Official Title:	A Phase I Study of Dose-Adjusted Etoposide, Prednisone, Vincristine, Cyclophosphamide, and Doxorubicin Plus Escalating Doses of Inotuzumab Ozogamicin (DA-EPOCH-InO) in Relapsed or Refractory B-Cell Acute Lymphoblastic Leukemia
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University of Washington (UW)
Fred Hutchinson Cancer Research Center (FHCRC)
Seattle Cancer Care Alliance (SCCA)

Consent to take part in a research study:

A phase 1 study of dose-adjusted etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin plus escalating doses of inotuzumab ozogamicin (DA-EPOCH-InO) in relapsed or refractory B-cell acute lymphoblastic leukemia

Principal Investigator: Ryan Cassaday, MD. University of Washington; Fred Hutchinson Cancer Research Center. (206) 606-1202

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

University of Washington Medical Center Paging Operator: Please ask the operator to page the hematology/oncology fellow on call.

If you are serving as a legally authorized representative, the terms "participant", "you", and "your" refer to the person for whom you are providing consent or parental permission.

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to look at the effects of a combination treatment regimen called dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) plus inotuzumab ozogamicin. This combination will be referred to as DA-EPOCH-InO in the remainder of this consent form.

People who agree to join the study will be asked to attend approximately 40 visits over 4 months; participants will also be asked to agree to staying in the hospital for the first 6 days of the study for observation. The study involves physical exams, assessment of your disease and your health, blood draws, and occasional bone marrow biopsies.

We do not know if this drug combination would help treat B-cell acute lymphoblastic leukemia (ALL) and could even make your condition/disease worse. DA-EPOCH-InO could cause side effects such as nausea, vomiting, hair loss, abnormal blood cell counts, fever, and abdominal pain as described below in this form.

You do not have to join this study. You can choose to receive standard methods to treat your ALL 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 B-cell ALL that has come back (relapsed) or that has not responded to treatment (refractory). Up to 24 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?

Etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, and inotuzumab ozogamicin are anti-cancer drugs already approved by the U.S. Food and Drug Administration (FDA). DA-EPOCH is commonly and effectively used in the treatment of high-grade lymphomas and is generally well-tolerated, even in older adults.

We are doing this study to determine the effects of the combination of dose-adjusted EPOCH plus inotuzumab ozogamicin in patients with relapsed or refractory acute lymphoblastic leukemia. We want to know:

- What is the optimal dose of InO when given with DA-EPOCH;
- What side effects occur when DA-EPOCH-InO is given and how long they last;
- What overall effects, good or bad, DA-EPOCH has on relapsed/refractory B-cell ALL.

If you join this study, we would give you DA-EPOCH-InO at one of four dose levels. DA-EPOCH will be started at the same level no matter what, but some of the medication doses you receive may increase or decrease depending on the effects observed with the previous cycle you received. On the other hand, you will be assigned to a dose of InO at one of four dose levels. Your dose may be decreased depending on the side effects observed. People who join at the beginning of the study will receive very low amounts of InO added to DA-EPOCH. People who join later will receive larger amounts of InO, until effects (good or bad) appear. We will watch carefully for any side effects.

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

If you decide to participate in this study, and meet the requirements necessary for participation, the following tests, procedures and treatments will be conducted at various time points throughout the study.

1) **Medical History & Physical Exam:** You will be asked questions about your medical history. This includes ongoing conditions you have and medications you are taking. Physical exams and vital sign measurements will assess your overall health status; this includes blood pressure, heart rate, temperature, respiration, height and weight.

2) **Electrocardiogram (EKG):** A noninvasive test that will measure the electrical activity and health of the heart.

3) **Blood Tests:** Blood samples will be taken for routine and research tests. Approximately 5 teaspoons will be taken at screening for both routine and research tests. Approximately 2 teaspoons will be taken for routine tests at the

start of each cycle after Cycle 1. Approximately 1 teaspoon will be taken for routine monitoring mid-treatment cycle.

4) **Pregnancy Test:** If you are a female who could potentially become pregnant, a pregnancy test will be performed before you begin study treatment.

5) **Bone Marrow Aspirate &/or Biopsy:** Multiple bone marrow aspirate/biopsy procedures may be done throughout the study to determine the amount of cancer present in your bone marrow. Some marrow will be used for research purposes, and some will be used for routine tests. For the bone marrow aspirate, a sample of the inner bone marrow cells are taken by a needle inserted into a bone in your body (typically the pelvis or hip bone). In a bone marrow biopsy, a very small piece of the bone will be removed. These procedures are completed using local anesthesia.

6) **Left Ventricular Ejection Fraction (LVEF):** LVEF is a measurement of heart function. The left ventricle is the heart's main pumping chamber, so ejection fraction is usually measured only in the left ventricle. Ejection fraction is a measurement of the percentage of blood leaving your heart each time it contracts. It can be measured with an ultrasound, called an echocardiogram (ECHO) or a special type of imaging test called a MUGA scan. This test will only be performed if medically indicated by your doctor.

7) **Computed Tomography (CT) Scan:** A CT is a medical imaging method that takes 3-dimensional pictures of sections of the body. CT scans of the neck, chest, abdomen and pelvis will be done if your doctor believes your cancer is present in more areas than just your bone marrow. If you have certain other imaging tests as part of your medical care, your doctor may also consider the results of those tests. This may allow you to avoid having extra CT scans.

Treatment Procedures

Each cycle of therapy is given approximately every 28 days.

All participants will receive the following:

1) **Etoposide (E)** is administered intravenously (through an IV, line or port) on days 1-4 of each cycle.

2) **Doxorubicin (H)** is administered intravenously (through an IV, line or port) on days 1-4 of each cycle.

3) **Vincristine (O)** is administered intravenously (through an IV, line or port) on days 1-4 of each cycle.

4) **Cyclophosphamide (C)** is administered intravenously (through an IV, line or port) on day 5 of each cycle.

5) **Prednisone (P)** is administered orally or intravenously (through an IV, line or port) twice a day on days 1-5 of each cycle.

6) **Inotuzumab ozogamicin (InO)** is administered intravenously (through an IV, line, or port) once a day on days 8 and 15 of each cycle. You will need to stay for one hour after each InO infusion to be watched for any infusion-related reactions.

You will receive either filgrastim (Neupogen®) or pegfilgrastim (Neulasta®) in addition to your DA-EPOCH-InO therapy. These are synthetic versions of a substance that is naturally produced in your body. When certain medications are used to fight cancer cells they can also negatively affect the white blood cells that help your body fight off infections. Filgrastim and pegfilgrastim are used to prevent or reduce the risk of infection by helping the white blood cells recover after the study treatment.

Filgrastim is administered by an injection once a day starting on day 6, 7, or 8 during each cycle. It will continue until your white blood cell count has recovered to a level deemed acceptable by your provider.

Pegfilgrastim is administered by a single injection on day 6, 7, or 8 during each cycle.

Follow-Up

In the follow-up portion of this study we will be keeping track of your B-cell ALL via regular visits with a physician of your choice. In order to do this we will obtain information from you by conducting physical exams (as described earlier). A typical follow-up schedule is every 3 months for 2 years and then every 6 months for 3 years (total follow-up time of 5 years). These visits may be performed by physicians outside of your study team as long as medical records documenting these visits are made available to the study team for review. This information will help us learn the long-term effects of the study treatment, DA-EPOCH-InO.

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 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.

Procedures Summary

Procedure	Screening	Within 3 Days Before Each Cycle	Monitoring During Cycles (1 or more times per week)	Interim Response Assessment	Post Therapy	Follow-up
Medical History & Physical Exam	X	X			X	X
EKG	X					
Blood Tests	X	X	X		X	X
Bone Marrow Aspirate & Biopsy	X			X	X	
Pregnancy Test	X					
CT Scan	X			X	X	
Left Ventricular Ejection Fraction (LVEF) via ECHO or MUGA (if deemed medically necessary)	X					

How long would you stay in this study?

The total time expected on this study may be up to approximately 5.5 years. If you join this study, you would stay in this study for at least one 28-day cycle but no more than four (4) 28-day cycles. You would receive DA-EPOCH-InO for up to 4 months. After that, you would have follow-up exams in the office or clinic every 3 months for 2 years, then every 6 months for 3 years.

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

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

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

What are the side effects (risks)?

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. 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 DA-EPOCH-InO. In some cases, side effects can last a long time or never go away.

Treatment for your disease may lead to an increased risk of bleeding due to low levels of fibrinogen (blood plasma protein) in your blood. Low levels of fibrinogen can also result in blood clots, which may lead to swelling in the arms and legs. Clots can also travel to the lungs, causing shortness of breath, or to the brain, causing a stroke. This may be serious or life-threatening. If you develop low fibrinogen levels, you may receive a transfusion of a blood product called cryoprecipitate to prevent complications such as bleeding.

There is also a risk of death.

Etoposide

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• Hair Loss • Nausea • Vomiting • Loss of Appetite • Diarrhea • Low White Blood Cell Count • Low Platelet Count • Anemia	• Low Blood Pressure • Swelling of Lips and/or Mouth • Abdominal Pain • Liver Damage • Weakness, Numbness, Tingling, Pain in Hands &/or Feet • Hypersensitivity	• Absence of Menstruation • Temporary Blindness &/or Eye Pain • Poor Circulation/Low Blood Oxygen Levels (bluish skin discoloration) • Tongue &/or Facial Swelling • Lung Inflammation &/or Scarring • Laryngospasm • Rash • Metabolic Acidosis • Mucositis • Myocardial Ischemia: *decreased blood flow to the heart due to a blockage of the coronary arteries. Symptoms include chest pain,*

		neck/jaw/shoulder/arm pain, increased heart rate, shortness of breath, nausea &/or vomiting. This can be life-threatening- seek immediate medical attention if you have chest discomfort. • Itching • Reversible Posterior Leukoencephalopathy Syndrome (RPLS): *condition that may cause seizures, high blood pressure, headache, confusion, blindness and fatigue.* • Seizure • Stevens-Johnson Syndrome: *severe, painful red &/or purple rash that spreads to most of the body also characterized by blisters, tongue swelling &/or shedding of skin. This can be life threatening- seek immediate medical attention.* • Toxic Epidermal Necrolysis (TEN): *similar to Stevens-Johnson Syndrome- painful red rash that spreads quickly, blisters on the skin and mucous membranes, peeling skin &/or fever. This can be life threatening- seek immediate medical attention.* • Toxic Megacolon: *widening of the large intestine characterized by severe abdominal pain, bloating, fever, rapid heart rate, bloody/frequent diarrhea &/or dehydration. This may be life threatening- seek immediate medical attention.* • Vasospasm

Prednisone

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• High Blood Pressure • Headache	• Congestive Heart Failure: *inability of the heart to pump blood as well as it should- characterized by*	• Increased Intracranial Pressure • Seizure

• Difficulty Falling/Staying Asleep • Personality Changes (mood swings, severe depression, euphoria, emotional instability) • Bruising • Thin, Fragile Skin • Impaired Wound Healing • Carbohydrate Intolerance • Diabetes • Edema • Muscle Mass Loss &/or Weakness • Infections	*shortness of breath when exercising or lying down; fatigue, swelling of legs, ankles, feet; irregular heartbeat; persistent cough or sudden shortness of breath with pink/blood tinged mucous; chest pain; fainting. This may be life threatening- seek immediate medical attention.* • Petechiae: *very small broken blood vessels in skin or lining of the mouth which may result in bleeding* • Bloating • Stomach Ulcer • ALT, AST, Alkaline Phosphatase increased • Facial Reddening • Weak/Brittle Bones • Cataracts • Sweating	• Vertigo • Hives & Fever • Menstrual Irregularities • Cramping • Pancreatitis • Ulcerative Esophagitis • Bone Decay of Femoral and Humoral Heads • Fracture of Long Bones, Vertebra • Steroid Myopathy • Tendon Rupture (particularly Achilles tendon) • Kaposi's Sarcoma: *a raised red, purple, brown or black tumor caused by a viral infection- often occurring on lower limbs, back, face, mouth, genitalia.* • Bulging of Eye • Glaucoma &/or Increased Intraocular Pressure • Hypersensitivity • Blood Clots

Vincristine

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• Pain, Tingling &/or Numbness in Hands &/or Feet • Hair Loss • Constipation	• Edema • High/Low Blood Pressure • Loss of Control of Voluntary Movements, Difficulty Walking, Loss of Coordination • Dizziness • Fever • Headache • Rash • Increased Uric Acid Levels • Parotid Pain	• Heart Attack • Coma • Cranial Nerve Dysfunction • Seizure • Vertigo • Death of Intestinal Tissue &/or Holes in Intestine • Decrease in Kidney Function • Hemolytic Uremic Syndrome: *damaged red blood cells clog the kidneys leading to kidney failure- a treatable condition*

	• Abdominal Cramps and/or Pain • Loss of Appetite • Diarrhea • Nausea • Mouth Sores • Anemia • Low White Blood Cell Count • Low Platelet Count • Bowel Obstruction due to Temporary Paralysis of Intestinal Muscles • Vomiting • Weight Loss • Painful &/or Difficult Urination • Urinary Retention &/or Increase in Urinary Output • Vein Inflammation, Irritation, Necrosis • Back, Jaw, Limb, Muscle &/or Bone Pain • Deep Tendon Reflex Loss • Increased risk of bleeding	*characterized by bloody diarrhea/urine, vomiting, abdominal pain, fatigue, swelling, confusion, bleeding from nose and mouth. This may be life threatening- seek immediate medical attention.* • Blood Clots • Hepatic Sinusoidal Obstructive Syndrome (SOS): *blockage of veins in the liver characterized by swelling in the abdomen, increased bilirubin levels and liver size* • Muscle Wasting • Temporary Blindness • Uncontrolled Eye Movement • Deafness • Difficulty Breathing • Sore Throat • Hypersensitivity

Cyclophosphamide

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• Hair Loss • Absence of Menstruation • Hormone Suppression • Impaired Ovulation • Nausea • Vomiting • Swelling of Lips and/or Mouth • Low White Blood Cell, Neutrophil, Platelet and Red Blood Cell Count due to Impaired Bone Marrow Function	• Fever • Abdominal Pain • Loss of Appetite • Diarrhea • Mucositis • Low Sperm Count &/or Decreased Sperm Motility • Sterility • Hemorrhagic Cystitis: *sudden blood in urine and bladder pain. This may be life threatening- seek*	• Acute Respiratory Distress Syndrome: *sudden failure of the respiratory system characterized by rapid, difficult breathing and low blood oxygen levels. This may be life threatening- seek immediate medical attention.* • Bladder/Urinary Fibrosis • Confusion • Shortness of Breath • Abnormally Slow Heart Rate • Inflammation &/or Blood Surrounding the Heart

• Blood in Urine	*immediate medical attention.* • Blurred Vision • Increased Uric Acid Levels • Tumor Lysis Syndrome: *usually seen within a few days of starting treatment. A large increase in dying cancer cells can result in metabolic complications noted by nausea, vomiting, swelling, shortness of breath, kidney failure. This may be life threatening- seek immediate medical attention.* • Impaired Wound Healing • Liver &/or Heart Damage • Radiation Recall: *a skin rash that looks like a severe sun burn- seen in people who have recently received radiation therapy* • Increased risk of bleeding	• Hemorrhagic Colitis: *sudden, severe abdominal pain and bloody diarrhea &/or vomiting &/or fever. This may be life threatening- seek immediate medical attention.* • Hepatic Sinusoidal Obstruction Syndrome (SOS) • Hypersensitivity • Low Potassium &/or Sodium Levels • Lung Inflammation &/or Scarring • Yellow Discoloration of Skin &/or Whites of Eyes • Return of Old Infections • Acute Mesenteric Ischemia: *inadequate blood flow to intestines leading to severely damaged colon- marked by severe abdominal pain and bloody stool. This may be life threatening- seek immediate medical attention.* • Multi-organ Failure • Nerve Damage • Scarring of Ovaries • Pancreatitis • Skin/Fingernail Color Changes • Pneumonia • Pulmonary Hypertension • Kidney Infection/Damage • Reversible Posterior Leukoencephalopathy Syndrome (RPLS) • Rhabdomyolysis: *breakdown of muscle tissue that releases dangerous proteins into the bloodstream. The kidneys have a difficult time removing these proteins, leading to kidney failure. Symptoms include abdominal pain, muscle pain, nausea, vomiting, fever, rapid heart rate, dehydration, dark*

		red/brown urine, reduced or no urine output. This may be life threatening- seek immediate medical attention. • Secondary Cancer • Sepsis &/or Septic Shock • Stevens-Johnson Syndrome • Testicular Atrophy: *decrease in size of male reproductive organs & possible loss in function.* • Low Platelet Count • Blood Clots • Toxic Epidermal Necrolysis • Toxic Megacolon

Doxorubicin

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• General Feeling of Discomfort, Illness, Uneasiness • Hair Loss • Sensitivity to Sunlight • Temporary Discoloration of Saliva, Sweat, Tears and/or Urine • Absence of Menstruation • Dehydration • Abdominal Pain • Loss of Appetite • Diarrhea • Mucositis • Nausea • Vomiting • Low White Blood Cell Count • Low Neutrophil Count • Low Platelet Count • Anemia • Weakness	• Inflammation &/or Damage to Heart • Itching • Radiation Recall • Rash • Infertility (may be temporary) • Increased Uric Acid in Blood • Sores on Lining of Esophagus, Stomach, Small Intestine • Hardening of Veins • Fever • Low Sperm Count &/or Decreased Sperm Motility • Hepatitis/Transaminases Increased • Bilirubin Increased • Fever • Infection	• Coma • Death of Intestinal Tissue • Conjunctivitis • Darkening of Nails, Skin, Mouth • Inflammation of the Cornea • Increased Tear Production • Secondary Cancers • Seizure • Sepsis &/or Shock • Stevens-Johnson Syndrome • Hypersensitivity • Toxic Epidermal Necrolysis

Inotuzumab ozogamicin (InO)

Likely (>20% of patients)	Less Likely (10-20%)	Rare but Serious (<10%)
• Low platelet count (thrombocytopenia) • Low neutrophil count (neutropenia) • Infection • Low red blood cell count (anemia) • Low white blood cell count (leukopenia) • Fatigue • Hemorrhage • Fever (pyrexia) • Nausea • Headache • Fever with low neutrophils (febrile neutropenia) • Abnormal liver function tests • Abdominal pain • Abnormally high levels of bilirubin in the blood	• Clotting of blood within the liver (veno-occlusive disease): although it may be mild and not require further treatment, sometimes it may cause a severe decrease in liver function and may be life-threatening or fatal. • Decreased appetite • Inflammation of the mouth; mouth sores (stomatitis) • Chills • Diarrhea • Constipation	• Infusion-related reactions: over-reaction by the body to a foreign substance characterized by hives, itching, swelling, red face, shortness of breath &/or difficulty breathing. This can be life-threatening; seek immediate medical attention. • Abnormal ECG values (QT prolongation)

Filgrastim/pegfilgrastim

Likely (>20% of patients)	Less Likely (4-20%)	Rare but Serious (<4%)
• Nausea, Vomiting • Pain in Bone	• Anemia- *may cause tiredness or require a transfusion* • Damage to the lungs- *may cause shortness of breath* • Internal bleeding- *may cause coughing up of blood* • Swelling or tenderness of vessels • Allergic Reaction- *characterized by rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat. This may be life threatening- seek immediate medical attention.*	• Rupture of spleen leading to bleeding in the belly- *characterized by sudden or severe pain in the left side of the abdomen spreading up to your shoulder. This may be life threatening- seek immediate medical attention.*

Risks after stem cell transplantation

In patients with any blood cancer (including ALL), there is a potential for an increased risk of severe complications following allogeneic stem cell transplant (a procedure in which a person received blood-forming stem cells from a donor) in patients who previously received InO.

Reports of veno-occlusive disease (clotting of blood within the liver), infections, and severe graft versus host disease (which can include skin, liver and gastrointestinal symptoms), including fatal reports, have been received for patients who received allogeneic stem cell transplant after InO therapy.

Patients treated with InO who then go on to allogeneic stem cell transplant should inform their transplant physicians that they have received InO in the past.

Reproductive risks

Chemotherapy and radiation treatments could cause sterility (unable to have children).

Taking DA-EPOCH-InO 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 and are a female of childbearing potential, you would have to agree to use an effective method of birth control. 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.

The effects of fathering a child are also unknown. Men of childbearing potential who join this study must also agree to use one or more forms of effective and acceptable birth control.

If you are a participant who must use contraception, we strongly recommend that you do so from the time this form is signed until at least 5 months after the last dose of DA-EPOCH-InO (for men), or until at least 8 months after the last dose of DA-EPOCH-InO (for women).

What are the benefits?

We do not know if this study would help you. The use of DA-EPOCH-InO is still investigational, and we are testing it to find the highest safe dose. We hope the information from this study will help us test DA-EPOCH-InO further 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 may include:

1) Standard Treatment

2) Another Research Study

3) No Treatment

4) 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.
- Pfizer (the maker of inotuzumab ozogamicin) and their agents.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Research Center, University of Washington, Seattle Children's, and Seattle Cancer Care Alliance.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required.

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.

Would we pay you if you join this study?

You may be reimbursed for the cost of some travel and lodging if you travel 30 miles or more to the study site. Please let the study team know if you require lodging as the study staff will make hotel arrangements on your behalf.

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:

- Costs of tests that are given more often than usual.
- Cost of DA-EPOCH.
- Paying the people who give DA-EPOCH-InO and the cost of the equipment they use.
- 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 study drug (inotuzumab ozogamicin)

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

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact your study doctor. You can call Dr. Cassaday at (206) 606-1202. 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/or tissue samples be used for?

Your information and tissue samples (such as blood and tumor cells) will be used for the purposes of this study.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

During this study, if the researchers learn new information that may be important to your general health or to your disease or condition, they will 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.

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

Your responsibilities

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

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

For more information

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

If you have questions about:	**Call:**
This study (including complaints and requests for information)	(206) 606-1202: Dr. Ryan Cassaday, Sponsor-Investigator (206) 606-1286: Research Manager
If you get sick or hurt in this study	(206) 606-1202: Dr. Ryan Cassaday, Sponsor-Investigator
Your rights as a research participant	206-667-4867: Director of Institutional Review Office, Fred Hutchinson Cancer Research Center 206-543-0098: Human Subject Division, University of Washington
Your bills and health insurance coverage	(206) 606-1377: Patient Financial Services, Seattle Cancer Care Alliance

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

University of Washington Medical Center paging operator- please ask the operator to page the hematology-oncology fellow on call.

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

Legally Authorized Representative: Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask questions;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to consent on behalf of the participant for him or her to participate in this study.

Legally authorized representative:

Printed Name	Signature	Date

Relation to the participant

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