Official Title	Phase 1 Study of FLAG-Ida with Pivekimab Sunirine (PVEK) for Adults with Newly Diagnosed Adverse-Risk Acute Myeloid Leukemia and Other High-Grade Myeloid Neoplasms
NCT Number	NCT06034470
Document Type	Informed Consent Form
Document Date	12/19/2025

Fred Hutchinson Cancer Center
University of Washington

Consent to take part in a research study:

Phase 1 Study of FLAG-Ida with Pivekimab Sunirine (PVEK) for Adults with Newly Diagnosed Adverse-Risk Acute Myeloid Leukemia and Other High- Grade Myeloid Neoplasms

Investigator: Jacob Appelbaum, MD, PhD. University of Washington; Fred Hutchinson Cancer Center. Pager: 206-314-2788

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

Call the paging operator at the University of Washington Medical Center at 206-598-6190, and ask for the Fellow on call for Hematology/Oncology.

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to see whether adding the drug pivekimab sunirine (here abbreviated as "PVEK") to a chemotherapy regimen called FLAG-Ida is safe and effective for adults with AML or another high-grade myeloid neoplasm.

People who agree to join the study will likely be admitted to the hospital and be asked to attend frequent clinic visits over several months, as is standard for patients with AML and related diseases. The study involves the administration of multiple doses of intravenous chemotherapy.

We do not know if the combination of PVEK and FLAG-Ida would help treat AML and other high-grade myeloid neoplasms and could even make your condition/disease worse. Both PVEK and FLAG-Ida could cause side effects during administration (e.g. chills) as well as after administration (e.g. low blood counts and complications thereof), as described below in this form.

You do not have to join this study. You can choose to receive standard methods to treat your 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 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 AML or a related high-grade myeloid neoplasm. Up to 30 people will join this study.

Research is not the same as treatment or routine 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 combination of PVEK and FLAG-Ida chemotherapy. We want to know if this combination is safe, whether one or two doses of PVEK in combination with FLAG-Ida is safe, and ultimately whether this combination is an effective treatment for AML and other high-grade myeloid neoplasms.

We are studying PVEK [pivekimab sunirine, previously known as IMGN632]. PVEK is an experimental antibody-drug conjugate targeting CD123, a protein that is often expressed on cancer cells in AML and related malignancies. PVEK is currently being tested as a treatment for AML. We are also studying FLAG-Ida chemotherapy, which consists of fludarabine ("FL") [trade name: Fludara], cytarabine ("A") [Cytosar-U], granulocyte colony stimulating factor ("G") [Neupogen], and idarubicin ("Ida") [Idamycin]. Granulocyte colony stimulating factor is a growth factor used to stimulate cancer cells and make them more sensitive to chemotherapy drugs, and fludarabine, cytarabine, and idarubicin are all standard chemotherapy drugs used to treat AML and other cancers.

FLAG-Ida alone has been used widely to treat people with AML and related blood cancers and has been found to be safe and effective. PVEK has been used alone or in combination with lower-intensity chemotherapy drugs for the treatment of AML. However, PVEK has not yet been tested in people together with higher-intensity chemotherapy such as FLAG-Ida.

The purpose of this research is:

- To find a dose of PVEK that can be given safely in combination with FLAG-Ida.
- To find out what effects, good or bad, PVEK plus FLAG-Ida chemotherapy has on people with AML and other high-grade myeloid neoplasms.

In this study, we want to learn how much PVEK can be given safely with FLAG-Ida. People who join at the beginning of the study will receive a single dose of PVEK. If we find this dosing safe, people who join later may receive 2 doses of PVEK together with FLAG-Ida. We will watch carefully for any side effects.

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

If you decide to take part in this study, the procedures and visits you can expect are described as follows:

- **Baseline Assessment**. You will need tests, including a bone marrow and/or peripheral blood analysis, two heart tests (one to see how your heart pumps blood and another to measure your heart's electrical activity), and a physical exam to see if you meet the requirements for participation in this trial. Please tell your medical team of any past or current medical problems. These tests and physical exam are usually considered part of regular cancer care. If you have recently had some of these tests, they may not need to be repeated. You will also need a central venous catheter inserted to receive chemotherapy and to simplify blood draws and transfusions.
- **Collection of Research Specimens**. We will collect research blood samples before each infusion of PVEK (up to 4 cycles), and if feasible, when you stop treatment with PVEK. The purpose of these blood samples is to see if your body develops antibodies to PVEK.

  In addition to the samples mentioned above, you will have the option of participating in additional research by providing extra blood or bone marrow specimens to be stored in a repository for future laboratory research, e.g. to understand why some people do/do not respond to this treatment. You do not need to give extra specimens to participate in the trial. If you do agree to donate specimens for future research, an additional tube of blood or up to 10 ml of bone marrow per bone marrow procedure may be collected for research storage. We would only collect research bone marrow specimens at the time of bone marrow tests done for regular cancer care; extra bone marrow procedures for purposes of research specimen collection will not be required.
- **Study Treatment.** You will be assigned to received PVEK in combination with FLAG-Ida chemotherapy at one of following dosing schedules:
  - **Dose level 1**: will receive a single dose of PVEK at a dose of 0.03 mg/kg through the vein (IV) on day 1 of FLAG-Ida chemotherapy.
  - **Dose level 2**: will receive a single dose of PVEK at a dose of 0.045 mg/kg, through the vein (IV) on day 1 of FLAG-Ida chemotherapy.
  - **Dose level 3**: will receive two doses of PVEK, each dose at 0.045 mg/kg, through the vein (IV) on days 1 and 22 of FLAG-Ida chemotherapy.
  - **Dose level -1**: will receive a single dose of PVEK at a dose of 0.015 mg/kg through the vein (IV) on day 1 of FLAG-Ida chemotherapy.

  The first group of 3 patients will be enrolled at dose level 1. At that time, information on side effects will be reviewed carefully to decide, based on how

well the treatment was tolerated, whether the next group of 3 patients will be treated at the same dose level, at the next higher dose level, or at the next lower dose level. Additional slots will be opened in dose cohorts of 3 patients. The trial will continue until 12 patients are treated at a single dose level. At that time, the trial will be stopped.

FLAG-Ida will be given as follows:

- G-CSF will be given as a shot underneath the skin once every day for 6 days, starting the day before the rest of the chemotherapy (days 0-5).
- Fludarabine will be given in your vein over 30 min each day for a total of 5 days (days 1-5).
- Cytarabine will be given in your vein over 2 hours each day for a total of 5 days (days 1-5).
- Idarubicin will be given in your vein every day for 3 days (days 1-3).

- **Monitoring during Study**. During the trial, you will need routine procedures, tests, and close follow-up. This care is part of routine monitoring for patients receiving chemotherapy. Some examples of these tests, procedures, and care include the following:
  - A medical history
  - Physical examinations
  - Blood tests
  - Bone marrow examinations (i.e., aspiration and/or biopsy)
  - Radiology tests such as a chest x-ray if clinically indicated
  - Ultrasound of your heart or other heart tests if there are any concerns about your heart function
  - Electrocardiogram (ECG)
  - Red blood cell or platelet transfusions

How long would you stay in this study?

If you join this study, you would stay in it for up to up to 8 months. The exact length of treatment would depend on the side effects and your response to the treatment. If you still have your cancer after the first cycle of study treatment ("induction" chemotherapy), you may be eligible to have the treatment cycle repeated. If this were the case, your doctors would discuss this with you. If you do not achieve a good response ("remission") after 2 cycles of induction chemotherapy, you would not be eligible for additional cycles as part of this trial, and you would need to discuss further treatment with your doctor. If you achieve a remission with the first 1 or 2 courses of study treatment, you would be able to receive up to 3 cycles of additional chemotherapy ("post-remission" chemotherapy) on this study to further decrease the amount of cancer cells that may still be left in your body. These 3 cycles of post-remission chemotherapy will consist of cytarabine, given in your vein every 12 hours on days 1-6 for a total of 12 doses. If you received PVEK in the first 1 or 2 cycles of induction chemotherapy, you will receive one dose of PVEK through the vein on day 1 of each post-remission chemotherapy cycle, using the same dose of PVEK as given during induction chemotherapy. The consolidation chemotherapy would be started after your blood counts are better and you have recovered from side effects that you may have experienced during induction therapy. This recovery usually takes about 1 month. Each cycle of post-remission chemotherapy would start only after recovery from the previous cycle, which takes about 1 month.

The study doctor or your doctor may 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. If you are thinking about dropping out of this study, please tell the study doctor.

Long-term follow-up means keeping track of someone's medical condition for a long time. After you have finished the study treatment, you may return to your primary oncologist or choose to receive additional care at the Fred Hutchinson Cancer Center/University of Washington (Fred Hutch/UW). After you finish the study, the study doctors may want to know about your health after you leave Fred Hutch/UW. The study doctors may contact you or your doctor up to every 3 months for 5 years to see how you are doing. 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 PVEK plus FLAG-Ida.

You do not have to be in long-term follow-up. You could say "yes" or "no". Either way, you could still join the study. If you drop out of the study, you would be asked if we could call you up to every 3 months for 5 years. 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)?

In this part of the consent form, we describe the side effects we expect from the treatments in this study. PVEK plus FLAG-Ida 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 the study treatment. In some cases, side effects can last a long time or never go away. There also is a risk of death.

PVEK

Very Common, some may be serious side effects of PVEK (10% or more of patients experienced at least one of these side effects):

- ***Edema (peripheral or generalized).*** The presence of excess interstitial fluid in the tissue or extremities, leading to swelling.
- ***Infusion related reactions.*** Patients have experienced mild to severe infusion associated reactions, which, in rare cases, may be life threatening. Infusion reactions have been reported during or after infusion, including rapid heart rate, chills, vomiting, high blood pressure, low oxygen, shortness of breath and rash. It is unknown if you will experience these or other types of infusion related reactions. On the day prior to and day of receiving PVEK, you will be given pre-medication to help prevent an allergic reaction, and you will be monitored closely both during and after infusion.
- ***Nausea (feeling like throwing up)***. Most cases have been mild. However, several patients experienced mild and severe nausea. Tell your doctor if you experience nausea and he or she can prescribe medications to help you feel better.
- ***Diarrhea.*** Passing frequent and/or loose or watery stools.
- ***Febrile neutropenia (fever and lower than normal white blood cells in the blood).*** Severe events have been reported in patients receiving treatment with PVEK.

Common, some may be serious side effects of PVEK (1% to less than 10% of patients experienced at least one of these side effects):

- ***Damage to the blood vessels in the liver (Related to veno-occlusive disease).*** This can result in blockage of the veins and damage to the liver. Also known as veno-occlusive disease (VOD), severe and life-threatening cases have been reported. The risk of VOD may increase with cumulative exposure to study drug. If you are planning to receive an additional treatment, called hematopoietic stem cell transplant, after participating in this study, you may have an increased risk of your liver being damaged due to this side effect of veno-occlusive disease occurring following this treatment. The outcome of such a side effect may be life- threatening or may lead to death.

G-CSF

Likely (more than 20% of patients)	Less likely (4-20%)	Rare but serious (3% or less)
• Nosebleed • Anemia which may require blood transfusions • Diarrhea • Bone pain • Fever • Tiredness • Hair loss	• Fluid in the body which may cause low blood pressure, shortness of breath, swelling of ankles • Damage to the lungs which may cause shortness of breath • Cough • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Kidney problems which may require dialysis • Swelling or tenderness of vessels • Headache • Rash	• Chest pain, shortness of breath • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • Rupture of the spleen causing sudden or severe pain in the left side of abdomen spreading up to your shoulder

Fludarabine

Likely (more than 20% of patients)	Less likely (4-20%)	Rare but serious (3% or less)
• Cough • Shortness of breath • Infection, especially when white blood cell count is low • Anemia, which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Increased risk of unusual infections lasting more than 6 months • Vomiting, nausea, loss of appetite • Tiredness, fever • Pain	• Damage to organs (brain, lungs, others) which may cause tiredness, changes in thinking or shortness of breath • Chest pain • Swelling of the body • Kidney problems which may require dialysis • Internal bleeding which may cause belly pain, black tarry stool, blood in vomit, coughing up blood, blood in urine, nose bleeds • Diarrhea • Sores in mouth	• Coma, seizures (with high doses) • Stroke, which may cause paralysis, weakness, headache • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Heart attack which may cause chest pain, shortness of breath • Blood clot which

	which may cause difficulty swallowing • Changes in vision • Chills • Muscle weakness, numbness, tingling or pain of the arms and legs • Feeling of "pins and needles" in arms and legs • Confusion • Hearing loss • Increased sweating • Rash, which may be severe with blisters and peeling which can involve mouth and other body parts	may cause swelling, pain, shortness of breath • Liver damage which may cause yellowing of eyes and skin, swelling • Blindness

Cytarabine

Likely (more than 20% of patients)	**Less likely (4-20%)**	**Rare but serious (3% or less)**
• Anemia which may cause tiredness, or may require blood transfusions. • Bruising, bleeding • Infection, especially when white blood cell count is low. • Blood clot. • Diarrhea, loss of appetite, nausea, vomiting, pain in belly. • Sores in mouth, throat, and GI tract including rectum which may cause difficulty swallowing or pain. • Rash • Fever	• Heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness • Abnormal heartbeat which may cause fainting • Chest pain • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat. • Damage to the lungs which may cause shortness of breath. • Severe blood infection • Liver damage which may cause yellowing of skin or eyes • Kidney damage which	• Brain damage, Posterior Reversible Encephalopathy syndrome, which may cause headache, seizure, blindness. • Difficulty speaking, trouble standing or walking, coma.

	may cause swelling, may require dialysis • Difficulty emptying the bladder or urinating • Numbness and tingling of the arms and legs • Muscle pain • Dizziness, confusion • Headache • Flu-like syndrome with fever, bone pain, rash, redness of eyes, or chest pain • Swelling and redness of the eye • Infection at injection site which may cause rash • Hives • Itching • Hair loss	

Idarubicin

Likely (more than 20% of patients)	**Less likely (4-20%)**	**Rare but serious (3% or less)**
• Infection, possibly in the blood, especially when white blood cell count is low. • Bruising, bleeding • Anemia which may cause tiredness, or may require transfusion. • Pain in belly. • Diarrhea, nausea, vomiting. • Hives. • Headache. • Redness, pain or peeling of palms and soles. • Hair loss.	• Heart failure or attack which may cause shortness of breath, swelling of ankles, and tiredness. • Abnormal heartbeat which may cause fainting. • Liver damage which may cause yellowing of eyes and skin. • Sores in mouth which may cause difficulty swallowing. • Reddish discoloration of the urine, sweat and saliva. • Swelling and redness at the site of injection. • Swelling and redness at the site of previous	• Kidney damage which may require dialysis.

	radiation. • Loss of nails, darkening of the skin and nails	

Reproductive risks

Chemotherapy treatment could cause sterility (unable to have children).

Taking the study medicine 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 3 months after the last dose of study treatment. You should discuss this with the study doctor or a member of the study staff.

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.

The effects of the study treatment on a pregnancy you could cause are also unknown. If you could get someone pregnant, you must also agree to use one or more forms of effective and acceptable birth control from the time this form is signed until at least 3 months after the last dose of study treatment. You should discuss this with the study doctor or a member of the study staff.

Non-physical risks

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

- You might not be able to work.
- Breach of confidentiality.

What are the benefits?

We do not know if combining PVEK with FLAG-Ida would help treat AML or another high-grade myeloid neoplasm. The use of PVEK is still investigational. This particular combination with PVEK has not been tried before, and we are testing it to find the highest safe dose and to see its effects on people with AML and related diseases. You could take FLAG-Ida without joining this study. The research treatment in this study might be less effective than FLAG-Ida alone.

You might get better if you receive this study treatment, but your condition could stay the same or even get worse. We hope the information from this study will help other people with these cancers 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, 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.
- AbbVie, Inc. (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 (IND sponsor of this study) and University of Washington.
- 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 disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you

about lab tests. Or a court may order that study information 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 prevents health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

Would we pay you if you join this study?

There is no payment for being in this study.

Financial Conflicts of Interest

One member of the study team, Dr. Roland Walter, has a financial or other relationship with AbbVie Inc., a company that provides financial support and supplies PVEK for this study. The University of Washington developed a Conflict Management Plan to limit the possible effects of this relationship on decisions regarding the conduct of this study, as well as your safety and welfare.

Would you have extra costs if you join this study?

If you join this study, you may 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 might be:

- Cost of tests that are given for the study more often than for standard care.
- Cost of the study drugs (except PVEK).

- Paying the people who give PVEK, and the cost of the equipment they use.
- Cost of people and equipment to give FLAG-Ida.
- 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:

- PVEK

If PVEK is approved as a treatment while this study is still going on, you or your insurance company might have to pay for PVEK in order to complete this study.

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.

If you sustain physical illness or injury as a result of the study drug, the study doctor and institution will treat you or refer you for treatment. The sponsor will reimburse the institution for the reasonable and necessary costs of your medical care.

There are no funds to pay you for 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/or tissue samples be used for?

Your information and, if you agree to participate in the collection of research specimens. tissue samples (such as blood and tumor cells) will be used for the purposes of this study, i.e. to help us understand if the combination of PVEK and FLAG-Ida would help treat AML and other high-grade myeloid neoplasms and to study, in the laboratory, what makes this treatment work or not work.

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.

Will my information and/or tissue samples ever be use for future research?

After we do tests on tissue in this study, some tissue may be left over. We invite you to donate this leftover tissue for future research. This may include genetic research. We would like to use your information for future research.

If you join this study, you would not have to donate tissue or information for future research. You would be free to say "yes" or "no." Regular medical care would not change if you say "no."

If you say "no," your tissue and information (even if made anonymous) will not be used in future research.

If you donate tissue and information, it would be stored in a secure location. If we want to use your tissue for other research or share it with other scientists for research, an ethics review committee (IRB) would review the request. The IRB would decide if we need to ask you for permission to do the research.

Your donated tissue and information would be used only for research. This research could be done by for-profit companies. Researchers would not report their results to you or your doctors. The research results would not be included in medical records. The results would not affect your medical care.

Research with tissue and information might help develop new products. If these products make money, there is no plan to share the money with the participants who donate the tissue.

If you donate tissue and information for research, you could withdraw the donation at any time by calling Dr. Jacob Appelbaum at 206-314-2788. You would have no penalty for withdrawing the donation, and regular medical care would not change. We could not return donated tissue to you or your doctor, but we might be able to destroy the donated tissue. We could not destroy tissue if it is stored or shared without any label saying who donated it. In this case, it could still be used for research.

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 study treatment. 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 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)	206-314-2788 (Dr. Jacob Appelbaum) 206-606-8311 (Dr. Appelbaum's clinical research manager)
If you get sick or hurt in this study	206-314-2788 (Dr. Appelbaum)
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	206-606-6226 (Fred Hutch Patient Financial Services)

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

OPTIONAL Future Research

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

Do you agree to donate your tissue and information to study cancer? (circle one) **YES** **NO**

Do you agree to donate your tissue and information to study other health problems, such as diabetes, Alzheimer's disease, or heart disease? (circle one) **YES** **NO**

Is it OK if someone contacts you in the future to ask you to donate more tissue or information for research? (circle one) **YES** **NO**

Is it OK if we send your genetic information to one or more databases for future research? (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 were a witness for a participant who was not able to read this written consent form, sign below to indicate (1) you were present at the consent discussion in person, (2) you witnessed the verbal presentation of the written consent form, and (3) the participant had the opportunity to ask questions and agreed to take part in the study.

Impartial Witness:

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: RG1123378
Current consent version date: 11/06/2025
Previous consent version date: 08/20/2025
Copies to: Patient, Medical Records, Research File