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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CC# 16201: Pharmacodynamic Effects and Predictive Biomarkers of JAK/STAT Inhibition with Ruxolitinib in Operable Head and Neck Cancer: a window trial

This is a clinical trial, a type of research study. Your study doctor, William Ryan, M.D. from the UCSF Department of Otolaryngology Head and Neck Surgery will explain the clinical trial to you.

Clinical trials include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have stage I-IVa Head and Neck Squamous Cell Carcinoma (HNSCC) and plan to have surgery. If you consent to join this study and are eligible, you will receive the investigational drug ruxolitinib during the period of time between your diagnostic biopsy (if you do not have leftover tissue from a previous biopsy or surgery) and surgery.

Why is this study being done?

The purpose of this study is to find out if ruxolitinib shrinks tumors in patients with HNSCC, by analyzing biomarkers in blood and tumor samples. Biomarkers are markers in blood and tissue that can be used to evaluate your disease and find out how your cancer cells are responding to the study drug.

Ruxolitinib works to block the activation of a protein related to tumor growth and therapy resistance in patients with HNSCC. Ruxolitinib is approved by the United States Food and Drug Administration (FDA) for the treatment of myelofibrosis but not for head and neck cancer. Therefore, ruxolitinib is being used in this study as an investigational drug.

Incyte, the manufacturer of ruxolitinib, is supplying ruxolitinib for use in this study and providing money to the UCSF Helen Diller Family Comprehensive Cancer Center to perform this study.

How many people will take part in this study?

A total of 23 people will participate in this study. We plan to enroll 18 patients at UCSF. Five patients were enrolled at the University of Arizona.

What will happen if I take part in this research study?

Before you begin the main part of the study...

You will need to have the following tests and procedures to find out if you can be in the main part of the study. Some of these tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

Within 12 weeks of receiving study drug:

- EKG (electrocardiogram) – An EKG records the electrical activity of your heart. 12 wires or "leads" will be attached to your chest with an adhesive and you will be asked to lie still while the machine prints out an electrical "record" of your heart activity. This takes about 15-30 minutes (within 12 weeks of receiving study drug).

Within 8 weeks of receiving study drug:

- History and physical examination (within 8 weeks of receiving study drug):
  - Medical history review – You will be asked about your health, any current and past illnesses.
  - Physical examination, to include medical evaluation and surgical evaluation of your tumor.
- Vital signs - Your heart rate, breathing rate, blood pressure, and body temperature, height, and weight will be recorded.
- Performance Status You will be asked about your general health, how you have been feeling, and about your daily activities.

Within 4 weeks of receiving study drug:

- Blood drawing (approximately 5 tablespoons) - A blood sample will be taken by inserting a needle into a vein in your arm for:
  - Routine safety tests
  - Liver function tests
  - Clotting tests

- Pregnancy testing– If you are a woman of childbearing potential you will have a urine or blood pregnancy test. An additional negative pregnancy test must also be obtained within 72 hours of receiving study drug.

- CT, PET-CT scan *or* MRI of the neck - An MRI may be done instead of a CT/PET-CT if you are allergic to the dye injection used for CT scans.
  - CT scan: A CT (computed tomography) scan uses special x-ray equipment to make detailed pictures of body tissues and organs. For the CT scan, you may be given a "contrast material" (a special dye that makes it easier for doctors to see different tissues in your body). The contrast material may be given orally, intravenously, or rectally (less likely). Oral contrast material is given to you to drink and is used to help outline the stomach and intestines. Intravenous (IV) contrast material is given to you by injecting the contrast material into a line, which is attached to a needle in your arm, and is used to get clearer pictures of

your body. A rectal contrast fills up the loops of your lower bowel so the doctors can see your tumor better. After you have been given the contrast material, you will lie flat on a table that will move you into the CT scan machine. You will be asked to lie still and may be asked to hold your breath for a few seconds. The CT scan is done in the radiology department and takes about half an hour.

- PET-CT scan: A PET (Positron Emission Tomography)-CT scan is a special type of test to show how the organs and cells work in your body and is done to show activity of the cells in your tumor. You will be asked to not eat for six hours prior to the scan and to drink at least two large glasses of water within one hour of the study. Your PET scan will begin with an injection of a radioactive substance into a vein in your arm. You will be asked to rest quietly for a period of time (usually about 20 to 40 minutes) as the radioactive substance circulates throughout your body. After this time, you will be positioned within a large ring (similar to a big donut hole) on a scanning bed. Once positioned properly, the bed will move you into the scanner. As pictures are being taken, you will be asked to remain very still so clear images will be taken. The imaging time takes about one hour.

- MRI: An MRI (Magnetic Resonance Imaging) exam takes an image of your head and neck to observe the location and size of your tumor. For the MRI scan, you may be given a "contrast material" (a special dye that makes it easier for doctors to see different tissues in your body). Gadolinium is contrast material that causes some tumors to appear much brighter than normal tissue on MRI scans (these tumors may not be visible without gadolinium). The contrast material may be given to you in your arm through an intravenous catheter (a tiny tube inserted into a vein). You will then lie down on a narrow bed, which will be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will lie there quietly for about one hour, during which time you will hear a loud machine-like noise. The MRI scan is done in the radiology department and takes approximately an hour and a half to complete.

- The researchers will obtain blood and tissue samples to look at the biomarkers in your samples before receiving study drugs. These results will be compared to the biomarkers in blood and tissue samples obtained after you receive study drug, to see if the biomarkers in your samples changed after the study drug was given.

  - BLOOD DRAWING (5 tablespoons): The sample will be tested for biomarkers.
  - TISSUE BIOPSY:
    - If leftover tissue can be obtained from a previous biopsy or surgery that was performed, you will not need to have a biopsy done.
    - If leftover tissue from a prior biopsy or surgery is not available, either an incisional/core biopsy (surgical procedure) or a fine needle aspiration (FNA) biopsy will be performed. The type of biopsy will be at the discretion of the study doctor and typically depends on the location of your tumor.
    - As part of this study, we will obtain a small piece of tumor tissue using a special needle. This procedure will be done at the site where we can most easily get a piece of the tumor and the biopsy can involve the lungs, liver,

bone, lymph node, skin or other. The biopsy needle will be inserted into tumor tissue and a small piece of the tumor will be removed. 1-3 passes with this needle will be made. The tissue biopsy is used to confirm your diagnosis and make sure you are eligible to be in this research study. The tissue is also being used to help us determine if certain types of tumors might respond better to certain treatments. This procedure takes about 30 minutes. You will sign a separate consent form for this procedure.

- INCISIONAL BIOPSY/CORE BIOPSY (surgical procedure): The doctor will use a local anesthesia on the skin to numb the area where a hollow needle (about the size of the tip of a ball-point pen) will be inserted. Then the doctor will make a cut through the skin into the area of the tumor. If a "punch biopsy" is done, a rounded knife is used to cut the through the skin. The doctor will then remove a piece of the tumor by inserting the hollow needle one or more times into the tumor. The doctor will then close the area of the biopsy with stitches. You will sign a separate consent form for this procedure. This will take 15-30 minutes.
- FINE NEEDLE ASPIRATION (FNA): This is a special type of biopsy. The doctor will insert a fine (very thin) needle through your skin and into your tumor and will remove a very small sample (less than ½ a teaspoon) of your tumor. Either an ultrasound or CT scan will be used to guide the placement of the needle. You will sign a separate consent form for this procedure. This procedure will take about 15-30 minutes.

During the main part of the study...

If the tests and procedures show that you can be in the main part of the study, and you choose to take part, then you will be given ruxolitinib and undergo the following tests and procedures.

<u>Ruxolitinib</u>

Ruxolitinib will be taken by mouth every morning and every evening, with or without food, for 14 to 21 days before your surgery. You will stop taking ruxolitinib after the morning dose on the day of your planned surgery. If there are logistical/scheduling issues that delay surgery, ruxolitinib may be taken for up to 28 days.

- You will take 4 tablets in the morning and 4 tablets in the evening or 3 tablets in the morning and 3 tablets in the evening. Each tablet is 5mg so you will either take a total of 40 mg or 30 mg daily. The amount you take will be based on the results of clotting tests performed on your blood samples.

- If you are not able to swallow the study tablets, ruxolitinib can be administered through a nasogastric or percutaneous gastrostomy tube (feeding tube) as follows:
    - Place three or four tablets, depending on the dosage amount you are assigned to take, in approximately 3 tablespoons of water and stir for approximately 10 minutes.
    - Within 6 hours after the tablets have dissolved, it can then be administered through the feeding tube.

- The tube should then be rinsed with approximately 5 tablespoons of water.

- If you miss a dose or happen to vomit, do not take an additional dose, but take the next scheduled prescribed dose.

- You will keep a drug diary to record the doses of study drug taken and return all unused study drug to the study doctor

- While taking the study drug you should avoid grapefruit, grapefruit juice, starfruit and Seville oranges because these can affect the amount of drug in your blood.

Pre-surgery (within 5 days of planned surgery):

- History and physical examination
- Repeat CT, PET-CT, or MRI scan for tumor measurements. This scan will be the same type that was done before you began the study drug.
- Blood drawing (5 tablespoons):
  - Routine safety tests
  - Liver function tests
  - Clotting tests
  - Biomarker tests

When you are finished receiving ruxolitinib…

Day of Surgery:

- Tissue samples will be collected at the time of your planned surgery for biomarker studies. The doctor performing the surgery or pathologist reviewing your specimens may set aside any leftover tumor material soon after it has been removed from your body. Your scheduled surgery will not be affected in any way by the collection of left-over tissue samples for research because the tissue collected for this research study will be obtained after your tumor tissue has already been removed from your body. The additional samples will not be collected if we think it will affect the sample needed for your clinical care.

Four Weeks after Surgery Visit:
You will return 4 weeks after your surgery for standard of care exams/procedures. The information collected from this visit will be used as part of the study data.

- History and physical examination
- Vital signs and weight
- Performance Status
- Blood draw (5 tablespoons):
  - Routine safety tests
  - Liver function tests

Final Study Visit:
You will return 12 weeks after your surgery for standard of care exams/procedures listed below. The information collected from this visit will be used as part of the study data.

- History and physical examination
- Vital signs and weight

- Performance Status
- Blood draw (5 tablespoons):
    - Routine safety tests
    - Liver function tests

Study Location: All study procedures will be done at the University of California, San Francisco.

How long will I be in the study?

You will be asked to take Ruxolitinib for 14-21 days prior to surgery. After you are finished taking Ruxolitinib, the study doctor will ask you to visit the office for follow-up exams for at least 4 weeks after surgery and 12 weeks after surgery for routine standard of care exams/procedures.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the Ruxolitinib 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.

The study doctor may stop you from taking part in this study at any time if he believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking ruxolitinib. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to ruxolitinib:

Ruxolitinib is indicated for the treatment of myelofibrosis (MF). Therefore, most of the studies measuring the safety of ruxolitinib were conducted with patients with MF. Patients with diseases other than MF (including healthy volunteers, polycythemia vera, multiple myeloma, prostate cancer and rheumatoid arthritis) who received ruxolitinib have had similar side effects. These side effects are more common in patients with myelodysplastic syndrome who received prolonged treatment with ruxolitinib. These side effects and risks are less common in patients treated for less time and for a different indication.

The most frequently reported side effects in patients with MF who have been treated with ruxolitinib are:

Likely (observed in greater than 30% of patients)
- Anemia (low red blood cells)
- Thrombocytopenia (low platelets)

Less Likely (observed in 10-30% of patients)
- Raised ALT (blood proteins that may indicate mild liver damage)
- Bruising
- Raised AST (blood proteins that may indicate mild liver damage)
- Hypercholesterolemia (increase in cholesterol)
- Neutropenia (low white blood cells)
- Dizziness
- Headache
- Urinary tract infections

Rare (observed in less than 10% of patients)
- Weight gain
- Flatulence
- Herpes zoster (shingles)
- Tuberculosis (<1%) – bacterial infection of the lungs
- Progressive multifocal leukoencephalopathy (PML)(<1%) – a viral disease characterized by progressive damage or inflammation of the brain

Risks and side effects related to study procedures:

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

- **Electrocardiogram (EKG) risks:** The EKG involves placing electrodes on the skin. You may experience an allergic reaction to the adhesive used to attach the electrodes to the skin. These symptoms are generally mild and clear up on their own. Please let your doctor know if you are aware of any allergies.

- **Radiation risks:** This research study involves exposure to radiation from CT or PET/CT scans. Not all this radiation exposure is necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately 12 mSv, which is equivalent to 4 times the yearly natural background of radiation in the US, which is 3 mSv (a mSv, or millisievert, is a measurement of radiation). In the event there is no tumor tissue available for analysis and tumor localization must be guided by CT, the additional radiation exposure would be a maximum of 14 mSv. In this case, the total radiation dose could be as high as 26 mSv, equivalent to slightly less than 9 times the yearly natural background. This amount of radiation may involve a low risk of cancer. If you are pregnant or breast feeding, you

SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

- **CT scan risks:** CT scans involve the risks of radiation (see above). In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, from mild (itching, rash) to severe (difficulty breathing, shock, or rarely, death). The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may not be allowed to have a CT scan.

  Having a CT scan may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in one position for a long time. If contrast material is used, you may feel discomfort when it is injected. You may feel warm and flushed and get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache.

- **PET/CT scan risks:** The PET/CT involves exposure to radiation. The radiation exposure comes from a tracer which is a radioactive chemical injected into a vein in your arm. The tracer lets the doctor see how your cells are functioning. As with all injections, it may feel like a small sting and there may be possible bruising at the injection site. For some patients, having to lie still on the scanning table for the length of the procedure may cause some discomfort or pain. The radioactive solution does not remain in your system for a long period of time. See Radiation Risk.

- **MRI risks:** Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which in the process could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI. Having an MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.

  Because the risks to a fetus from MRI are unknown, pregnant women must not participate in this study.

- **Contrast agent (gadolinium) risks**: A few side effects of gadolinium injection such as mild headache, nausea, and local pain may occur. Rarely (less than 1% of the time) low blood pressure and lightheadedness occurs. This can be treated immediately with intravenous fluids. Very rarely (less than on in one thousand), patients are allergic to gadolinium. These effects are most commonly hives and itchy eyes, but more severe reactions have been seen which result in shortness of breath.

Patients with severe kidney disease sometimes have a bad reaction to gadolinium contrast. The condition is called nephrogenic systemic fibrosis (NSF). It can cause skin to tighten or scar and can damage internal organs. Sometimes it can be life threatening. There are no reports of NSF in patients with normal kidney function. Before you have a MRI scan requiring an injection of gadolinium contrast, you will have a blood test in order to check the function of your kidneys. Based on your medical history and the results of the test, a doctor will decide whether it is safe for you to undergo the MRI scans.

- **Drug Interaction Risks:** Ruxolitinib taken in combination with other medicines may be associated with other risks that are unknown at this time. Although there is limited information on how ruxolitinib might interact with other medications, it is important to share with your study doctor any medications (prescription, over-the-counter, and herbal supplements) that you are taking.

- **Reproductive risks:** You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important to understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. A pregnancy test will be required prior to starting the study.

- **Tumor Biopsy:** The biopsy has small but serious risks. While we make every effort to minimize the pain related to the procedure, the procedure is usually uncomfortable and sometimes painful. Wherever the biopsy is done in your body, it can lead to bleeding in that area, damage of organs near where the biopsy is done, or infection. While it is uncommon, sometimes bleeding or pain from the biopsy will require you to stay overnight in the hospital or require you to go to the operating room to control any bleeding. We check your laboratory values before the biopsy to make sure that the procedure is as safe as possible and to minimize your chance of having a complication. Additionally, if the biopsy involves the lungs, it can cause the lungs to deflate and if this occurs, you might require treatment to correct this. We try to take as little tissue as possible when we do the biopsy, and this means that sometimes the biopsy procedure can be unsuccessful and require a repeat biopsy to get enough tissue. Other potential risks will be described to you and discussed with you by doctors who conduct these biopsies.

- **Fine Needle Aspiration (FNA):** The general risks associated with this procedure are pain, discomfort, infection, and bleeding. If it is necessary for you to have a biopsy, the exact risks associated with the procedure you will be receiving will be discussed with you.

- **Safe Handling of Medications:** Handling ruxolitinib and having contact with any urine, feces or vomit from patients receiving ruxolitinib may pose some risk to you and your caregivers. To avoid exposure to ruxolitinib and any associated risks, you and your family members/caregivers will be educated by a member of the study team on how to safely handle ruxolitinib, properly dispose of ruxolitinib, and how to clean products that may be contaminated with ruxolitinib.

- **Genetic Testing Confidentiality Risks:** There is a risk someone could get access to the personal information in your medical records or other information researchers have kept

about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

- **Unknown Risks:** The experimental study drug may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope Ruxolitinib will be more useful against cancer compared to the usual treatment, there is no proof of this. We do know that the information from this study will help doctors learn more about Ruxolitinib as a treatment for cancer. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study.
- Taking part in another study.
- Getting no treatment.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will my specimens and information be used?

Researchers will use your blood and tissue specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other cancer studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share the de-identified information and specimens.

Your blood and tissue specimens will be stored in a repository, also called a ‘tissue bank’, at UCSF. The manager of tissue bank and select tissue bank staff members will have access to your specimens and information about you, but they will not release any identifying information about you to researchers using your specimens. We may give your specimens and certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to an unrestricted or controlled-access government health research database, but we will not give them your name, address, phone

number, or any other identifiable information. Your specimens and information will be kept indefinitely until they are used up or destroyed.

Research results from these studies will not be returned to you and will not be put in your medical record. The research will not change the care you receive.

Researchers may use your blood and tissue specimens to look at all of your DNA (this is called "whole genome sequencing". DNA contains information that determines things like eye color, height, or disease risk that are passed on from parent to child. Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis.

Donating data and specimens may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

There will be no direct benefit to you from allowing your specimens and data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. If your specimens, the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing at,

William Ryan, MD
University of California, San Francisco
[redacted]

and any remaining data will be destroyed. However, we cannot retract any data has been shared with other researchers.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with

your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. 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.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- Incyte pharmaceuticals
- The National Cancer Institute (NCI) and other government agencies, e.g., the Food and Drug Administration (FDA), involved in keeping research safe for people.

What are the costs of taking part in this study?

Incyte is supplying ruxolitinib at no cost to you.

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. Any procedures done only for research will not be charged to you or your insurer. There is a possibility that your insurer may not cover standard medical care costs because you are in a research study or because you are receiving medical services out of network.

Before you agree to be in this study, you may want to contact your healthcare payer/insurer to see if your plan will cover the costs required as part of your participation. You may request more information about the costs of participating in this study and discuss this with the study team.

If you have any questions, your doctor and the study team will be able to provide you with answers.

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

Another way to get the information is to call **1-800-4-CANCER (1-800-422-6237)** and ask them to send you a free copy.

Will I be paid for taking part in this study?

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

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. William Ryan, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him [redacted].

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs or covered by the University of California or the study sponsor Incyte, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Dr. William Ryan, at [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent
Date	Witness – Only required if the participant is a non-English speaker