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University of Washington
Fred Hutchinson Cancer Center
CONSENT FORM

RG1006269
Acalabrutinib in combination with anti-CD19 Chimeric antigen receptor T-cells (CART) in B-cell lymphoma

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24 HOUR EMERGENCY PHONE NUMBER(S): UWMC Paging Operator
(206) 598-6190
Please ask the operator to page the hematology/oncology fellow on call.

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to see if giving acalabrutinib (Calquence; manufactured by AstraZeneca) along with axicabtagene ciloleucel (axi-cel; an FDA approved T-cell immunotherapy) will be safe and help improve the treatment of relapsed or refractory Diffuse large B-Cell lymphoma (DLBCL) and follicular lymphoma (FL), for people who would have otherwise received axi-cel alone.

People who agree to join the study will be asked to attend about 10 visits over 15 months. The study involves treatment with acalabrutinib, collecting your blood to create CAR-T cells and chemotherapy to reduce your cancer.

We do not know if acalabrutinib in combination with axicabtagene ciloleucel will help treat Diffuse large B-Cell lymphoma (DLBCL). It could possibly make your condition/disease worse. Acalabrutinib could cause side effects such as bleeding, infections, low blood cell counts and abnormal heart rhythms as described below in this form.

You do not have to join this study. You can choose to receive standard methods to treat DLBCL or FL 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 Diffuse large B-Cell lymphoma (DLBCL) or follicular lymphoma (FL). Up to 50 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 if acalabrutinib can be given safely in combination with axi-cel (a CAR-T immunotherapy) in relapsed or refractory DLBCL and FL. We also want to see how well patients will respond to this combination treatment.

We are studying acalabrutinib (Calquence). Acalabrutinib is a small-molecule Bruton's tyrosine kinase (BTK) inhibitor.

Acalabrutinib is an approved drug for the treatment of adult patients with mantle cell lymphoma and chronic lymphocytic leukemia/small lymphocytic lymphoma.

In this study, we want to learn what effects, good or bad, acalabrutinib in combination with axi-cel have on people with DLBCL and FL. If you join this study, we would give you acalabrutinib and axi-cel and watch carefully for any side effects.

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

Screening Procedures:

- **Informed Consent:** Review of your understanding of this Informed Consent Form and providing your signature and the date.
- **Demographics:** Recording of your age, date of birth, gender, race, and ethnicity, according to local regulations regarding collection of this information.
- **Medical & Surgical History:** Review of your medical history, current medical conditions and recent changes to your health, any medical procedures that you may be currently undergoing, and any prior cancer treatment you have received.
- **Medication History:** Review of any medications you have taken recently or are taking currently.
- **Physical Examination**: A complete physical examination, including measurement of your height and weight.
- **Vital Signs:** Measurement of your vital signs (blood pressure, heart rate, respiratory rate, and body temperature).
- **Bone Marrow Biopsy:** A bone marrow biopsy may be done. A small piece of bone is removed. This is done under local anesthesia.
- **Routine Blood Draw:** Collection of blood for laboratory tests including routine and special blood chemistries, blood counts, and blood clotting factors to evaluate your overall health and organ function (for example, liver, heart, kidneys).

- **Pregnancy Test:** Collection of 1-2 teaspoons [5-10 mL] of blood or a urine sample for a pregnancy test if you are a woman with reproductive potential. This test must be re-confirmed negative 2 days before you start acalabrutinib
- **Imaging Assessment:** Computed tomography (CT) scans and positron emission tomography (PET) scans will be performed to see the amount of cancer in your body
- **ECHO or MUGA:** An ECHO is a test that uses high frequency sound waves to make pictures of your heart. A MUGA is a diagnostic test to evaluate the pumping functions of your ventricles in your heart.

Treatment with Acalabrutinib

- **Routine Blood Draw:** Collection of blood for laboratory tests including routine and special blood chemistries, blood counts, and blood clotting factors to evaluate your overall health and organ function (for example, liver, heart, kidneys).

Leukapheresis: This is a procedure to separate and collect white blood cells. It is the first step in CAR (chimeric antigen receptor) T-cell therapy. The collected T-cells are used to make a special version of T-cells called CARs. You will sign a separate standard of care informed consent detailing the procedure and risks of leukapheresis.

Lymphodepleting Chemotherapy: You will receive chemotherapy to reduce the amount of cancer in your before you receive your CAR-T cells. The standard of care chemotherapy you will be given will include cyclophosphamide and either fludarabine or bendamustine on different days before your axi-cel infusion. The risks of these two drugs are described below. The purpose of lymphodepleting chemotherapy is to create space for CAR-T cells to survive and expand.

- **Routine Blood Draw:** Collection of blood for laboratory tests including routine and special blood chemistries, blood counts, and blood clotting factors to evaluate your overall health and organ function (for example, liver, heart, kidneys).

Axi-cel Treatment: A couple of days after you complete lymphodepleting chemotherapy, you will receive the infusion of axi-cel. You will be given this treatment in a hospital to make sure you are closelywatchedfor any side effects after infusion. You will sign a separate standard of care informed consent detailing the procedure and risks of axi-cel treatment.

- **Routine Blood Draw:** Collection of blood for laboratory tests including routine and special blood chemistries, blood counts, and blood clotting factors to evaluate your overall health and organ function (for example, liver, heart, kidneys).

After you have finished taking acalabrutinib and axi-cel you would enter the **follow-up** part of the study. We would do these tests and procedures:

- **Physical Examination**: A complete physical examination, including measurement of your height and weight.
- **Vital Signs:** Measurement of your vital signs (blood pressure, heart rate, respiratory rate, and body temperature).
- **Bone Marrow Biopsy:** A bone marrow biopsy may be done. A small piece of bone is removed. This is done under local anesthesia.
- **Routine Blood Draw:** Collection of blood for laboratory tests including routine and special blood chemistries, blood counts, and blood clotting factors to evaluate your overall health and organ function (for example, liver, heart, kidneys).

- **Imaging Assessment:** Computed tomography (CT) scans and positron emission tomography (PET) scans will be performed to see the amount of cancer in your body

How long would you stay in this study?

If you join this study, you would stay in this study for about 15 months.

You would take acalabrutinib every 12 hours starting up to 3 weeks and before leukapheresis (a procedure to use your blood create CAR-T cells). After that, you will receive chemotherapy to reduce the amount of cancer in your body before you receive the CAR-T cells. After you receive the CAR-T cells, you would have follow-up exams in the office or clinic every 3 months for up to 1 year if you are doing well on acalabrutinib and there is no evidence of your lymphoma returning.

Doctors could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You are not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

Long-term follow-up means keeping track of someone's medical condition for a long time. If you join this study, we would see you every 3 months for 1 year and then follow you for up to 5 years. We would also ask your doctor to send a copy of your medical records. This information will help us learn about the long-term effects of acalabrutinib in combination with axi-cel immunotherapy.

You do not have to be in long-term follow-up. You could say "yes" or "no". Either way, you could still join this study. If you drop out of the study, you would be asked if we could contact you regarding the status of your cancer.

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

What are the side effects (risks)?

This form lists side effects of *individual* drugs. Other side effects could occur when we use these drugs *together*.

As of 30 April 2021, approximately 6130 patients have received acalabrutinib through their participation in clinical trials with either single agent acalabrutinib or acalabrutinib in combination with other anti-cancer agents (other drugs) for the treatment of blood cell cancers, non- blood cell cancers, or rheumatoid arthritis.

Acalabrutinib is an approved drug for the treatment of adult patients with mantle cell lymphoma (MCL) who have had prior treatment with MCL, and chronic lymphocytic leukemia/small

lymphocytic lymphoma (CLL/SLL). Acalabrutinib is also being investigated in clinical trials for other types of cancers.

Acalabrutinib works by blocking the action of the protein that signals B-cells (your cancer cells) to multiply. This helps stop the spread of your cancer cells. As with any drug, this may also be associated with having side effects. The full side effect profile of acalabrutinib is not yet known. Side effects can vary from mild to very serious and may vary from person to person. You may have some or no side effects. Some side effects usually get better without any treatment.

Everyone taking part in the study will be watched carefully for any side effects. You should talk to your study doctor about any side effects that you have while taking part in the study. If you have severe side effects from the study drug, the study doctor may ask you not to continue in the study.

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

Serious side effects that may occur with <u>acalabrutinib</u> include:

Hemorrhage (Bleeding)
Events of bleeding have occurred in patients treated with acalabrutinib. These include minor events such as nose bleeds, bruising, or ecchymosis (bleeding in skin) and major events which could rarely lead to death such as internal bleeding in the bowel or bleeding in the brain. If you are using any blood thinners (drugs that prevent your blood from clotting e.g. aspirin or warfarin) your risk for bleeding may be increased.

Infections
Infections have been reported to occur in patients receiving acalabrutinib. The most commonly reported infections were upper respiratory infection, sinus infection, and pneumonia (lung infection). Infections that are uncommon or rare, but which can result in severe disability or death, have also occurred in patients receiving acalabrutinib. These infections include hepatitis B virus (HBV) reactivation and progressive multifocal leukoencephalopathy (PML). HBV reactivation is where a type of liver virus infection becomes active again if you had a previous infection with that virus. PML is a rare, serious brain infection caused by a virus, usually in patients with weakened immune systems, and can result in severe disability or death.
Tell your study doctor right away if you experience any symptoms of an infection such as fever, runny nose, sore throat, cough, and feeling tired. If you have previously had HBV or any other viral liver infection, your study doctor may need to monitor you closely.

Cytopenias (Low Blood Cell Counts)
Patients receiving acalabrutinib can experience low blood cell counts. Your study doctor will do blood tests while you receive acalabrutinib to check your blood cell counts, which include:

- White blood cells - cells that fight against infections
- Red blood cells – cells that carry oxygen throughout your body
- Platelets – cells that help your blood to clot

Second Primary Malignancies
The development of a second cancer has been reported to occur in some patients who receive acalabrutinib. The majority of these cancers were skin cancers. If you develop a second cancer,

you may need to stop the study drug, and your doctor may need to do further tests to diagnose what the cancer is.

Atrial Fibrillation/Atrial Flutter
Atrial fibrillation and atrial flutter are abnormal heart rhythms, which have been reported to occur in some patients who receive acalabrutinib. Atrial fibrillation or flutter may occur more commonly in patients with other risk factors for cardiac (heart) disease, such as hypertension (high blood pressure), diabetes mellitus, acute infections, or a previous history of atrial fibrillation. While atrial fibrillation or flutter often may not cause symptoms, some patients may experience palpitations (feeling like your heart is beating too hard or too fast), fainting, chest pain, or shortness of breath. If you have any of the symptoms described above, tell your doctor.

Acalabrutinib side effects considered to be potentially caused by the drug are provided in the table below. These side effects are based on analyses of safety data from patients who received single-agent acalabrutinib.

Very Common (at least 10% of patients)	Common (at least 1% but less than 10% of patients)	Uncommon (less than 1% of patients)
• Leukopenia/neutropenia *(low white blood cells)* • Anaemia *(low red blood cells)* • Diarrhoea *(frequent or loose stools)* • Nausea • Constipation *(bowel movements that are infrequent and hard to pass)* • Vomiting • Abdominal pain • Fatigue *(feeling tired)* • Infection • Musculoskeletal pain • Arthralgia *(joint pain)* • Second primary malignancy *(development of second cancer)* • Headache • Dizziness • Bruising *(bleeding in skin)* • Rash • Haemorrhage/haematoma *(bleeding or collection of blood outside blood vessels)*	• Thrombocytopenia *(low platelets)* • Atrial fibrillation/flutter *(a type of abnormal heart rhythm)* • Asthenia *(lack of energy)* • Epistaxis *(nose bleeds)* •	• Tumour lysis syndrome*

*Tumour Lysis Syndrome (TLS) can occur when a drug kills a large amount of cancer cells at the same time causing the contents of the cancer cells to spill into the blood stream. This can lead to parts of your body not working, which can be life-threatening if not monitored and treated promptly. Cases of TLS (including one case of TLS caused by acalabrutinib) have occurred in patients receiving acalabrutinib. If your study doctor thinks you are at risk for TLS, you will be closely monitored during the study.

<u>Side Effects Potentially Associated with Acalabrutinib</u>

Liver Toxicity

Increases in the blood level of liver enzymes (enzymes are proteins that participate in chemical reactions in the body) may occur with acalabrutinib treatment. The role of acalabrutinib in causing the increases in these enzymes has not been established. Temporary, rarely severe liver enzyme increases have been observed in some patients treated with acalabrutinib, and these increases usually resolve with or without acalabrutinib discontinuation. Uncommonly, very high increases may potentially be associated with liver damage. You may get an increase of aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels, two major types of liver enzymes, in a blood test but not have any symptoms or feel unwell. Your study doctor will monitor your liver enzymes regularly during treatment.

Unknown/Unexpected Side Effects

It is possible that some patients could have side effects that we do not know about yet, including severe or life-threatening allergic reactions. Acalabrutinib when taken in combination with other medicines may be associated with other risks that are unknown at this time, including those that could lead to death. Although there is limited information on how acalabrutinib may interact with other medications, it is important to inform your study doctor about any medications (prescription, over-the-counter, and herbal supplements) that you are taking. There may be rare or unknown side effects which have not been seen thus far. Therefore, if you suffer any health issues or injuries, or your condition gets worse, it is important that you tell your study doctor or nurse of any side effects, you may experience, not just those listed above, and if any of the side effects become serious. Your doctor will determine if the side effects are related to the experimental drugs or chemotherapy and will adjust study medications as necessary. You may receive lower doses of chemotherapy than the doses that demonstrated survival benefit.

Many side effects go away shortly after the study drug is stopped, but in some cases side effects can be serious, long lasting or permanent. Your doctor may prescribe you medication to help you overcome these side effects. For more information about side effects, ask the study doctor and/or the research staff.

Leukapheresis Risks

There are some risks with the leukapheresis procedure. These include:

- Discomfort and bleeding at the site where the needles are inserted
- headache,
- muscle cramping,
- feeling of anxiety,
- hypotension (decrease in blood pressure),
- chills,
- nausea,
- vomiting,
- dizziness,
- fainting,
- infection at the site
- increased bleeding

If a severe discomfort should occur during leukapheresis, the procedure will be stopped immediately and you will be monitored until you are ready to go home.

Lymphodepleting Chemotherapy Risks

You will be given cyclophosphamide and either fludarabine or bendamustine for lymphodepleting chemotherapy. There are some risks with this type of chemotherapy.

Cyclophosphamide Risks:

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cyclophosphamide, more than 20 and up to 100 may have:
• Infection, especially when white blood cell count is low • Blood in urine • Nausea, vomiting, diarrhea, loss of appetite, pain in belly • Sores in mouth • Absence of menstrual period which may decrease the ability to have children • Hair loss, skin changes, rash, change in nails

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cyclophosphamide, from 4 to 20 may have:
• Fluid around the heart • Scarring of the lungs which may cause shortness of breath • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Loss or absence of sperm which may lead to an inability to father children • Stuffy nose

RARE, AND SERIOUS In 100 people receiving Cyclophosphamide, 3 or fewer may have:
• Damage to the heart or heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness • Swelling of the body including the brain which may cause dizziness, confusion • A new cancer including cancer of bone marrow (leukemia) caused by chemotherapy • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body

Fludarabine Risks:

COMMON, SOME MAY BE SERIOUS In 100 people receiving Fludarabine, more than 20 and up to 100 may have:
• Cough • Infection, especially when white blood cell count is low • Bruising, bleeding • Increased risk of unusual infections lasting more than 6 months • Vomiting, loss of appetite • Tiredness, fever • Pain

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Fludarabine, from 4 to 20 may have:
• Damage to organs (brain, lungs, others) which may cause tiredness, changes in thinking or shortness of breath

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Fludarabine, from 4 to 20 may have:
• Anemia, kidney problems which may cause tiredness, bruising, or swelling • Nausea, chills • Feeling of "pins and needles" in arms and legs • Confusion

RARE, AND SERIOUS In 100 people receiving Fludarabine, 3 or fewer may have:
• Kidney damage which may require dialysis

Bendamustine Risks:

COMMON, SOME MAY BE SERIOUS In 100 people receiving Bendamustine, more than 20 and up to_100 may have:
• Anemia which may cause tiredness, or may require blood transfusions • Constipation, diarrhea, nausea, vomiting • Fever, tiredness • Bruising, bleeding • Infection, especially when white blood cell count is low • Loss of appetite • Headache • Cough

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Bendamustine, from 4 to 20 may have:
• Sores in mouth which may cause difficulty swallowing • Scarring of the lungs • Swelling and redness at the site of the medication injection • Weight loss • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Severe blood infection • A new cancer resulting from treatment of a prior cancer • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • Kidney damage which may cause swelling, may require dialysis • Damage to the liver • Blisters on the skin • Rash • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body • Shortness of breath

RARE, AND SERIOUS In 100 people receiving Bendamustine, 4 or fewer may have:
• High blood pressure which may cause dizziness, blurred vision

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.

- 18-FDG PET/CT: 19 mSv
- CT-neck: 3 mSv
- CT-chest: 7 mSv
- CT-abdomen: 8 mSv
- CT-pelvis: 6 mSv

Bone Marrow Aspiration and Biopsy Risks
The risks of this procedure include bleeding, infection, local nerve damage, pain from the needle sticks, and pain from aspirating the bone marrow with a syringe. Care will be taken to avoid these complications.

Central Line Access Risks
You will be required to get a central line in order to get leukapheresis if you do not already have one. You may receive a central venous catheter placement or some other type of line. The risks of this procedure vary between which type of central line would be best for you. Some risks include air embolism, inflammation of the vein, infection, blood clot, nerve irritation and injury and/or irritation to the heart muscles resulting in arrhythmia.

Reproductive risks

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

If you join this study, you would have to use an effective method of birth control from the time this form is signed until at least 2 after the last dose of acalabrutinib or 4 months after the last dose of CAR-T, whichever is later. If you are already using a method of birth control, you would have to check with the study doctor or a member of the study staff to make sure it is acceptable.

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

Meals and Dietary Restrictions
Acalabrutinib is best taken with water and can be taken with or without food. You should avoid using herbal remedies or dietary supplements, especially St. John's wort, unless approved by the study physician.

What are the benefits?

We do not know if this study would help you. We are testing acalabrutinib in combination with axi-cel to see its effects on people with relapsed or refractory DLBCL and FL who are otherwise

eligible to receive axi-cel alone. You might get better if you receive acalabrutinib in combination with axi-cel, but your condition could stay the same or even get worse. We hope the information from this study will help other people with DLBCL and FL 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, or no treatment.

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.
- AstraZeneca (the sponsor of the study) and their agents.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center and University of Washington.
- Office for Human Research Protections, Food and Drug Administration, Department of Health and Human Services, 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.

Would we pay you if you join this study?

There is no payment for being in this study.

You may be eligible for reimbursement of certain travel-related costs. Please speak with a member of the study team for additional information.

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 Axicabtagene ciloleucel (axi-cel) Treatment including the preparation of the product and the infusions
- Paying the people who give acalabrutinib and axi-cel and the cost of the equipment they use.
- Cost of people and equipment to give acalabrutinib and axi-cel. There is no charge for acalabrutinib itself.
- 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:

- The cost of acalabrutinib

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 Dr. Ajay Gopal, MD at (206) 606-2037. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information and research blood samples be used for?

Your information and blood samples will be used for the purposes of this study.

During this study, if the researchers learn new information that could possibly be important to your general health or to you disease or condition, they will not be able to share that information with you because these tests will not be kept in your medical record. It will be part of your research record and be used for exploratory research purposes only.

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 the study. You and the doctor could talk about the follow-up care and testing that would help the most.
- Before you leave the study, the doctor might ask you to continue in the long follow-up part of the study.

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

Your responsibilities

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

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-606-2037 (Dr. Ajay Gopal, MD)
If you get sick or hurt in this study	206-606-2037 (Dr. Gopal, MD)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	206-606-1377 (Patient Financial Services, Fred Hutchinson Cancer Center)

Emergency number (24 hours): 206-598-6190
(UWMC Paging Operator)

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

Do you agree to have blood collected prior to treatment with Acalabrutinib, prior to cell collection, at the lymphodepleting chemotherapy timepoint (after cells are collected and before CAR-T), and shortly after CAR-T for research purposes?

(circle one)

YES **NO**

Signatures

Please sign below if you:

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

Participant:

Printed Name	Signature	Date

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

Impartial Witness or Interpreter:

Printed Name	Signature	Date

Researcher's statement

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

Person obtaining consent signature:

Printed Name	Signature	Date

---------- Use this section only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

_____
Printed Name of the Impartial Witness

_____ _____
Signature of Impartial Witness 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.

_____
Printed Name of Interpreter

_____ _____
Signature of Interpreter Date

Copies to: Researcher's file
Subject
Subject's medical record (if applicable)