PENN MEDICINE
RESEARCH SUBJECT
COMBINED INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title:	An Open-Label Phase I/II Safety and Efficacy Study of Itacitinib in Combination with Everolimus in Subjects with Relapsed/Refractory Classical Hodgkin Lymphoma
Sponsor:	The University of Pennsylvania
Principal Investigator:	Jakub Svoboda, MD Abramson Cancer Center of the University of Pennsylvania Philadelphia, PA 19104 215-614-1846
Emergency Contact:	24 Hour Emergency – Call 215-662-4000 Ask for Oncologist On-Call

1 WHY AM I BEING ASKED TO VOLUNTEER?

You are being asked to participate in this research study because you have Hodgkin lymphoma that has come back or gotten worse after previous treatment. Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, your clinical care will not be affected. Before agreeing to participate in this research study, it is important that you read the following explanation of the proposed procedures and how long you will be in the study. This document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time.

Please take time to read the following information carefully. You may wish to discuss it with your family, friends, and your personal doctor (i.e., your family doctor or primary care doctor). If you have any questions, you may ask your study doctor and/or the research team for more information. Take time to decide whether or not you wish to take part. If you decide to participate, you will be asked to sign this form. If you decide to participate, you can change your mind at any time and withdraw from the study without giving a reason.

2 WHAT IS THE PURPOSE OF THIS RESEARCH STUDY? WHAT DOES THIS STUDY INVOLVE?

The study will assess how safe and well-tolerated a combination of the study drugs itacitinib and everolimus in patients with Hodgkin lymphoma. We also hope to learn how effective this experimental combination is in treating Hodgkin lymphoma, when given together.

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"Experimental" means the combination of these two drugs has not been approved by United States Food and Drug Administration (US FDA). While everolimus is approved for some forms of cancer, it is not specifically approved for treatment of Hodgkin lymphoma. However, it has been shown to result in response in some Hodgkin lymphoma patients and also is part of the national guidelines for treating relapsed Hodgkin lymphoma. Itacitinib is an experimental drug and is not approved. The hope is that adding itacitinib will improve the effectiveness of everolimus.

Everolimus is a type of drug called an m-TOR inhibitor. Cancer cells require a protein called mTOR which feeds the cancer cells and allows the cancer cells to grow. As an mTOR inhibitor, everolimus blocks mTOR from feeding the cancer cells. So, the growth of cancer cells is limited. However, cancer cells can find other ways to grow. Itacitinib is a drug that blocks enzymes known as Janus protein tyrosine kinases (JAK). "Kinases" are proteins inside cells that help cells live and grow. Itacitinib specifically blocks a specific enzyme known as JAK1 that helps cells live and grow. By blocking JAK1, itacitinib prevents the growth of cancer cells. Everolimus is FDA-approved for the treatment of certain cancers. Itacitinib has not been approved by the FDA.

3 WHO IS SPONSORING THIS STUDY?

The University of Pennsylvania is the sponsor (entity responsible for the design, conduct and regulatory oversight of the study). Incyte Corporation is the manufacturer of investigational drug itacitinib, and will be providing the drug during this research study. Everolimus is manufactured by various pharmaceutical companies and will be acquired by you and/or your insurance from a commercial pharmacy.

How long will I be in the study?

You will be in the study about 2 years (24 months).

During that time, you will receive study treatment until your disease gets worse, you experience unacceptable side effects, and/or your physician no longer believes the therapy is of benefit to you, whichever occurs first.

If your physician believes that additional months of treatment will continue to benefit you, they may extend treatment beyond 24 months.

Once your study treatment is discontinued, the study team will continue to follow you up to 2 years from your end of treatment (EOT) visit.

4 WHAT AM I BEING ASKED TO DO?

This is an open-label research study, which means that both the researchers and participants know which treatment is being administered. This study has two phases. The study doctor will tell you which phase of the study you will be enrolled in, before you sign the consent. The first part, called Phase I, will determine the safest dose of the itacitinib to give to patients in combination with the everolimus. The dose of everolimus is the same for both Phase I and Phase II (unless you develop toxicities). Once Phase I is completed, the safest and most appropriate dose of itacitinib to give to patients will be identified. A second

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group of patients will be enrolled at that dose level in Phase II. The goal of Phase II is to determine how well the itacitinib and everolimus work in combination and what the side effects are.

The study team will tell you which dose of itacitinib you are receiving and any side effects that have been seen in other patients. Your dose may also be reduced if you experience any unacceptable side effects during your treatment on this study. Your study doctor will explain this to you in more detail.

What will happen if I join this study?

If you agree to be in this study, the following tests, examinations, or procedures are done to evaluate your cancer, overall health, and eligibility. You must meet all study entry requirements in order to qualify for this study. The results of these tests will be reviewed with you by your study doctor and/or the study staff. You will be asked to visit the study site/clinic during your participation in the study. This includes the possibility of attending multiple visits during a 28-day "screening" period, weekly visits during the first month of treatment and, subsequently, one visit every 28 days, until the end of year 2. If your physician believes that additional months of treatment will continue to benefit you, they may extend treatment beyond 24 months and you will continue to visit every 28 days. Once treatment has stopped, follow up visits will be every 3 months after the end of treatment.

Screening Period

"Screening" begins after you sign this informed consent form. You will need to have completed certain exams, tests, or procedures to find out if you qualify for the study. Some of these tests are part of routine care, and may be done even if you do not participate in the study. If you have had some of these tests/procedures recently, they may not need to be repeated. These tests and procedures need to be completed within 28 days of your first dose of study drug. If you have already had any of these tests/procedures performed within the specified timeframe, these test may not need to be repeated. The study team will discuss this with you.

- You will be asked if you have any questions about this study before any tests or study procedures are conducted.
- The study doctor will perform a comprehensive physical exam including your height and weight.
- Your medical history and medication history will be obtained, including the signs and symptoms of your cancer, details of other treatments you have received for your cancer as well as how you responded to them.
- Your current medications, vitamins, and herbal supplements will be reviewed. You will have your vital signs measured, which include blood pressure, heart rate, breathing rate, and body temperature.
- The study doctor will assess your ability to perform daily activities (performance status).
- Blood samples (approximately 3 tablespoons) will be drawn to check for the following:
  - Blood cell counts (number of each type of blood cell)
  - Blood chemistry levels (to test your kidney and liver function)
  - Lipid (fats) level testing (to obtain baseline)
  - Blood clotting test (to monitor the time it takes for your blood to clot)

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- Pregnancy Test (women of childbearing potential only). If you are pregnant, you cannot participate in this study.

- Serology: a test to look for hepatitis B, C, and HIV. About 2 teaspoons of blood will be taken for this test. The Study staff will tell you if the results of the hepatitis tests are positive. The results of these tests must be negative in order for you to be in the study. If you do not want to be tested you should not take part in this research study.

  If you test positive for hepatitis B, C, and/or HIV, we are required to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born.
- A Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), or Positron Emission Tomography (PET)-CT scan of your disease sites will be performed. If these scans were recently performed as part of your routine care, they may be used as your screening scans.
- Quality of life questionnaire will also be collected at baseline.
- You will be asked to start an antibiotic to prevent a rare form of pneumonia which can sometimes happen in patients with weakened immune system.
- You will also be asked to take an antiviral drug (e.g., acyclovir) to prevent varicella (chickenpox) re-activation or other viral infections

IMPORTANT NOTE ABOUT EVEROLIMUS: Since everolimus is part of the national guidelines for treating patients with relapsed/refractory Hodgkin lymphoma, you will be responsible for obtaining the everolimus; if you are unable to access everolimus, you will not be able to participate in this study. Everolimus is an oral medication that you will obtain through a licensed pharmacy in the United States. Before you begin any screening procedures, we will confirm that your insurance company will agree to cover the cost of everolimus while you participate in this study. If your insurance company will not cover the cost of everolimus while you participate in this study, you will be responsible for the cost should you decide to enroll in the study. You will have access to a social worker or an appropriate person in the pharmacy to help you with this process as necessary.

Procedures associated with the administration of the study drug(s)

When all of the above tests/procedures have been completed, you have been found eligible to enter this study, and you agree to participate, you will be scheduled to receive study drug.

5 HOW WILL THE STUDY DRUGS BE GIVEN TO ME DURING THIS STUDY?

Itacitinib and everolimus are both tablets and are to be taken by mouth once a day (preferably in the morning) with a glass of water, with or without food, at the same time each day. The tablets must not be chewed or crushed. The starting dose of itacitinib in Phase I will be 300 mg (it comes in 100 mg tablets – so you will be taking 3 tablets of itacitinib daily) and everolimus comes in various strength, but most often it will be given as one 5 mg tablet. The itacitinib may be reduced to 200 mg daily or increased to 400 mg daily depending on any side effects, but do not change the dose unless instructed by your physician. The dose for Phase II will be determined from the Phase I results, and your study doctor will explain this to you. The dose of everolimus for Phase I and Phase II will be 5 mg daily.

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For your safety, there are some medications that you will not be able to take during the study. Your study doctor can tell you what those are. If you are taking one of these medications and are unable or unwilling to stop taking prior to the study, you will not be able to participate.

You should not take other medications to treat your cancer while participating in this study. It is important that you check with your study doctor before starting any new medications (including over the counter medications, vitamins or herbal supplements). If you experience adverse events and/or changes in medications between study visits, you should contact your study doctor. If you are unwilling to follow any of the procedures that are part of the study, you should not participate. You will be given the opportunity to ask any questions you have. You should not agree to participate in the study until all of your questions have been answered to your satisfaction. It is important to remember to bring all used and unused study medication with you at each visit.

You will need to bring your everolimus to the clinic, so that the study team may examine the everolimus, which you should have gotten from a commercial pharmacy. Be sure to bring all information and the unopened packaging with you to every visit. You will be given a diary to record when you take your study drugs at home between visits. You will be asked to bring this completed diary and your remaining study drugs and/or empty pill bottles/blister cards to each study visit. When you return the remaining study drugs and/or empty pill bottles/blister cards and diary, the study team will review everything to make sure you are taking the drug appropriately and completing this diary as requested.

Study Tests/Procedures

When you are on the study, exams, tests, and procedures will be done to evaluate your health and response to the study drug(s). At each of these study visits you will be asked how you are feeling, if you have had any adverse events, if you may be pregnant, if you have had any medical procedures, and about any medications you are taking. It is important you check with your study doctor before starting any new medications. Taking other drugs (including alcohol, over-the-counter medications, herbal preparations, illegal drugs, or nutritional supplements) may cause additional side effects or even life-threatening reactions when combined with the drugs being used in this study. If you experience adverse events, changes in your health and/or changes in medications, please contact your study doctor or a study team member.

You will have the following tests, procedures, and assessments done at the time points below during study treatment:

Study Calendar	Cycle 1, Day 1	Cycle 1, Day 8	Cycle 1, Day 15	Cycle 1, Day 22	Cycles 2-End of Treatment, Day 1
Physical Examination, including weight; address any previous adverse events/issues and any new complaints	X	X	X		X
Assessment of your ability to perform your daily activities (performance status)	X	X	X		X
Assessment of your vital signs (including blood pressure, heart rate, temperature, oxygen levels)	X	X	X		X

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Study Calendar	Cycle 1, Day 1	Cycle 1, Day 8	Cycle 1, Day 15	Cycle 1, Day 22	Cycles 2-End of Treatment, Day 1
Routine Blood Tests (about 2-3 tablespoons of blood) for laboratory safety tests, including your blood counts, blood clotting, cholesterol levels, kidney functions, and liver functions	X	X	X	X	X†
Your study doctor (or other study team member) will ask if you have had any adverse events, and, if so, how often and how severe		X	X		X
Your study doctor (or other study team member) will ask if you have had any changes in other medications, or if you are taking new medications	X	X	X		X
Return all bottles of study drugs		X	X		X
Quality of life questionnaire**	X	X	X		X
Disease assessment by MRI, CT or PET scan					X*

*You will have disease assessments by CT Scan, by PET Scan, or by MRI every 2 months for the first 4 months (around first day of cycles 3 and 5) and then every 4 months for the duration of study (up to 2 years, unless you are still benefiting from the medication). You will also have imaging after the two years – about every 6 months for 2 years unless your disease gets worse or if you were started on a different treatment.

** Quality of Life questionnaire will not need to be repeated if it has been completed within 14 days prior to starting therapy.

† Not performed when visit is via telemedicine. If clinically indicated, these tests may be performed at an outside testing facility.

Your active treatment (when you will take the study drugs) will last about 2 years (24 months), unless you are still benefiting from the treatment. You may also be taken off the study drugs sooner, if your disease gets worse, you experience intolerable side effects, or you decide you no longer wish to participate. After you have stopped receiving study drug treatment, you will continue to participate in follow-up for up to 2 years after, unless you specifically ask us not to contact you or the study ends. You can also choose to leave the study at any time without giving a reason. Leaving the study will not affect your future medical care.

To safeguard your welfare during COVID surges and/or situations that may negatively impact your safety, telemedicine visits may be utilized. The telemedicine option will be discussed with you prior to the scheduled visit. Certain tests will not be done; but if your physician thinks they are needed, tests may be performed at an outside testing facility (e.g., LabCorp, Quest Labs).

End of Study Visit

Within 28 days after your last dose of the study drug, you will be asked to come back to the clinic for an End of Study Visit and undergo the following tests/procedures. Your doctor will let you know what day you are to return to the clinic for these tests.

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- Complete Physical Examination including an assessment of your vital signs.
- An evaluation of your performance status (your ability to perform daily activities)
- Review of any current medications you are taking and any adverse events/symptoms you may have experienced.
- Routine blood tests (about 2 -3 tablespoons of blood)- includes blood cell counts (number of each type of blood cell) and blood chemistry levels (to test your kidney and liver function and the minerals in your blood)
- Pregnancy test if you are a woman of childbearing potential. A sample of your blood (about 1 teaspoon) will be used to perform this test.
- CT scan- imaging tests to assess your disease
- Quality of life questionnaire

Post-Study Procedures

Follow-up

After you complete your study treatment, we will continue to follow-up with you to see how you are doing for another two years. This study follow-up will be done every 3 months (+/- 30 days) for the first year after you stop taking the study drug, and then every 6 months (+/- 30 days) for the second year after you stop taking the study drugs. This follow-up will take place during regular follow-up visits with your doctor. At these visits you will undergo follow-up assessments per your routine care, which includes routine laboratory tests and disease assessment scans. You may also be followed up by a study team member by telephone or by review of your medical records to gather information related to your overall health and any additional cancer treatment procedures you may have undergone.

If you undergo high-dose chemotherapy with an allogeneic stem cell transplant within one year of completing study treatment, you will be followed for one year after the transplant, in order to collect additional data.

6 WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

While on the study, you are at risk for the following side effects. Some of these side effects may be potentially serious or life-threatening, and may include death. You should discuss these with the study doctor. There also may be other side effects that are not known and other very rare side effects that are known but not included in this list. If you experience side effects from the study drug(s) and/or procedures, your study doctor may delay or skip a dose of the study drugs, or ask you to stop taking study drugs. Your doctors may also give you other drugs to help lessen these side effects. Many side effects go away shortly after the study drugs are stopped, but in some cases side effects can be serious, long lasting or permanent.

As there is little experience using everolimus in combination with itacitinib, it is not yet clear how they will work together. This means that it is possible that the study drug may change how well everolimus works in treating your disease (i.e. may make it more or less effective).

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Side Effects Seen in Previous Studies using the Study Drug Itacitinib

Itacitinib has been tested in healthy human subjects, as well as subjects with rheumatoid arthritis, (disorder that affects joints, commonly of hands and feet), psoriasis (skin disorder), and myelofibrosis (MF) (a disease in which the bone marrow becomes replaced by scar tissue).

Subjects with rheumatoid arthritis, psoriasis, or MF reported adverse events that occurred while they received itacitinib; most side effects that occurred (in healthy subjects or subjects with rheumatoid arthritis or psoriasis) were mild and improved after stopping the study drug.

Itacitinib has also been tested in blood cancers in combination with INCB040093 (a PI3K inhibitor) and in patients who had cancer of pancreas and lungs in combination with chemotherapy drugs like gemcitabine, *nab*-paclitaxel, or docetaxel.

Listed below are adverse events that were found to be commonly occurring in subjects treated with itacitinib in combination with chemotherapeutic agents. These events are thought to be possible side-effects of itacitinib. Some of these events were also considered serious and required the patient to be treated.

Very Common (Events occurring in 10% or more of study patients)

- Anemia (low red blood cells)
- Neutropenia (low levels of a certain type of white blood cell)
- Thrombocytopenia (low levels of a type of clotting cell in blood)
- Diarrhea
- Nausea
- Vomiting
- Asthenia/Fatigue
- Pneumonia (Infection of the lungs)
- Upper respiratory tract infection
- Cough
- Pyrexia (fever)
- Peripheral edema (swelling in the legs or arms)
- Dyspnea (shortness of breath)
- Dizziness
- Pain in extremity
- Night sweats
- Abdominal pain
- Headache
- Arthralgia (joint pain)
- Pruritus (itching)

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- Increased bilirubin (may indicate liver damage or disease)

Common (Events occurring in at least 1%, but less than 10%, of study subjects)

- Febrile neutropenia (fever with low levels of a type of white blood cell)
- Leukopenia (low levels of white blood cells)
- Mucocutaneous fungal infection (fungal infection of skin and lining of the body, such as the mouth)
- Sepsis (infection of the blood)
- Urinary tract infection (infection of the bladder)
- Bruising
- Nasal congestion
- Contact dermatitis
- Compulsive skin picking

Some subjects may be more likely than others to experience a drop in blood cell counts, therefore your blood cell counts will be monitored and itacitinib may be discontinued or interrupted until your blood cell counts improve. During this time you will also be provided supportive care, which may include a blood transfusion or treatment with growth factors such as Neupogen. You may become anemic (low red blood cell count) while you take itacitinib, and that may cause you to feel fatigued or short of breath. If your platelet count (part of your blood cell counts) becomes low while you take itacitinib, it may lead to bleeding and/or bruising. In addition to the risk of lowered red blood cells (anemia) and lower platelets (thrombocytopenia), there is a small risk of decrease in the level of white blood cells in subjects taking itacitinib. A low white blood cell count might make you more likely to develop infections (i.e.; fungal infections, urinary tract infections etc.).

Inform your study doctor if you have had serious infections in the past or if you develop signs of infection during the study (including fever or chills; warm, tender, red areas on the skin or drainage of pus; cough or shortness of breath; or abdominal pain). Let your study doctor know if you experience fatigue, shortness of breath, or chest pain (possible signs of anemia) or bruising, nosebleeds, bleeding in the mouth, or rash with pinpoint red spots (possible signs of low platelets).

Side Effects from Previous Studies using the Study Drug Everolimus

Listed below are adverse events that were found to be commonly occurring in subjects treated with everolimus. These events are thought to be possible side-effects of everolimus. Some of these events were also considered serious and required the patient to be treated:

Very Common (Events occurring in at least 10% of study patients)

- Mouth lining tenderness, including redness, irritation, and swelling or sores in the mouth
- Rash
- Diarrhea
- Felling weak or tired
- Infections

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- Nausea
- Fluid in your arms and legs which can cause swelling
- Loss of appetite
- Headache
- Abnormal or loss of taste
- Nosebleeds
- Inflammation of lining of the digestive system
- Lung and breathing problems
- Vomiting
- Itching
- Cough
- Shortness of breath
- Dry skin
- Nail changes
- Fever
- Lowering of blood cells that help your blood to clot which can cause you to bleed more easily
- Lowering of protein in your blood (hemoglobin) that helps carry oxygen

  Increase in the level of cholesterol and triglyceride levels (fats in your blood). Increased levels of these fats in your blood are an important risk factor for heart disease.

  Increase in the level of liver enzymes in your blood which may be a sign your liver is not working properly.

  Kidney problems which may cause an increase in the level of creatinine (a waste product of muscle use) in your blood and increase the level of protein in your urine. These increases are an indication that the kidneys are not working as well as they did before. In very rare cases, this toxicity could lead to kidney failure.
- Chills
- Weight loss
- Bleeding or bruising

Common (Events occurring in at least 1%, but less than 10%, of study subjects)

- Changes in your blood sugar levels (glucose) which could lead to diabetes
- Increased blood pressure
- Dry mouth and mouth pain
- Skin changes (acne)
- Difficulty sleeping or changes in sleep patterns
- Dehydration

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- Abdominal pain
- Stomach virus
- Passing gas
- Constipation
- Irritability
- Joint stiffness or pain
- Mouth pain
- Difficulty swallowing
- Heartburn
- Stomach pain
- Low white blood cell counts (which may make it easier to get an infection)

Everolimus may be associated with changes within the lungs such as inflammation (pneumonitis) which can cause lung or breathing problems. Tell your doctor immediately if you have new or worsening cough, shortness of breath, difficulty breathing, or wheezing. In some patients, lung or breathing problems have been severe, and can even lead to death. If you develop new lung problems, you should stop taking everolimus and contact your doctor immediately, so that he/she can determine the cause of your new symptoms. In rare cases, this drug has been associated with an embolism or blockage in your lungs.

Everolimus can make people with prior hepatitis B or hepatitis C infection more likely to have a flare-up of their hepatitis (called 'reactivation'). If you have risk factors or a history of hepatitis B or C infection, your doctor will monitor you closely throughout the study. If your blood test results show that your hepatitis B or C infection has reactivated, you may be asked to take antiviral medication or you may be asked to stop taking everolimus.

Everolimus can make people more likely to have an infection such as pneumonia or a bacterial or fungal infection. In some patients infections have been severe, and can even lead to death. You may need to be treated as soon as possible. Tell your doctor immediately if you have a temperature of 100.5°F or above, chills, or do not feel well. Everolimus can cause mouth ulcers and sores. Tell your doctor if you have pain, discomfort, or open sores in your mouth. You might need treatment with a special mouthwash or mouth gel. Your study doctor will explain this to you in more detail.

You should not receive live vaccines (common live vaccines are the nasal spray flu vaccine and the shingles Zostavax vaccine) or have close contact with people who have received live vaccines within 7 days of starting everolimus and while on this study without consultation with your study doctor.

Everolimus may contribute to increased levels of an enzyme called blood lactate dehydrogenase which gives information about the health of certain organs.

Uncommon (Events occurring in at least 1%, or less than 10%, of study subjects)

- Severe decrease in red blood cells or all blood cells
- Loss of taste
- Rash of small blisters

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- Bronchitis
- Coughing up of blood and congestive heart failure (fluid build-up and shortness of breath), as well as non-cardiac chest pain and impaired wound healing
- Increased daytime urination

Everolimus can cause serious side effects, such as worsening side effects from radiation treatment, that can sometimes be severe. Tell your healthcare provider if you have had or are planning to receive radiation therapy.

Everolimus can cause impaired wound healing. Tell your healthcare providers if you have any elective procedures planned or undergo surgery while taking this drug.

If you experience any hypersensitivity or signs of serious allergic reaction such as rash, itching, hives, difficulty breathing, difficulty swallowing, or dizziness, please contact your doctor.

Other Study-related risks

Recent animal studies of itacitinib in rats showed development of benign 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.

Certain adverse reactions, such as lymphedema, have been reported by patients using everolimus. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate frequency or establish a causal relationship to drug exposure.

There may be other side effects or risks that are not known at this time. Tell the study doctor if you notice or feel anything different so they can determine if you are having a side effect.

Risks of Blood Draws

Blood samples will be taken for tests throughout this study. The amount of blood to be taken by these blood draws is very small and may be associated with discomfort and/or bruising at the site where the needle is inserted; and less commonly, fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, bleeding, and/or infection.

Risks of Radiology Tests

During your participation in this study, you may undergo routine radiology tests to assess your disease. These can include CT, MRI, and PET/CT scans. Each of these procedures has risks associated with it, and you should talk to your study doctor or the person doing these procedures about the risks before they start.

- Radiation Exposure: This research study involves exposure to radiation from the CT and PET/CT scans. Therefore, you will receive a radiation dose. Some of these procedures may not be necessary for your medical care and will occur only as a result of your participation in the study. At

doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very likely that you will see no effects at all.

- PET/CT Scans: A PET/CT scan is a type of imaging test that helps doctors see how the organs and tissues inside the body are actually functioning. The test involves injecting a very small dose of a radiotracer into a vein. Although a radiotracer chemical is used in this test, the amount of radiation exposure is low. The dose of tracer used is so small that it does not affect the normal processes of the body. You may experience discomfort related to lying still for a prolonged period of time.

- Magnetic Resonance Imaging (MRI): An MRI is a scan that uses radio waves and a strong magnetic field to provide images of internal organs and tissues. The known risks associated with an MRI are minimal. The procedure uses radio waves and a magnetic field to take pictures. The greatest risk of having an MRI is the chance of metal objects flying through the air toward the magnet and hitting you. To reduce this risk, all people involved with the study are instructed to remove all metal from their clothing and all metal objects from their pocket. You must tell your study doctor if you have any metal plates or clips in your body. No metal objects are allowed to be brought into the magnet room at any time. Metal objects inside your body can affect the test results and could lead to injury. Because the magnetic field of the MRI scanner attracts metal, these studies will not be performed on anyone with a pacemaker or any non-removable metallic foreign objects in their body. If you have any such object on your body, you will not receive the scan. You may feel claustrophobic (fear of being closed in) or anxious. You may experience some discomfort and fatigue from lying in a confined space. There are no known effects from exposure to the magnetic fields. Multiple needle-sticks may be necessary if a vein cannot be properly accessed and this will be carried out upon your permission. It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

- CT Scans: A computed tomography (CT) scan is an imaging method that uses x-rays to create crosssectional pictures of the body. You will be asked to lie on a narrow table that slides into the center of the CT scanner. Depending on the study being done, you may need to lie on your stomach, back, or side. Once you are inside the scanner, the machine's x-ray beam rotates around you. It is important to remain still during the exam, because movement causes blurred images. You may be told to hold your breath for short periods of time. The scans take about 15 minutes or less to complete.

  – It is important to inform your study doctor if you have had an allergic reaction to IV contrast material in the past, or if you have an allergy to iodine. Most CT contrast reactions (approximately 95%) are mild to moderate in degree and most resolve themselves without treatment. However, life-threatening reactions and fatalities, mostly of cardiovascular origin, have occurred. People with heart disease, kidney disease or allergies are more likely to have a more severe reaction to contrast agents. If you have a history of kidney disease, allergies or heart disease, please inform the study staff. Likely contrast reactions include feelings of overall warmth (especially in the bladder area after injection), a metallic taste during the injection, and warmth, burning sensation, or momentary pain during the contrast injection at the injection site.

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Less likely contrast reactions include nausea, vomiting, headache, hives, and itching. Rare but serious contrast reactions include faster than normal heart rate (tachycardia), high blood pressure (hypertension), low blood pressure (hypotension), heart attack, kidney failure, fluid in the lungs (pulmonary edema), serious allergic reaction, and death. There is also a risk that multiple needle sticks will be necessary to ensure proper intravenous line placement. There may be a small amount of pain or bruising with the placement of the intravenous catheter (IV) and a small risk of infection at the injection site.

Reproductive Risks

Female Participants

You should not become pregnant while on this study and for 120 days after your last dose of study drug because the study drugs could have a negative effect on an unborn baby. In addition, you should not breastfeed while on this study as these drugs may also affect a breast-feeding child. Pregnant women and women who are breast-feeding are not allowed to participate in this study. If you become pregnant, you will no longer be able to participate in this study.

If you are able to have children, you must agree to use two medically accepted barrier forms of birth control, including:

- Diaphragms with spermicide (cannot be used in combination with cervical cap),
- Cervical cap with spermicide (only if you have not given birth)
- Male condom or female condom (cannot be used together)
- Contraceptive sponge (only if you have not given birth)
- Hormonal contraceptives (estrogen/progestin pill or progestin-only pill), contraceptive skin patch, vaginal contraceptive ring, or subcutaneous contraceptive injection

-OR

One of the above barrier methods in combination with:

- Intrauterine Device (IUD)
- Surgical sterility (tubal ligation or a partner that has undergone a vasectomy)
- Contraceptive rod implanted into the skin

-OR

You must agree to completely abstain from intercourse during participation in this study and for 120 days after your last dose of study drug. Abstinence at certain times of the cycle only, such as during the days of ovulation, after ovulation and withdrawal are not acceptable methods of birth control.

Your study doctor must approve your form of birth control. Ask your study doctor about the contraceptive methods that are available and which might be the best for you.

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Even when you use an approved contraceptive method, there is always a small risk that you could still become pregnant. If you do become pregnant during the course of this study or up to 120 days after your last dose of study drug, you must discontinue study treatment, tell the investigator immediately, and consult an obstetrician or maternal-fetal specialist. If you become pregnant while on this study, we will ask permission to collect information about your pregnancy.

Male Participants

You should not father a child while on this study and for 120 days after your last dose of study drug, because the drugs involved could have a negative effect on an unborn baby. If your female spouse or partner has the potential to become pregnant, you and your female partner must use two medically accepted forms of birth control including condoms, diaphragms, cervical cap, an intra-uterine device (IUD), surgical sterility (vasectomy or a partner that has undergone a tubal ligation), or oral contraceptives, OR you must agree to completely abstain from intercourse during participation in this study and for 120 days after your last dose of study drug. Abstinence at certain times of the cycle only, such as during the days of ovulation, after ovulation and withdrawal are not acceptable methods of birth control. Your study doctor must approve your form of birth control. Ask your study doctor about the contraceptive methods that are available and which might be the best for you.

You should also inform your female partner of the potential harm to an unborn child. She should know that if a pregnancy should occur during the course of this study or up to 120 days after your last dose of study drug, you will need to report it to the study doctor immediately, and she should promptly notify her doctor.

The study doctor will also ask to follow-up on the pregnancy.

You must also agree to not donate sperm during the study and for a period of 120 days after your last dose of study drugs.

7 WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE STUDY?

During the course of this study, we may find more information that could be important to you (such as new information about how the drug works or newly discovered side effects). If we discover new information about the study that could affect your decision to stay in the study, you will be notified in a timely manner. You will be able to ask questions about this new information and can discuss it with your family, friends, or doctor.

8 WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

Taking part in this study may or may not make your health better. However, while you may not benefit personally, the knowledge learned from your participation in this research study may benefit other patients in the future. It is possible that your disease and/or health may worsen as a result of participating in this study.

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9 WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?

Your participation in this study is entirely voluntary. Other possible options include:

- Getting treatment or care for your cancer without being in a study.
- Brentuximab, pembrolizumab, and nivolumab are drugs that are approved for patients who have Hodgkin Lymphoma that has come back or gotten worse after previous treatment. You have been asked to participate in this study because your disease did not improve after treatment with these approved medications, or you are not able to tolerate these medications. You will not be able to take these approved treatments if you enroll in this study.
- Taking part in another study.
- Not receiving treatment at this time.
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

10 WILL I BE PAID FOR BEING IN THIS STUDY?

You will not be paid for taking part in this study.

11 WILL I HAVE TO PAY FOR ANYTHING?

Incyte Corporation will supply the drug itacitinib, at no charge while you take part in this study. You will be responsible for obtaining the everolimus and the antiviral medication which are not covered by the study and can be obtained from licensed commercial pharmacy in the United States (i.e. coverage under your insurance plan or purchasing on your own). If you cannot obtain everolimus, you will not be eligible to participate in this study. You will also be responsible for any deductibles or applicable co-pays for the standard tests, exams or procedures that would be done for your routine clinical care, such as office visits, scans and blood work. You and/or your insurance provider will be responsible for standard tests, exams or procedures that would be done even if you were not in this study. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance. There will be no charge to you for those laboratory tests and other procedures that are being done specifically for the purposes of this research study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Website at: http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Website.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and request a free copy.

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12 WHAT HAPPENS IF I AM INJURED OR HURT DURING THE STUDY?

If you have a medical emergency during your participation on this study, you should go to the nearest emergency room. You should contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor or seek treatment outside of Penn Medicine. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at Penn Medicine. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

Penn Medicine will offer you the care needed to treat side effects and/or injuries that occur while you are taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for Penn Medicineto pay you or give you other compensation for the injury.

Financial compensation for such things as traveling, parking, lost wages, disability or discomfort due to injury is not routinely available.

You will not lose any of your legal rights when you sign this form.

13 WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?

You will receive study treatment for 2 years (24 months). Treatment may be extended if your physician believes there is a benefit to you. You may stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first. You can also choose to leave the study at any time without giving a reason. It is important to tell the doctor if you are thinking about stopping so any risks for the treatments that you received can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you. Leaving the study will not affect your future medical care.

The doctor may stop you from taking part in this study at any time if he/she believes that it is in your best interest, if you do not follow the study rules, or if the study is stopped. If new information becomes available that might affect your choice to stay in the study, your study doctor will notify you as soon as possible.

This study may also be stopped at any time by your study doctor, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Principal Investigator or the sponsor feels that it is in your best interest to discontinue the study. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions, or you become pregnant
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study due to new information regarding side effects.
- It is determined that you are no longer benefiting from the study therapy
- For any other reason that is not known at this time

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If you are removed from the research study, your study doctor will explain to you why you were removed. The study doctor and study team will help arrange for your continued care.

14 WHAT MAY HAPPEN TO MY INFORMATION COLLECTED ON THIS STUDY?

Collection of Identifiable Specimens

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Most uses of biospecimens or information do not lead to commercial products or to profit for anyone.

Whole genome sequencing (WGS) will not be conducted on your samples. WGS involves analyzing your entire personal genetic code. WGS can be conducted to determine changes and mutations in DNA. The significance of these results may not be well defined. Not all genetic variations affect one's health.

Future Use of Data and Specimen

Your specimen will not be stored for future use.

Your coded information will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

The following identifiers will be retained with your information: your unique subject number.

Your information may be stored and used for future research purposes for an indefinite amount of time.

There are no plans to tell you about any of the specific research that will be done.

We may share your identifiable information with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. We will not follow up with you to tell you about the specific research that will be done. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

You will not be given the results from testing that may be performed on your information as part of future research.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by coding your information. The key to this code (which links your name back to the personal health information collected during this study) will be stored in a secure area and only Penn Medicine study team will have access to this code.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving

health care and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information, or have changed your mind, you can contact the Principal Investigator at the number listed on the first page of this form, and you may instruct us to destroy any remaining information. However, your information will not be removed from analyses which have begun.

15 HOW WILL MY PERSONAL INFORMATION BE PROTECTED DURING THE STUDY?

If you decide to participate in this study, the study doctor and staff will collect medical and personal information about you as part of completing the study. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. This study is being overseen by the Food and Drug Administration (FDA); therefore, they may review your research records. Please refer to the information below which explains more specifically how your personal information will be protected. If you do not want to allow these uses, you should not participate in this study. Information identifying you will be kept confidential as described below.

If you test positive for Acquired Immunodeficiency Syndrome (AIDS/HIV), Hepatitis B, and/or Hepatitis C, we are legally required to report the positive test results to the City of Philadelphia Health Department and/or the PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements reporting infectious diseases to the PA Health Department, please visit http://www.health.pa.gov and type 'Reportable Diseases' into the site search bar.

16 WILL I RECEIVE THE RESULTS OF RESEARCH TESTING THAT MAY BE RELEVANT TO MY HEALTH?

Clinically relevant research results will be disclosed to you; this will be done in the context of discussion with your study doctor and/or clinical treatment team. Results from clinical testing done as part of this research will be placed in your medical record. Results placed in the medical record and will be available to you per HIPAA regulations, as noted above.

17 WHAT INFORMATION ABOUT ME MAY BE COLLECTED, USED OR SHARED WITH OTHERS?

The following personal health information will be collected and used for the purposes of this study.

- Name, address, telephone number, gender, date of birth
- The history and diagnosis of your disease

- Specific information about the therapy you received, including previous treatment(s) you may have had
- Information about other medical conditions that may affect your care
- Medical data including [include as appropriate: laboratory test results, health status, EKGs, CTs, MRIs, pathology results, etc.
- Information on side effects (adverse events) you may experience, and how these were treated
- Long-term information about your general health status and the status of your disease. This may include information from other health care providers.
- Data that may be related to tissue samples that may be collected from you
- Numbers or codes that will identify you, such as your medical record number
- Information related to study visits and other tests/procedures performed while you are participating on this study.

While collected as part of this study by your study doctor and study team, identifying information (including your name, address, telephone number, medical record number, or any number/codes that will directly identify you) will be kept as confidential as possible and will not be routinely disclosed outside of Penn Medicine. Personal health information that could be used to identify you will not be sent to Incyte Corporation and/or their designated representatives.

You will be assigned a unique subject registration number upon enrollment. This number and your initials will be used to identify you throughout the course of this study so that your identity is protected. The key to this code (which links your name back to the personal health information collected during this study) will be stored in a secure area and only Penn Medicine study team will have access to this code. However, some of the study data (e.g. date of birth) could be used in combination with other information, in order to identify you. If you have questions about the specific information that will be released, you should ask your study doctor.

Why is my personal health information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study, and will be used to conduct and oversee this research study, and to help guide your medical care.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases

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Who can see or use my information?

Which Penn Medicine personnel may use or disclose my personal health information?

The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of Penn Medicine, and Penn Medicine support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide care as part of this study or as part of your routine care, to manage accounting or billing matters, etc.). This includes members of the Institutional Review Board (IRB), an Ethics Committee at Penn Medicine who are responsible for reviewing and overseeing research studies to ensure that they are safe and being well managed.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of UPHS and the School of Medicine, might receive my personal health information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your study-related records, including the results of the research study tests and procedures, to those listed below. This study data may be processed and transmitted using secure computer systems. In all disclosures outside of Penn Medicine, you will not be identified by name, medical record number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. In records and information disclosed outside of Penn Medicine, you will be assigned a unique code number.

Your original medical records also may be reviewed by the sponsor of this study or its designated representatives, the Institutional Review Board overseeing this study, and any of the regulatory or safety oversight organizations outlined below. They may review these records for the purpose of checking data collected for the study, to make sure the study is being done properly, and to analyze the results of the study.

Individuals or organizations responsible for administering the study:

- The University of Pennsylvania (the sponsor of this study) and their designated representatives are responsible for administering the study.

Regulatory and safety oversight organizations:

- The U.S. Food and Drug Administration (FDA)
- Other regulatory agencies and/or their designated representatives, including international agencies
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law

Once your personal health information is disclosed to others outside of Penn Medicine, it may no longer be covered by United States federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. If you sign this form, we will collect your health information until the end of the research study. We may collect some information from your medical records even after you finish taking part in this study or after your death. We will keep all of the information forever in case we need to look at it again. We will protect this information and keep it confidential.

Your information may be held in a research database. However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- Penn Medicine's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

The data from this study may be published or used for teaching purposes, however you will not be personally identified in any publication. Your identity will remain confidential unless disclosure is required by law.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the Penn Medicine and the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Can I change my mind?

You have the right to withdraw your permission for the use of your personal health information, but if you do so, you must stop taking part in this study. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study and no new information will be collected. However, even if you do withdraw your permission to use the data about you, we are required by the FDA to record anything that relates to the safety of the investigational drug under study.

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18 ELECTRONIC MEDICAL RECORD AND RELEASE OF STUDY RELATED INFORMATION

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

You have the right to see and get a copy of your medical records kept by the University of Pennsylvania. However, you will not be able to review or receive some of your records related to the study until after the entire study has been completed. When the study is over, you may write to the study doctor to ask to see or copy all of your medical information that was collected during the study. You also have the right to say

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how your medical information may be used, and to have any incorrect data about yourself updated or corrected.

19 WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE TO THE PUBLIC?

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

20 WHO CAN I CALL WITH QUESTIONS, COMPLAINTS OR IF I'M CONCERNED ABOUT MY RIGHTS AS A RESEARCH SUBJECT?

If you have questions, concerns or complaints regarding your participation in this research study you should speak with the Principal Investigator listed on page one of this form. If you have any questions about your rights as a research subject, you may contact the Office of Regulatory Affairs at Penn Medicine with any questions, concerns or complaints by calling (215) 898-2614.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). You may also visit the NCI website at http://cancer.gov/. For NCI's clinical trials information, go to http://cancer.gov/clinicaltrials/. For NCI's general information about cancer, go to http://cancer.gov/cancerinfo.

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When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, the study has been explained to you, your questions have been answered, you have had time to make your decision, and you have decided to volunteer to participate. You have been given the names of study staff that you can contact if you need assistance or if you have any additional questions or concerns. You agree to follow all of the instructions of your study doctor to the best of your ability, and report any changes in your health that may occur during the study.

Your signature also means that you are permitting Penn Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the Penn Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

You agree that your primary care physician can be informed about your participation in this clinical trial.

A copy of this signed and dated consent form will be given to you.

_____	_____	_____
Name of Subject (Print)	Signature of Subject	Date
_____	_____	_____
Name of Person Obtaining Authorization (Print)	Signature of Person Obtaining Authorization	Date

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