we will give you a signed and dated copy of this consent 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 planning to have your prostate surgically removed. We will enroll up to 15 patients on this research 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 this research study. You are free to say "yes" or "no," or to drop out after joining. There is no penalty or loss of benefits if you say "no." Whatever you decide, your regular medical care would not change.

Why are we doing this research study?

We are doing this research study to determine whether the study drug olaparib, when given to men with prostate cancer prior to surgical removal of their prostate will result in favorable changes in the prostate cancer. Specifically, we want to know if taking olaparib for 90 days can result in more men with no evidence of prostate cancer in their prostate at the time of its surgical removal (this is also called a higher pathological complete response rate). In theory, a higher pathological complete response rate could increase the chances that men with prostate cancer will remain cancer free following their prostatectomy.

Olaparib is a drug that works by interfering with the activity of a substance called PARP, which is inside cells (individual unit that makes up the tissues of the body). PARP repairs DNA. DNA is the substance in cells that controls cell growth. By interfering with DNA repair, olaparib can decrease the growth of cancer cells. A capsule formulation of olaparib (tradename Lynparza™) is approved by both the European Commission (EC), US Food and Drug Administration (FDA) and other countries for the treatment of women with advanced ovarian cancer.

A tablet formulation of olaparib is being tested in this study. Olaparib is not approved to treat prostate cancer, thus its use in this research study is considered investigational or experimental. Olaparib is a drug taken by mouth.

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If you join this study, we would give you olaparib for 90 days 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 (Up to 28 days prior to starting study drugs)
If you choose to participate in this study, you will first sign this Informed Consent Form before any study-related procedures are performed, and your study doctor will have up to 28 days to complete screening tests and procedures 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. The following tests and procedures will be done at the beginning of the study, also known as screening period. Your study doctor can give you more details about these tests and procedures.

- We will ask you 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.
- Collect a blood sample (approximately 20 mL or 4 teaspoons)
    - to study biomarkers. Biomarkers are DNA, RNA, proteins and other molecules in your blood. The intent of this research is to discover ways that the study drugs work and how your body responds to them. Your blood and tissue samples contain genes, which are made up of DNA (deoxyribonucleic acid) and which serve as the "instruction manual" for the cells that make up our bodies. RNA (ribonucleic acid) helps to carry out DNA's "instructions". Genomic research is the study of how variation in DNA and RNA, including mutations, can contribute to disease and drug response. The Sponsor will look at variation in your genomic and other biomarkers. Biomarker information will be analyzed together with the clinical data collected in this study. Your samples may also be used to help develop new tests. These results are for research only.
    - for standard laboratory tests
    - to measure prostate-specific antigen (PSA)
- Give you a physical examination and digital rectal examination.
- Evaluate ECOG performance status (criteria used to assess how your disease is progressing and how the disease affects the daily living abilities).

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- Perform an electrocardiogram (ECG) to check the electrical activity of your heart.
- Record your vital signs such as heart rate, blood pressure, height and weight.
- Assess tumor and document clinical stage of disease. Patients will undergo bone scan and Computed Tomography (CT)/Magnetic Resonance Imaging (MRI) of the pelvis if defined as having high risk disease or at the investigator's discretion.

Treatment Period

If you are eligible for this study and choose to participate, you will start the study medication, olaparib. You will take two 150 mg tablets of olaparib (300 mg total) twice daily for 90 days. You should take olaparib tablets at the same time each day, approximately 12 hours apart with one glass of water. The olaparib tablets should also be swallowed whole, not chewed or crushed, dissolved or divided. You should also not drink grapefruit juice while taking olaparib, as this can affect the way the study medication works. Olaparib tablets can be taken with or without food. You will be given a diary to record your study drug dosing. Study staff will instruct you on how to fill out your diary.

If vomiting occurs shortly after the study drug tablets are swallowed, the dose should only be replaced if all of the intact tablets can be seen and counted. Should you miss a scheduled dose for whatever reason (e.g., as a result of forgetting to take the tablets or vomiting), you will be allowed to take the scheduled dose up to a maximum of 2 hours after that scheduled dose time. If greater than 2 hours after the scheduled dose time, the missed dose is not to be taken and you should take your next dose at the next scheduled time.

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.

Day 1 Visit

- Give you a physical examination.
- Record your vital signs such as heart rate, blood pressure, height and weight if performed ≥ 96 hours prior.
- Collect a blood sample (approximately 20 mL or 4 teaspoon) if screening assessments were done > 28 days prior
    - to study biomarkers.
    - for standard laboratory tests
    - to measure prostate-specific antigen (PSA)

- Dispense olaparib (30-day supply as indicated).

Day 30 (± 5 Days), 60 (± 5 Days), and 90 (± 5 Days) Visits

- Give you a physical examination.
- Evaluate ECOG performance status.
- Record your vital signs such as heart rate, blood pressure, height and weight.
- Collect a blood sample (approximately 20 mL or 4 teaspoon)
    - to study biomarkers
    - for standard laboratory tests
    - to measure prostate-specific antigen (PSA)
- Dispense olaparib (30-day supply as indicated)

Day 90 (± 14 Days)

- Prostatectomy

Day 132 (± 5 Days) or End of Study Visit

- Give you a physical examination.
- Evaluate ECOG performance status.
- Record your vital signs such as heart rate, blood pressure, height and weight.
- Collect a blood sample (approximately 20 mL or 4 teaspoon)
    - to study biomarkers
    - for standard laboratory tests
    - to measure prostate-specific antigen (PSA)

How long would you stay in this study?

If you join this study, you will take the study drug for 90 days. After you finish the study drug, you will undergo your planned surgery and follow-up with your surgeon per their advice. We will also follow-up with you in clinic approximately 30 days after your last dose of olaparib.

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 leave 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.

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If you leave the study for any reason before completing 90 days of treatment, we will follow-up with you until 30 days after your last dose of olaparib.

What are the side effects (risks)?

In this part of the consent form, we tell you the side effects from the tests and treatments in this study. There may be side effects we do not know about yet. We carefully watch everyone in the study for side effects. Side effects may be mild or very serious. Your health care team may give you medicines 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. There also is a risk of death.

If you join this study, we would tell you if we discover new side effects that could affect you. You should talk to your study doctor about any side effects that you have while you are in this study.

Olaparib (also known as Lynparza®):

Olaparib is available by prescription to treat ovarian cancer. The following side effects thought to be caused by olaparib occurred in women treated with olaparib for ovarian cancer.

Tell your study doctor right away if you notice any of the following side effects – you may need urgent treatment:

Common Side Effects (affects more than 1 in 10 patients)
• Nausea (feeling sick) • Vomiting (being sick) • Weakness and/or tiredness • Indigestion and/or heartburn (dyspepsia) • Loss of appetite • Headache • Cough • Change in taste of foods (dysgeusia) • Dizziness • Diarrhea. Your doctor may prescribe a medicine to treat this. If it gets severe, tell your doctor right away. • 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 white blood cells that support the immune system (lymphopenia) which can be associated with increased susceptibility to infection.

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Common Side Effects (affects more than 1 in 10 patients)
• Increase in blood creatinine seen from a laboratory test showing how your kidneys are working. • Mean cell volume elevation (an 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. • 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.
Less Common Side Effects (affects 1 to 10 in 100 patients)
• Sore mouth (stomatitis) • Pain in the stomach area under the ribs (upper abdominal pain) • Rash • Allergic reactions • Itchy rash on swollen, reddened skin (dermatitis)

Olaparib taken in combination with other medications may be associated with other risks that are unknown at this time. You need to tell your study doctor of all medications and supplements (i.e., herbal products, vitamins and nutritional supplements) that you take. While you are in this research study, you will not be allowed to receive other anti-cancer therapy (i.e., chemotherapy, immunotherapy, hormonal therapy, radiotherapy, biological therapy) and certain vaccines. Your study doctor will be provided with a list of medication that you must avoid while you are taking your study medication so it is important to consult with the study doctor before taking anything new.

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, take special care when driving or using tools or machines.

Other potential risks:

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

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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 less than 1% of patients treated with olaparib in previous studies, and some reports have been fatal. 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. If you experience any new or worsening symptoms of shortness of breath, cough and fever, you should contact your study doctor ***as soon as you can***.

Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) have been reported in less than 1% of all patients treated with olaparib in previous studies and the majority of cases have been fatal. It is not known if olaparib caused MDS and/or AML in these patients as they had other possible causes, in particular they had received extensive previous chemotherapy.

- MDS is a pre-cancerous condition where the bone marrow is not as good at producing blood cells as it was before (can be red blood cells and/or white blood cells and/or platelets). This condition has the potential to transform into acute myeloid leukemia.

- AML is 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.

The study doctor may decide to interrupt and/or reduce your olaparib dose if you experience certain side effects. If your dose is reduced you will be given a new bottle of tablets.

The study doctor will monitor your blood cell levels during the study and may decide you need to have further tests, which may include obtaining your bone marrow sample or blood sample. Your study doctor will stop treatment with olaparib if you develop MDS or AML.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Blood draw risks:

You may feel some discomfort or pain from where the needle is placed in your vein to draw blood sample. Sometimes bruising may develop at the site where the blood was drawn or needle was placed, and occasionally infection or bleeding may occur at the puncture site. Light-headedness and/or fainting may also occur during blood collection.

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Electrocardiogram (ECG) risks:

You may feel discomfort during the attachment and removal of the ECG leads to and from the skin.

Radiation risks:

During your screening visit, bone scans, and computerized tomography (CT) scans or magnetic resonance imaging (MRI) may be used to evaluate your disease.

A **CT scan** provides multiple detailed pictures of the inside of the body, like an MRI scan but the CT scan uses radiation, and therefore exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, this amount of radiation should not create a significant risk to your health.

There is also 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. Uncommonly, 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.

The **bone scan** involves an injection, in the vein of your arm, of a radiotracer (radioactive compound that localizes in the bone). The injection of the radiotracer may feel like a small sting and there may be possible bruising at the injection site. Bone scan side effects are not common, and when encountered are usually mild, such as nausea and vomiting, or you may become uncomfortable lying still for the duration of the examination. You will be exposed to a limited and medically acceptable dose of radiation during the procedure. There is always a slight risk of damage from being exposed to any 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. For comparison, the estimated radiation dose from each of these tests is listed below.

- 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 as a result of the radiological evaluation and treatment for your cancer.

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Magnetic Resonance Imaging (MRI) risks:

Risks of MRI include claustrophobia, discomfort due to lying still for a prolonged period of time, and other factors which will be described to you and discussed with you at the MRI center. The most common contrast material used for MRIs is gadolinium. Persons with acute or chronic severe kidney insufficiency, or chronic liver disease experiencing kidney insufficiency, may develop a severe disease called nephrogenic systemic fibrosis (NSF) from gadolinium based contrast material. NSF triggers thickening of the skin, organs, and other tissues. The exact cause is unclear, and there is no effective treatment. Your kidney and liver function will be checked to see if you are eligible to receive gadolinium. The contrast solution that may be given for an MRI scan may cause an allergic reaction (rare). Severe allergic reactions can be life threatening. MRI contrast solution can cause kidney damage, especially if you are diabetic, dehydrated (lost body water) or elderly.

Reproductive risks:

If you join this study, you would have to use condoms while taking the study drug, and for 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. 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 and/or 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 or you are completing questionnaires. 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.

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What are the benefits?

We do not know if this study would help you. There may or may not be a direct benefit to you from taking part in this study. We are testing olaparib to see its effects on people with prostate cancer. 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:

- No treatment.
- Other research studies.
- Prostatectomy.
- Prostate radiation therapy.

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

What if I change my mind about taking part in this research study?

You are free to change your mind at any time. Your participation in this study is voluntary. You have the right to choose whether or not you want to take part in this research study and you may decide to stop participating in the study once you have started. You may discontinue study drug at any time, for any reason. Leaving the study will not result in any loss of benefits that you already have.

It is very important that you tell your study doctor right away if you decide you want to stop participating in this study. Your study doctor will talk with you about your choices.

If you decide to stop study drug, you will still come in for a follow-up visit 30 days after the last dose of study drug or before you start new cancer treatment, whichever happens first. Study procedures which include blood sample collection will be performed at this follow-up visit.

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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
- AstraZeneca (the manufacturers of olaparib) and their agents
- Institutional Review Board (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

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.

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.

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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 5 years following the completion of this study. Samples will be stored at University of Washington and/or Fred Hutchinson Cancer Research Center. Researchers will not report their results to you or your doctor. Your samples will be destroyed after use for the purposes of this study. All samples will be kept in locked research laboratories at University of Washington and/or Fred Hutchinson Cancer Research Center. These samples will not contain your name or other identifiable information. The samples will be given a unique number replacing any identifiable information. This unique number will be used to identify the sample and corresponding data. No personal details identifying the research participant will be available to any person. Analyses will be conducted at the University of Washington and/or Fred Hutchinson Cancer Research Center.

If you decide you no longer want your samples to be used for research purposes, you can inform the study doctor. Then, any sample that remains will no longer be used and destroyed/disposed of. Samples or related information that have already been used for this research study would not be returned.

If you stop the study for any reason, the information previously collected will remain in the study records and may be included in the analysis of results. This information cannot be removed from the study records.

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 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 standard doctor visits and laboratory tests.
- Cost of tests that are given more often than usual.
- 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:

- Olaparib (study drug)

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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 the study doctor, Dr. Robert Bruce Montgomery at **206-598-0860**. 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.

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 will only be used for the purposes of this research study.

During this study, if the researchers learn new information that may be important to your general health or to you disease or condition, they will not share that information with 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 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 study doctor could tell you about the effects of stopping olaparib. You and the study doctor could talk about the follow-up care and testing that would help the most.

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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 medication 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) 598-0860 (Dr. Robert Bruce Montgomery)
If you get sick or hurt in this study	(206) 598-0860 (Dr. Robert Bruce Montgomery)
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 (24-hour) phone:
(206) 598-6190 Request the on-call Oncology Fellow

Or

Emergency (24-hour) pager:
(206) 559-5058 Robert Bruce Montgomery, MD

Signatures

I have carefully read this consent form. This study has been explained to me and I have had the chance to ask questions about it. All questions have been answered to my satisfaction. I understand I have a choice whether to take part or not to take part in this study. The risks, benefits and alternative treatments have been explained to me. I agree to take part in this research study.

_____

Participant Printed Name

_____

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 the study purpose, procedures, risks and benefits, and alternative treatment options with the person signing above. I have answered all questions to his/her satisfaction. All elements of the consent form were reviewed in detail and discussed with the subject. The subject understands that participation is completely voluntary and consent may be revoked at any time. A copy of the signed consent form will be given to the participant.

_____

Person obtaining consent Printed Name

_____

Person obtaining consent Signature and Date

Protocol: 9985
Current version date: 11/20/2018
Previous version date: 06/29/2018
Copies to: Researcher's File
Subject
Subject's Medical Records