Phase 2 Window of Opportunity Study of IPI-549 in Patients with Locally Advanced HPV+ and HPV- Head and Neck Squamous Cell Carcinoma

NCT03795610

Document Date: 05/2023

University of California, San Diego
Consent to Act as a Research Subject

Phase 2 Window of Opportunity Study of IPI-549 in Patients with Locally Advanced HPV+ and HPV- Head and Neck Squamous Cell Carcinoma
(UCSD IIT 172058)

Assuntina Sacco, M.D. and her colleagues are conducting a research study sponsored by UC San Diego to find out more about the experimental drug called IPI-549. You are being asked to take part because you have locally advanced human papillomavirus positive (HPV+) or human papillomavirus negative (HPV-) head and neck squamous cell carcinoma and are a candidate for surgical removal of your tumor.

Your participation in this research study is voluntary. The purpose of this Informed Consent Form is to inform you about the nature of this research study so that you may make an informed decision as to whether you would like to participate. If you have any questions, please ask your study doctor or coordinator to explain any words or information that you do not understand.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to investigate how effective the drug IPI-549 is against the type of cancer that you have.

IPI-549 is considered experimental because it is not approved by the US Food and Drug Administration (FDA) for the treatment of cancer.

Participation in this study is entirely voluntary. A total of 28 participants will be enrolled at the University of California San Diego.

DURATION OF THE STUDY / HOW LONG IS EACH VISIT?

The study will involve a screening period (up to 28 days), a period where you will be required to take your study drug (14 days), and a safety follow up visit at approximately 30 days after your last dose of study drug.

Each of your study visits can last from approximately one to 7 hours.

WHAT ARE MY OBLIGATIONS IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study, you must be willing to do the following:

- Take IPI-549 by mouth (for a minimum of 14 days, you will continue taking IPI-549 until 24 hours before surgery) as long as you are on the study
- Attend the scheduled visits
- Tell the study staff about any other medicines that you are taking
- Tell the study staff about any side effects of the drugs
- You must return all unused IPI-549 supplies (the study drug) to the study doctor.
- Undergo tumor biopsy procedure at screening.

PROCEDURES

Screening Procedures

The Screening Visit (Visit #1) may take between 2 and 8 hours to complete and the procedures may be scheduled over multiple days. Some of these may be part of your regular medical 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. Your study doctor will talk to you about these tests.

- You will be asked about your medical history, including previous cancer therapies.
- You will be asked for your demographic information (initials, address, age, sex, race, and ethnicity).
- You will be given a physical exam and your weight, height and vital signs will be measured (your heart rate, blood pressure, and temperature). Measurements of you lymph nodes, spleen and liver will also be made.
- You will be asked about any medications you are taking or have taken in the past.
- You will be asked questions about your health and how your disease affects your daily life.
- An ECG will be taken (electrical tracing of the heartbeat or heart rhythm to see if your heart is functioning properly): During this procedure, you will be asked to lie down, and electrodes are affixed to each arm and leg and to your chest. This requires cleaning the site and, if necessary, shaving or clipping hair. You are usually required to remain still, and you may be asked to hold your breath for short periods during the procedure.
- Samples of your blood (approximately 2-3 tablespoons) will be drawn for laboratory tests:
    - Hematology or CBC (Complete Blood Count), which includes: white blood cell count, red blood cell count, platelet count, hemoglobin (oxygen-carrying pigment in red blood cells), hematocrit (measures the amount of space red blood cells take up in the blood). This is to aid in diagnosing anemia (low red blood cell count which

can result in fatigue), certain cancers of the blood, and to monitor blood loss and infection.

- Blood chemistry (which measures the levels of a number of chemical substances that are released from various tissues in the body to evaluate the function of the liver and kidneys).
- Hepatitis screening: You will be informed of the results of the tests. The results of the tests, if positive, will be reported to the county health department and entered in your medical record. Your study doctor will discuss this with you.
- Your blood may also be tested for the viruses Human Immunodeficiency Virus (HIV), Hepatitis B, and Hepatitis C to make sure that the study procedures are appropriate for you. You will be informed of the results of the tests. The results of the tests, if positive, will be reported to the San Diego County health department and entered in your medical record. Your study doctor will discuss this with you. If you tested positive for any of these viruses you cannot participate in this study.

- An extra sample of your blood (about 3 tablespoons) will be collected to measure biomarkers for research purposes. Biomarkers are biological molecules found in blood, other body fluids, or tissues which might indicate a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. Additional details of this extra blood collection are described after the study procedures below ('Biological Samples for Research').
- A pregnancy test (urine) will be performed if you are a woman of child-bearing potential. Pregnant women cannot be on the study.
- You will have a CT or MRI scan of your neck and chest to measure your disease.
  - CT scan: The CT (computed tomography) scanner is a free-standing machine with a large hole in the center. You will be asked to lie on your back with your arms raised above your head on a narrow table that slides into the hole. Participants who have difficulty with enclosed spaces such as those found with some MRI scanners do not usually have a problem with this type of test. A dye may be injected into a peripheral vein to better evaluate certain diseases and organs. The radiologist will decide if this is necessary. Tell the technician or radiologist if you have any allergies or have had difficulty with prior CT scans. It is very important that you remain still throughout the exam and hold your breath when asked. This will allow for better images. The actual scan time is usually about two minutes, although the entire procedure usually takes much longer.

    Risks of CT Scans: The CT involves exposure to radiation. In addition, the imager makes buzzing and whirling noise while it is taking pictures. The subject will be given a set of ear plugs to help with the noise. The subject may experience feelings

of claustrophobia or anxiety. He/she may also experience some discomfort and tiredness from lying still in a confined space during the imaging. For some people, having to lie still on the scanning table for the length of the procedure may cause some discomfort or pain.

- MRI: Magnetic Resonance Imaging (MRI) may be done instead of a CT scan. MRI uses magnetism instead of x-rays to build up a picture of the body. The scan is completely painless, but can be rather noisy and you have to lie very still inside the center of a large, doughnut-shaped magnet for approximately 30-60 minutes to get a good picture. If you have a pacemaker or other metal implants, the staff needs to know as the scan uses magnets.

- Tumor Tissue Collection: During your participation in this study you will be asked to undergo a tumor biopsy. A biopsy is a procedure where a sample of your tumor is removed. It will be a core biopsy that collects a small piece of tissue. You may need a general anesthetic (be asleep for the procedure) or a local anesthetic (have only the area of the biopsy numbed by injection) depending on the location of your cancer. There may be some temporary pain or discomfort associated with this routine procedure. The biopsy is helpful in describing your cancer before receiving the study drug, which allows researchers to determine whether a response during the study could have been predicted.

- An extra sample of your tumor tissue will be collected to measure biomarkers for research purposes. Additional details of this extra tissue collection are described after the study procedures below ('Biological Samples for Research').

Study Dosing Period

<u>Study treatment with IPI-549 (14 days prior to surgical resection)</u>

Day 1:
This visit should include collection of side effects/serious side effects and you will be asked about any medications you are taking.

You will be given the study drug and a drug diary and given instructions on how to fill it out and how to take your medication.

You will be instructed to take IPI-549 orally over a 14 day cycle starting on the day of this study visit.

You will be given IPI-549 and are expected to take it orally approximately every 24 hours. You should swallow IPI-549 whole with a glass of water (approximately 8 ounces or 240 mL). You must avoid grapefruit and grapefruit juice while on study drug. You are also advised to avoid food

and liquids other than water from 2 hours prior to dosing until 1 hour after dosing.
Your last dose of study drug should be taken within 24 hours of surgery

Samples of your blood (approximately 2-3 tablespoons) will be drawn for laboratory tests:

- Hematology or CBC (Complete Blood Count), which includes: white blood cell count, red blood cell count, platelet count, hemoglobin (oxygen-carrying pigment in red blood cells), hematocrit (measures the amount of space red blood cells take up in the blood). This is to aid in diagnosing anemia (low red blood cell count which can result in fatigue), certain cancers of the blood, and to monitor blood loss and infection.
- Blood chemistry (which measures the levels of a number of chemical substances that are released from various tissues in the body to evaluate the function of the liver and kidneys).

Pre surgery- Day 14 of study drug

This study visit will take place on day 14 of taking your study drug and prior to your surgery.

- You will be given a physical exam and your weight, height, and vital signs will be measured (your heart rate, blood pressure, and temperature). Measurements of you lymph nodes, spleen, and liver will also be made.
- You will be asked about any medications you are taking or have taken in the past and we will collect your side effects/serious side effects
- You will be asked questions about your health and how your disease affects your daily life.
- Samples of your blood (approximately 2-3 tablespoons) will be drawn for laboratory tests:
  - Hematology or CBC (Complete Blood Count), which includes: white blood cell count, red blood cell count, platelet count, hemoglobin (oxygen-carrying pigment in red blood cells), hematocrit (measures the amount of space red blood cells take up in the blood). This is to aid in diagnosing anemia (low red blood cell count which can result in fatigue), certain cancers of the blood, and to monitor blood loss and infection.
  - Blood chemistry (which measures the levels of a number of chemical substances that are released from various tissues in the body to evaluate the function of the liver and kidneys).
- An extra sample of your blood (approximately 1-2 tablespoons) will be collected to measure biomarkers for research purposes. Additional details of this extra blood collection are described after the study procedures below ('Biological Samples for Research').
- Tumor Tissue Collection. A tumor biopsy is a procedure where a sample of your tumor is

removed. A sample of your tumor tissue will be collected during surgery. The biopsy is helpful in describing your cancer after receiving the study drug, which allows researchers to determine whether a response occurred during the study

Follow up

You will have a safety follow up visit at approximately 30 days after the last dose of study drug. This visit will include collection of side effects, questions about any medications that you are taking, and about your health and how your disease affects your daily life, a physical exam, vital signs and height, lab tests (CBC and the complete metabolic panel), and MRI or CT scan if your study doctor needs you to.

Biological Samples

As described in the study procedures above, blood (approximately 2-3 tablespoons) and tissue samples will be collected from you throughout the study.

One blood and one tissue sample will be collected at the screening visit. Another blood sample will be collected at the pre-surgery visit (day 14 of taking the study drug), and tissue sample will be collected during your surgery.

The blood and tissue tests for research will examine the effect the study drug has on your body.

Study biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them. Your study doctor has no personal or financial interest in this research.

If you decide later that you do not want the specimens collected from you to be used for future research, you may tell this to Dr. Assuntina Sacco, who will use her best efforts to stop any additional studies. However, in some cases, such as if your samples have already been tested, the data from these tests are no longer linked to your identity and cannot be removed from the research database

Dr. Assuntina Sacco, her associates, or her successors in these studies will keep your DNA specimen and/or the information derived from it indefinitely.

There will be no direct benefit to you from this study since you will not be provided with any results or information regarding your DNA test. The investigator, however, may learn more about head and neck squamous cell carcinoma.

Federal and State laws generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

a) Health insurance companies and group health plans may not request your genetic information that we get from this research.

b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

c) Employers with 5 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

RISKS OF PARTICIPATION

Participation in this study may involve some added risks or discomforts. While you are on this study, you are at risk for the side effects listed below. You should discuss these with your study doctor. There may also be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the study drug is stopped, but in some cases, side effects may be serious, long-lasting, and may even cause death.

Risks associated with IPI-549:
The following side effects have been observed in people who received IPI-549.

Cardiac (relating to your heart)
An increase in heart rate (An increased heart rate can result in dizziness or shortness of breath. During your clinic visits your heart rate will be checked.)

Blood and lymphatic system disorders:
Anemia (low red blood cell count which can result in fatigue)
White blood cell count decreased (decreased cells that fight infection, which could result in lower ability to fight certain infections)

Gastrointestinal Disorders:
Diarrhea
Nausea
Vomiting
Abdominal pain

Bleeding into the stomach or intestine (gastrointestinal bleed) was observed in studies conducted in animals. This could result in black tarry stools or blood in the stool.

General disorders and administration site conditions:
Feeing very tired – fatigue
Fever
Local swelling

Metabolism and nutrition Disorders:
Hypomagnesaemia. Hypomagnesaemia is an electrolyte disturbance in which there is a low level of magnesium in the blood. Deficiency of magnesium can cause tiredness, generalized weakness, muscle cramps, abnormal heart rhythms, and increased irritability of the nervous system with tremors.

Nervous system disorders:
Headaches

Vascular disorders
Hypertension – high blood pressure

Skin and subcutaneous tissue disorders:
Rash
Itchiness
Maculopapular rash (which is a type of rash that is a flat, red area on the skin that is covered with small bumps. It may only appear red in lighter-skinned people)
The effect of IPI-549 on the skin, specifically when in direct sunlight or with artificial ultraviolet (UV) light (e.g., in tanning booths) is not known. (As a general precaution, it is advised to use appropriate protective measures to minimize exposure to direct sunlight or artificial UV light during the treatment period and for at least 30 days after the last dose of IPI-549.)

Liver Problems:
Increased liver enzymes (may indicate damage to the liver)
Blood bilirubin increased (liver problems which may cause yellowing of the skin)

Respiratory, thoracic and mediastinal disorders:
Shortness of breath
Pleuritic pain

Additional Risks and Discomforts Associated with Study Procedures

There may be other risks associated with participation in this study that are currently unforeseeable.

Risk of Testing for HIV or Hepatitis
Participation in this study will require that you be tested for HIV and/or hepatitis. These tests are necessary to make sure that these study procedures would be appropriate for you. Testing for HIV or hepatitis may result in a diagnosis of infection with this virus. You will be informed of the results of these tests; if you do not wish to know the results, you should refuse to participate in this study. In the event that you are diagnosed with HIV or hepatitis, your regular doctor will give you the results in a face-to-face discussion (not by telephone or mail), counseling will be offered to you, and the results will be entered in your medical record and provided to the California State Board of Health as required by law. In the event that you are diagnosed with HIV or hepatitis, you may be referred to a doctor who specializes in these illnesses. The diagnosis of HIV may result in earlier treatment and/or prevention of many complications from the illnesses. Efforts will be made to keep your personal information confidential. Awareness of a diagnosis of these illnesses may have serious personal or social consequences. Some of these consequences include possible difficulty obtaining health insurance or employment, and difficulty traveling to some foreign countries.

***Allergic Reactions*:** As with any drug, there is the chance of an allergic reaction, which may include difficulty breathing, rash, flushing, weakness, dizziness, lightheadedness, and swelling.

Risks of blood draws: There is a risk of discomfort or pain, bleeding, swelling and a small arm bruise and swelling when blood is drawn. Rarely, a clot or infection may occur at the site of the blood draw. Some people also become faint, dizzy, or light-headed during or immediately after the blood draw.

***Risks of ECG*:** Up to 12 self-adhesive electrodes (small blunt pieces of metal) will be attached to your skin on your arms, legs and chest. The areas where the electrodes will be placed will be cleaned; some areas may need to be shaved. Some skin irritation can occur where the electrodes are placed. Once the electrodes are placed, the test will begin. The test is completely painless and takes less than a minute to perform. After the test, the electrodes are removed.

***Risks of tumor biopsy*:** Pain, bleeding and infection at the biopsy site may occur. In rare cases, more severe bleeding may occur inside your body that may require hospitalization, surgery and blood transfusions or may result in death. It is very rare, but you may have an allergic reaction to the numbing medication, which may include difficulty breathing, rash, flushing, low blood pressure and swelling. Additionally, there is a moderate risk of nerve injury and local paralysis (complete loss of muscle function, which may or may not be permanent) or numbness if the biopsy is done on a lymph node close to nerves. Your study doctor will further explain the risks involved with a biopsy.

Reproductive Risks: You should not become pregnant or father a baby while on this study because the drugs in this study can affect a fetus and cause serious birth defects. Women should not breastfeed a baby while on this study. Some of the drugs used in this study may make you unable

to have children in the future. It is important you understand that you need to use birth control while on this study. If you are female and capable of child-bearing, a pregnancy test will be done before the study begins in order to be as sure as possible that you are not pregnant. Your participation requires that you use contraception methods (such as (e.g., condoms, implants, injectables, combined oral contraceptives, intrauterine devices, sexual abstinence, or sterilized partner) to prevent pregnancy for the duration of the study and through 120 days after the last dose of study medication. Ask about counseling and more information about preventing pregnancy.

Risks from X-rays and/or Scans: During your participation in this research study, you will be exposed to radiation from scheduled x-rays and/or imaging scans. The total exposure resulting from these imaging studies is calculated to be approximately 7.9 mSv. This amount is *more* than you would receive from one year of natural exposure in the San Diego area, which is approximately 1.6 mSv. Cumulative exposure from radiation may increase your risk of developing certain types of cancer in the future.

The principal investigator for this research study has determined and verified that all of the imaging scans prescribed for this study would typically be performed as part of the standard medical care required to adequately monitor your current illness. Scans are typically done as part of your standard care to assess your disease. Radiation exposure may be decreased if non-radiation imaging alternatives are utilized, such an MRI instead of a CT. If you are especially concerned with radiation exposure, or you have had a lot of x-rays or imaging scans already, you should discuss this with study doctor for this study, Dr. Assuntina Sacco, or your regular doctor.

Risks of MRI Scans: As part of this study, Magnetic Resonance Imaging (MRI) may be done. The imager makes a loud, banging noise while it is taking pictures. You will be given a set of ear plugs to help with the noise. You may experience feelings of claustrophobia or anxiety. You may also experience some discomfort and tiredness from lying still in a confined space during the imaging. There are no known effects from exposure to magnetic fields (MRI). However, some people undergoing this procedure become anxious. If this happens to you, you can stop the procedure at any time. If you have metal clips or plates in your body or a pacemaker, you should tell your study doctor about it. MRI may not be appropriate under some of the following conditions: a cardiac pacemaker; metal fragments in eyes, skin, or body; heart valve replacement; brain clips; venous umbrella; being a sheet-metal worker or welder; aneurysm surgery; intracranial bypass; renal or aortic clips; prosthetic devices such as middle ear, eye, joint, or penile implants; joint replacements; hearing aid; neurostimulator; insulin pump; I.U.D.; being pregnant or trying to become pregnant; shunts/stents; metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; and permanent eyeliner and/or eyebrows.

Risks of IV Contrast: As part of this study a CT scan may be done. There may be some reactions related to the contrast dye used in CT scans. Contrast dye is usually administered when you get a CT scan. Contrast dye may also be used in MRI scans. Some people may develop hives and itching or other allergic symptoms from this dye, swelling of the heart, cramps of the voicebox, breathing

distress caused by narrowing of the airways in lungs, low blood pressure, with loss of consciousness, and in rare cases, severe loss of blood and fluids leading to shock and death, fainting, seizures, and irregular heartbeats. In addition, if you have low kidney function, this dye can temporarily or permanently decrease your kidney function.

Risks of Genetic Testing: Some people involved in genetic studies have felt anxious about the possibility of carrying an altered gene that they could possibly pass on to their children. Even though we will do our best to keep your information confidential, there is the possibility that your genetic risk for certain diseases is accidently divulged to the wrong source, if that happens you might be discriminated against obtaining life or health insurance, employment or ability to adopt children.

Risks of Loss of Confidential Information: There is also a small risk that information from your health records will be released to an unauthorized party. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small. An identification code assigned by the study team to each participant will be used in place of your name to protect your identity when reporting trial-related data.

BENEFITS OF PARTICIPATION

If you agree to take part in this study, there may not be direct medical benefit to you. Other participants in the future, however, may benefit from the information learned from this research study, and the investigators may learn more about IPI-549.

ALTERNATIVES TO PARTICIPATION

If you choose not to take part in or stop participating in this research study, there may be other treatments. Refusal to take part in this study will not cause penalty or loss of benefits to which you are otherwise entitled.

You do not have to participate in this study to receive treatment for your cancer. Other possible treatments include treatment with other drugs or drug combinations, participation in other research studies, or supportive care only (no cancer treatment).

Please talk to your study doctor about these and other options

WHAT ARE THE COSTS/COMPENSATION FOR PARICIPATION?

The study drug, IPI-549, will be supplied at no cost while you take part in this study. The cost of getting the study drug, IPI-549, ready for you is also provided at no cost.

It is possible the study drug, IPI-549, may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of caring for your cancer while in this study, including the costs of your surgery, tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no cost. Before you decide to be in the study, you should check with your health plan/insurance company to find out exactly what they will pay for.

Examples of procedures and drugs that may be billed include the following: blood tests for routine analysis (blood cell count, blood chemistry, and pregnancy tests), physical exams, imaging scans, and other standard tests and procedures used to evaluate your disease.

There will be no payment to you for participating in this study.

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I PARTICIPATED?

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the UC San Diego Office of IRB Administration at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

VOLUNTARY PARTICIPATION

Participation in this study is entirely voluntary. If you choose not to participate or wish to withdraw your consent to participate in these study procedures at any time, it will in no way affect your regular treatments or medical care at this institution or loss of benefits to which you are entitled. Please contact Dr. Assuntina Sacco or a member of her study team, if you wish to withdraw from participation.

You will be informed of any new findings that might affect your willingness to continue participating in the study.

If health conditions occur which would make your participation in this study possibly dangerous, or if other conditions occur that would make participation in this study detrimental to you or your health, then your study doctor may discontinue your participation in this study.

Your study doctor or sponsor may stop your participation in this study at any time without your consent if:

- You become pregnant;

- You cannot follow the instructions given to you;
- You experience an unacceptable side effect;
- Dr. Assuntina Sacco or UCSD decides to end the study.

DO YOU HAVE ANY QUESTIONS?

Dr. Assuntina Sacco and/or _____has explained this study to you, and answered your questions. You may contact Dr. Assuntina Sacco at (858) 822-5800. You may also call the hospital 24-hour paging system at (858) 657-7000 and ask for the oncologist on-call. If you have other questions or research-related problems, you may call the Moores UCSD Cancer Center Clinical Trials Office at (858) 822-5354.

If you have questions about your rights as a research participant, your participation in this study, and/or concerns about this study, you may call the UC San Diego Office of IRB Administration (a group of people who review the research study to protect your rights and welfare) at (858) 246-4777.

A description of this clinical trial will be available on 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.

CONFIDENTIALITY

The confidentiality of your research records will be maintained to the extent allowed by law. This includes using locked filing cabinets and the use of passwords will be required to access your personal data on computers. Access to your information will be limited to study personnel who need to use it for the purpose of the research in this study. Only the minimum necessary information required will be collected, stored, used and reported. Your medical information will not be made publicly available unless disclosure is required by law or regulation.

Data obtained from this study will be given to the sponsor of this study, UCSD, V Foundation, and Infinity Pharmaceuticals, and/or its representatives, and may be published or given to regulatory authorities, including the Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, the UCSD Institutional Review Board, the Moores UCSD Cancer Center Data and Safety Monitoring Board (DSMB) and other governmental agencies in the United States or other countries in which regulatory approval of IPI-549 may be sought. Your identity will remain confidential. Study data is labeled with a code instead of your name or other information that can easily identify you.

You will be asked to sign a separate HIPAA authorization form to allow the study team to access and share information from your medical record. Your permission as described in this informed consent and HIPAA document does not have an automatic expiration date.

SIGNATURE AND CONSENT

Your participation in this study is voluntary, and you may refuse to participate or withdraw from the study at any time without prejudice or loss of benefits to which you are otherwise entitled. You will receive a signed copy of this consent document and a copy of "The Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

UC San Diego Office of IRB Administration
(858) 246-4777
(858) 246-3329 (FAX)

University of California, San Diego
9500 Gilman Drive, Mail Code 0052
La Jolla, CA 92093-0052

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The faculty and staff of the University of California, San Diego wish you to know:

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may seek information from the UC San Diego Office of IRB Administration - established for the protection of volunteers in research projects - by calling (858) 246-4777 from 7:30 AM to 4:00 PM, Monday through Friday, or by writing to the above address.