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Fred Hutchinson Cancer Center / University of Washington
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	A Pilot Study Examining the Impact of the Jak1 Inhibitor Itacitinib On the Sarcoma Tumor Immune Microenvironment
IND Number:	137,078
PROTOCOL NO.:	Fred Hutch IRB # CC9715
FUNDING SOURCE:	Incyte Corporation 1801 Augustine Cut-Off Wilmington, Delaware 19803
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STUDY-RELATED PHONE NUMBER(S):	Michael Wagner, MD 206-606-1767 Roxanne Moore 206-606-6425 (Office Hours) romoore@seattlecca.org Oncology Fellow On-Call 206-598-6190 (24 hours)

Emergency (24-hour) phone: Call the Fred Hutchinson Cancer Center at 206-606-7400 Monday through Friday from 9 am to 5 pm. At all other times call the paging operator at the University of Washington Medical Center at 206-598-6190 and ask the operator to page the oncology fellow on call.

Important things to know about this study.

Your doctors are inviting you to participate in a research study. The purpose of this research is to test if the study drug, itacitinib, causes changes in your immune system and your body's immune response to your cancer. The study will also look at the safety and efficacy of this study treatment.

People who agree to join the study will be asked to attend biweekly visits for the first month, then monthly visits until your disease progresses. The study involves tumor biopsies, tumor imaging, blood tests, visits with your doctor, and taking the oral study drug itacitinib daily.

We do not know if itacitinib would help prevent or treat your cancer and it could even make your cancer worse. Itacitinib could cause side effects such as kidney problems, internal bleeding, and congestive heart failure, as described below in this form.

You do not have to join this study. You could choose to receive standard methods to treat your sarcoma. 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. Afterwards, you can ask questions that will 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 Leiomyosarcoma, Undifferentiated Pleomorphic Sarcoma, Synovial Sarcoma, Myxoid/Round Cell Liposarcoma, or Chondrosarcoma. Additionally, your physician has determined that you have a tumor that is able to be biopsied via ultrasound-guidance. Up to 28 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 determine whether a new drug called itacitinib can reduce the numbers of cells that inhibit your immune system's response to your cancer.

In this study, we want to learn what effects, good or bad, itacitinib has on people with Leiomyosarcoma, Undifferentiated Pleomorphic Sarcoma, Synovial Sarcoma, Myxoid/Round Cell Liposarcoma or Chondrosarcoma. If you join this study, we would give you this study drug and watch carefully for any side effects. Additionally, you will have one biopsy prior to starting treatment with itacitinib, 1 biopsy after 2 months of treatment with itacitinib, with an additional

biopsy at the end of treatment visit. Your doctor may request additional biopsies if it is necessary.

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

You will generally have visits in the clinic at the beginning of each cycle, with the exceptions listed below. Below is a schematic of the treatment schedule:

Schedule of Events

	Screening	Cycle 1		Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6+	End of Treatment	Safety Follow-Up	Long-Term Follow-Up
		Day 1	Day 15	Day 1	Day 1	Day 1	Day 1	Day 1	Within 7 days of last dose	30 Days from EOT Visit	
Informed Consent	X										
Med History / Demographics	X										
Archival Tissue Collection	X										
Fresh Biopsy[1]	X				X				X		
Physical Exam and ECOG	X	X	X	X	X	X	X	X	X	X	
Prior and Concomitant Medication Review	X	X	X	X	X	X	X	X	X	X	
Review Adverse Events	X	X	X	X	X	X	X	X	X	X	
Vital Signs and Weight	X	X	X	X	X	X	X	X	X	X	
ECG	X								X	X	
Pregnancy Test	X	X		X	X	X	X	X	X	X	
Blood Test for Bleeding Risk[2]	X				X				X		
Standard Blood Tests	X	X	X	X	X	X	X	X	X	X	
Urinalysis	X								X		
Tumor Imaging[3]	X				X		X	X			
Correlative Studies Blood Collection	X	X	X		X		X	X	X		
Post-study anticancer therapy status									X	X	X
Survival Status									X	X	X

[1]Biopsy will be collected during screening, within 7 days prior to Cycle 3 Day 1, and at EOT visit if another biopsy has not been completed within the previous 6 weeks of the EOT visit.

[2]Bleeding risk blood tests (PTT/INR) will be collected only with research biopsies (up to 3 days before the biopsy).
[3]Tumor Imaging will be performed every 8 weeks (+/- 1 week) from Cycle 1 Day 1 until disease progression or last treatment, regardless of missed or out of window doses. MRI may be used if CT is contra-indicated.

Screening Tests

Screening evaluations will be performed for all subjects to determine study eligibility. These tests will be completed within 28 days of the first treatment. After you review and sign this informed consent form, these tests and procedures will be done:

- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Vital signs, height, and weight
- Prior/concomitant medications procedure evaluation
- Demographics (if allowed by local regulations, date of birth, sex, race, and ethnicity)
- Fresh-tissue tumor biopsy
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Up to 3 days prior to your research biopsy you will have blood tests done to assess potential bleeding risk
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug
- Urine sample collection for routine safety tests
- Serum (blood) pregnancy test if you are a person of childbearing potential
- Electrocardiogram (ECG) – tracing of the electrical activity of your heart
- Computed tomography (CT) scans or magnetic resonance imaging (MRI if you are unable to have a CT scan or if your doctor feels that this test is better to look at your disease).
- If available, study staff will obtain slides from left over tumor taken during prior surgeries or biopsies to be used for research testing. If this archival tumor is not available, you may still participate in the trial.

Treatment Period

If your screening results qualify and if you agree to take part in the study, you will then be enrolled on to the study. You will start taking itacitinib by mouth once per day on Cycle 1 Day 1. You will be required to record when you take itacitinib each day in a medication diary. The medication diary should be returned to your treating physician along with any leftover pills that you did not take. A cycle of itacitinib is 28 days.

Cycle 1 Day 1 and Day 15
The following evaluations will take place during these visits:

- Physical exam, as per standard of care including assessment of your general well-

being (called an ECOG score)

- Concomitant medications and procedures evaluation
- Review adverse events
- Vital signs and weight
- Serum or urine pregnancy test if you are a person of childbearing potential (Day 1 only)
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug

Cycle 2 Day 1
The following evaluations will take place during this visit:

- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Concomitant medications and procedures evaluation
- Review adverse events
- Vital signs and weight
- Serum or urine pregnancy test if you are a person of childbearing potential
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug

Cycle 3 Day 1
The following evaluations will take place during this visit:

- Fresh tumor biopsy (within 7 days of Cycle 3 Day 1)
- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Concomitant medications and procedures evaluation
- Review adverse events
- Vital signs and weight
- Serum or urine pregnancy test if you are a person of childbearing potential
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Up to 3 days prior to your research biopsy you will have blood tests done to

assess potential bleeding risk (coagulation panel)
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug
- Computed tomography (CT) scans or magnetic resonance imaging (MRI if you are unable to have a CT scan or if your doctor feels that this test is better to look at your disease).

Cycle 4 Day 1
The following evaluations will take place during this visit:

- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Concomitant medications and procedures evaluation
- Review adverse events
- Vital signs and weight
- Serum or urine pregnancy test if you are a person of childbearing potential
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug

Cycle 5 Day 1
The following evaluations will take place during this visit:

- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Concomitant medications and procedures evaluation
- Review adverse events
- Vital signs and weight
- Serum or urine pregnancy test if you are a person of childbearing potential
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug

Cycle 6 And All Future Cycles Day 1
The following evaluations will take place during this visit:

- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Concomitant medications and procedures evaluation
- Review adverse events

- Vital signs and weight
- Serum or urine pregnancy test if you are a person of childbearing potential
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug (**Cycle 7 Day 1 only)**
- Computed tomography (CT) scans or magnetic resonance imaging (MRI if you are unable to have a CT scan or if your doctor feels that this test is better to look at your disease). We will continue to perform these every 8 weeks while you are receiving study treatment.

<u>End of Treatment</u>
Your end of treatment visit will take place within 7 days of your last dose of itacitinib. The following evaluations will take place during this visit:

- Fresh tumor biopsy (within 14 days of end of treatment visit, if you did not have a research biopsy within 6 weeks before this visit)
- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Concomitant medications and procedures evaluation
- Review adverse events
- Vital signs and weight
- Electrocardiogram (ECG) – tracing of the electrical activity of your heart
- Serum or urine pregnancy test if you are a person of childbearing potential
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
    - Up to 3 days prior to your research biopsy you will have blood tests done to assess potential bleeding risk
    - Research blood tests – done to understand your immune system and sarcoma and how it may respond to the study drug
- Urine sample collection for routine safety tests
- We will ask you about you about your post-study anticancer therapy status

<u>Safety Follow-Up (30 days from end of treatment visit)</u>
Your safety follow-up visit will take place approximately 30 days after your end of treatment visit. The following evaluations will take place during this visit:

- Physical exam, as per standard of care including assessment of your general well-being (called an ECOG score)
- Concomitant medications and procedures evaluation
- Review adverse events
- Vital signs and weight
- Electrocardiogram (ECG) – tracing of the electrical activity of your heart
- Serum or urine pregnancy test if you are a person of childbearing potential
- Blood sample collection for:
    - Routine safety tests such as a complete blood count and comprehensive metabolic panel
- We will ask you about you about your post-study anticancer therapy status

Long-Term Follow-Up

Post-treatment survival and any initiation of new anticancer therapy information status will be monitored about every 12 weeks (±2 weeks) from the safety follow up visit or more frequently as needed, until one year has elapsed since initiating itacitinib therapy, disease recurrence, death, withdrawal of consent, or the study closes, whichever is earliest. Then we will either review your medical records or contact you via telephone every 6 months (+/- 3 months) to see how you are doing.

How long would you stay in this study?

You may be in the study for as long as your cancer responds to the study treatment, until you experience an unacceptable side effect, you no longer wish to participate, or your study doctor feels that it is in your best interest to stop your participation. You may stop participating at any time without penalty or loss of benefits. However, if you decide to stop participating in the study, we encourage you to talk to your study doctor and your regular doctor first.

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)?

There may be risks to you if you are in this study. You may have side effects while you are in the study. You will be carefully and regularly monitored by the study doctor for any problems. There may be risks or side effects of the study drug that are unknown at this time. You should tell the study doctor/staff about anything that is bothering you or any side effect you have, even if you do not think they are related to the study drug.

Risks of Itacitinib

The following is a list of the most medically significant or most common side effects reported in previous or ongoing studies and considered to be related to itacitinib. In some cases, side effects can be serious, long-lasting, or permanent. They can even cause hospitalization and death. Some side effects go away soon after you stop the study drug/therapy, and some may take time to resolve. The study doctor may alter the dosage regimen of itacitinib or give you medicines to help lessen the side effects. This is not a complete list of all side effects that may occur. For more information about risks and side effects, please ask the study doctor.

Recent animal studies of Itacitinib in rats showed development of benign (non-cancerous) tumors in the thyroid of rats, called follicular adenomas, and hibernomas. Follicular adenomas are benign lesions consisting of a type of cells in the thyroid gland called follicular cells. In humans, hibernomas are rare benign tumors consisting of brown fat tissue. The relevance of these animal findings to humans is unclear. Among patients who received Itacitinib in clinical trials, there was no case of thyroid tumor reported so far.

If you experience any side effects or have any other problems, you must immediately tell the appropriate study staff or your study doctor. If you feel that your symptoms or side effects are life-threatening, seek medical assistance immediately.

SIDE EFFECTS ASSOCIATED WITH THE USE OF ITACITINIB

Very Common (greater than or equal to 10%)

- Low red blood cell count (anemia)
- Fever (pyrexia)
- Headache
- Low white blood cell count (neutropenia)

SIDE EFFECTS ASSOCIATED WITH THE USE OF ITACITINIB IN COMBINATION WITH CORTICOSTEROIDS

Very Common (greater than or equal to 20%)

- Diarrhea
- Low levels of a type of clotting cell (platelet count decreased / thrombocytopenia)
- Swelling of the limbs (peripheral edema)

- Low red blood cell count (anemia)
- High blood sugar (hyperglycemia)
- Low white blood cell count (neutropenia / neutrophil count decreased)
- High blood pressure (hypertension)
- Cytomegaloviral infections
- Fever (pyrexia)

Very Common (greater than or equal to 15% but less than 20%)

- Increased liver enzymes (alanine aminotransferase increased)
- Low potassium in the blood (hypokalemia)
- Fatigue
- Nausea

Very Common (greater than or equal to 10% but less than 15%)

- Abdominal pain
- Joint pain (arthralgia)
- Increased liver enzymes (aspartate aminotransferase increased)
- Cough
- Decreased appetite
- Headache
- Low magnesium in the blood (hypomagnesemia)
- Vomiting

Common (greater than or equal to 1% but less than 10%)

- Acute kidney injury (kidney damage that happens within a few hours or days)
- Weakness (asthenia)
- Depression
- Painful or difficult urination (dysuria)
- Swelling (edema)
- Fall
- Gastrointestinal hemorrhage (significant bleeding)
- Blood in stool (hematochezia)
- Too much bilirubin in the blood (hyperbilirubinemia)
- A low blood protein (hypoalbuminemia)
- Low calcium levels in the blood (hypocalcemia)

- Hypogammaglobulinemia (a problem that makes it hard for the body to fight infections)
- Low phosphate in the blood (hypophosphatemia)
- Malnutrition
- Pneumonia
- Pneumonia cytomegaloviral
- Sepsis (a life-threatening complication of an infection)
- Fast heart rate (tachycardia)

One subject on trial experienced a serious adverse event of congestive heart failure with reduced ejection fraction. This means the amount of blood the heart is pumping is less than what your body needs. Heart failure is a rare side effect, though there is a possibility you may experience this while taking the study drug, itacitinib.

Reproductive risks

Itacitinib treatment could cause unknown reproductive risks. For this reason, we recommend that males or females who are considering having children in the future consider either sperm banking or egg freezing. Discuss this with your doctor.

Taking itacitinib 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 itacitinib. 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.

The effects of fathering a child are also unknown. Men who join this study 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 itacitinib.

Risks of Biopsy Procedures

This study also requires biopsies which could potentially cause significant bleeding or infection. Depending on the specific location of the tumor being biopsied there could be additional possible complications that might be serious. Ask your doctor to learn more about where your biopsy will be and if there are additional possible complications that you should be aware of.

Risks of Study Procedures

Blood draws: When you have your blood drawn you may feel some minor discomfort. Possible side effects include pain, redness, bruising or bleeding at the site of the needle

puncture. Some people feel lightheaded or faint when their blood is drawn. Rarely blood clots or an infection may occur.

CT Scans: You will be exposed to radiation at a level below the levels considered to cause harmful effects. If a contrast dye is used, there is a small risk of an allergic reaction. You may experience discomfort related to lying still in an enclosed space for a prolonged period of time.

MRI Scans: A loud banging noise will be produced. Earplugs or headphones will be available if needed. If a contrast dye is used, there is a small risk of an allergic reaction. You may experience discomfort related to lying still in an enclosed space for a prolonged period of time.

Radiation Risks

There are some risks from the CT scans used to watch your tumor status and health. These scans will expose you to radiation. A small amount of radioactive material will be injected into your vein and bind to your red blood cells. If you live in the US, you receive about 3 millisieverts of radiation each year. It comes from space and the earth around you. This is called “background radiation.” A “millisievert” (mSv) is a unit used to measure radiation dose. The radiation dose to your whole body from each of your scans will be about as follows:

- CT chest: 7 mSv
- CT abdomen: 8 mSv
- CT pelvis: 6 mSv
- CT biopsy: 5mSv

The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk will increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. You may need to have other x-rays or scans for your care. Your doctors will explain the risks of the other x-rays or scans.

Non-physical risks

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

- You might not be able to work.
- You might have financial expenses caused by transportation to and from the doctor’s office
- Results of research studies, including genetic tests, might be released by accident. This risk is very low, because we keep personal information private. If these results became known, you could have problems with family members or insurance.

What are the benefits?

We do not know if this study would help you. We are testing the effects of itacitinib treatment on your immune system. You might get better if you receive itacitinib, but your

condition could stay the same or even get worse. We hope the information from this study will help other people with sarcoma 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.

There may be other FDA approved treatment choices for your disease that you have not received yet. This may include older chemotherapies such as doxorubicin, ifosfamide, dacarbazine, gemcitabine, docetaxel, trabectedin, and eribulin as well as some newer FDA approved options such as pazopanib. If you participate in this trial, you will not be able to receive these treatments while you are on the study. Once you have completed treatment on the study, you may be still eligible for these other options. Talk to your doctor about these other treatments as they may be good options for you.

Other choices include: another “standard” treatment like chemotherapy, another research study, no treatment, or comfort care.

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

Protecting Privacy as an Individual and the Confidentiality of Personal Information

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

- The researchers involved in the study.
- Incyte Inc. (the maker of itacitinib) who is financially supporting the study.
- 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, 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 the 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.

Would you have extra costs if you join 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:

- Itacitinib
- Correlative blood tests for research
- Tissue slides and curls from a previous biopsy
- 12-lead ECG done at screening, end of treatment visit, and safety follow-up visit.
- Serum or urine pregnancy tests for people of childbearing potential
- Pre-treatment fresh-tissue biopsies taken during screening
- Post-treatment fresh-tissue tumor biopsies taken for research purposes while on this study at during screening, cycle 3 and end of treatment.

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 illnesses related to this research, immediately contact one of the study coordinators, their numbers are below. They will 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 because the tests are investigational and will not be linked to your identity.

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

Your tissue contains DNA. DNA makes up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases such as cancer. There are many different types of genetic tests. The testing on your tissue samples might include genetic testing called whole genome sequencing. Whole genome sequencing looks at all the known genes in your cells. This type of testing can provide useful information to researchers. It can also present risks if the test results became known to others, for example you could have problems with family members or insurance companies. There is also a risk that these test results could be combined with other genetic information to identify you.

We invite you to donate tissue samples for other 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.

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

If you donate tissue, 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 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 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 for research, you could withdraw the donation at any time by contacting your study team or physician. You would have no penalty for withdrawing the donation, and regular medical care would not change. We could not return donated tissue, 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 itacitinib. You and the doctor could talk about the follow-up care and testing that would help the most.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your responsibilities

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

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

For more information

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

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-606-1767 Dr. Michael Wagner 206-606-6425 Roxanne Moore
If you get sick or hurt in this study	206-606-1767 Dr. Michael Wagner 206-598-6190 UW operator and ask to page the oncology fellow on call
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 Hutchinson Cancer Center Financial Services Department)

Emergency number (24 hours): 206-598-6190 (ask for on call provider)

SUBJECT'S STATEMENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to take part in this research study. If I sign this form I will not lose any of the legal rights that I would otherwise have as a subject in a research study.

Read each question and think about your choice. When you decide on each question, please initial in the space provided for **YES** or **NO**.

Do you agree to donate your tissue to study cancer? (initial next to your choice) **YES _____ NO _____**

Do you agree to being contacted when you stop the study treatment, also called long-term follow-up? This means we would contact you by phone or email every 12 weeks to check on how you are doing, to receive information about your cancer status, and about your current cancer therapy. We would also ask your doctor to send a copy of your medical records. (initial next to your choice) **YES _____ NO _____**

CONSENT SIGNATURE:

_____
Subject Name (printed):

_____ _____
Signature of Subject (18 years and older) Date

RESEARCHER'S STATEMENT

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____
Printed Name of Person Conducting the
Informed Consent Discussion

_____ _____
Signature of Person Conducting the Informed Consent Discussion — Date

---------- **Use this witness 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 Impartial Witness

_____ _____
Signature of Impartial Witness — Date

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