Are you participating in any other research studies? _____ Yes _____No

Concise Summary: We are seeking consent for a research study in which we evaluate if panitumumab-IRDye800, an imaging drug, is able to identify head and neck cancer that has spread to the lymph nodes (metastatic lymph nodes). Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care.

Your participation is expected to take approximately 60 days, including the screening period. If you meet all the requirements to participate, you will come to clinic on Day 0 to receive the investigational study drug (panitumumab-IRdye800). Depending on which cohort you will enroll in, you may or may not receive the lymph node mapping agent (Lymphoseek;). Your surgery to remove the cancer tissue will occur 1-5 days after receiving the study drug. You will be asked to return to the clinic twice after surgery for safety follow up and to check how you are feeling. The following procedures will occur at different time points during your participation in the study: review of your medical history and current medications, physical exam, electrocardiogram (ECG), and blood draws for lab safety tests and research tests.

There are risks, discomforts, and inconveniences associated with any research study. Panitumumab-IRDye800 contains the panitumumab antibody, which is approved by the US FDA for treatment of certain types of advanced colorectal cancer. We do not believe that the study drug will increase your chances of experiencing know side effects from treatment with panitumumab; however, we do not know this for sure. The total dose of panitumumab that you will receive will be much lower than the usual dose that is given to patients receiving it as treatment for their cancer, and you will receive the study drug once. You may experience side effects such as skin reactions, fatigue, nausea and diarrhea. Infusion reactions, including fever, chills, difficulty or labored breathing, and low blood pressure, occurred in 4% of patients taking panitumumab.

You may not directly benefit from taking part in this study. However, information obtained from your participation in this study may benefit other people with cancer in the future. You do not have to participate in this study. The alternative to participating in this study is to undergo your planned surgical procedure without the additional imaging with the investigational study drug.

PURPOSE OF RESEARCH

You are invited to participate in a research study to determine the ability of panitumumab-IRDye800 to identify head and neck cancer that has spread to the lymph nodes (metastatic lymph nodes). Currently, to identify the presence of metastatic lymph nodes during surgical resection of head and neck cancers, patients undergo a neck dissection or sentinel node biopsy whereby some or all of the lymph nodes are taken out of the neck and sent for pathological evaluation. We hope to show that panitumumab-IRDye800 can help surgeons to identify

metastatic lymph nodes during the surgical procedure with equal or better accuracy than the current methods.

You are being offered this study because you have primary or recurrent head and neck cancer and your doctor has recommended surgery including a selective or radical neck dissection as treatment to remove the primary tumor and lymph nodes of the neck.

If you decide to terminate your participation in this study, you should notify Dr. Fred Baik at [redacted] or after hours at (650)-498-6000.

This research study is looking for 20 patients with head and neck cancer that are scheduled to undergo surgery for removal of the primary tumor and/or lymph nodes of the neck. Stanford University will be the only site to enroll research study participants for this study.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 2 years whereby you would participate for up to two months. The screening period will take up to 30 days. Your active study participation will take 30 days from the start of treatment.

PROCEDURES

If you choose to participate, Dr. Baik and his research team will perform the following procedures in addition to your normal pre-operative, surgery and follow-up clinic visits and examinations:

Screening Period
If you choose to participate in the study and sign this consent form, you will have to undergo the following exams and tests to determine if you are eligible to take part in this study. **If you have already had some of these exams and tests recently, they may not need to be repeated.** The screening period will not last more than 30 days.

We will perform the following procedures during screening for research:

- Performance status – a measure of how you are feeling.
- Electrocardiogram (ECG) – a test to measure and record the electrical activity of your heart. Sticky pads will be placed at different points on your body and you will be asked to lie still while the machine records your heart activity.

- Blood draw for lab safety tests (approximately 2 teaspoons will be collected).
- Pregnancy test if you are a woman who could have children (approximately ½ teaspoon of blood); if you are pregnant or breast feeding you cannot participate in this study because of the potential unknown risk to your unborn fetus or baby.

Treatment Period
If you are deemed eligible to participate, you will either be enrolled in cohort 1 if you were staged with no suspicion of metastatic lymph nodes (cN0) or cohort 2 if you were staged with suspicious or confirmed metastatic lymph nodes (cN+).

DAY 0 - PANITUMUMAB-IRDYE800 INFUSION (Cohorts 1 and 2)

- Physical exam, performance status, and blood draw for lab safety tests (approximately 1 teaspoon); these may be skipped if Screening was performed within 14 days of day 0.
- Review current medications and assessment for any adverse events
- Urine pregnancy test for women capable of having children if Screening pregnancy test was more than 72 hours ago.
- Vital signs will be measured prior to infusion, immediately following panitumumab-IRDye800 infusion, and approximately 30 minutes post panitumumab-IRDye800 infusion.
- Safety monitoring for approximately 30 minutes after the end of the infusion to watch for side effects. Your study doctor may prescribe other medications to treat or prevent side effects of panitumumab-IRDye800. At any time during this treatment, it is important for you to let your doctor or nurse know if you experience anything that does not feel normal.
- Blood draw for research tests (approximately 2.5 teaspoons)
    - Two samples will be drawn prior to the infusion to measure drug level (pharmacokinetics) and monitor for immune response to the study drug (immunogenicity).
    - One sample will be drawn about 1 hour after the panitumumab-IRDye800 infusion to measure drug level (pharmacokinetics).

DAY 1-4 LYMPH NODE MAPPING - DAY BEFORE SURGERY (Cohort 1 only)
This part of the study is only for patients enrolled in cohort 1.

- We will collect data from the Sentinel node mapping procedure that will be performed as **standard of care** as discussed with you by your treating surgeon. A summary of this procedure is provided below for you:
    - You will receive 4 injections of 0.1 mL (approximately a water drop) of sentinel node tracer around the tumor;
    - Because the sentinel node tracer is lightly radioactive, after injection 2D (lymphoscintigram) and 3D (SPECT/CT) images will be taken to follow the spread of the radioactive signal to the lymph nodes.
- In addition to collecting the imaging data, we will collect a blood draw for research tests (pharmacokinetics) (approximately 1 teaspoon).

DAY 2-5 – DAY OF YOUR SURGERY
Based on your availability and hospital scheduling, your surgery to remove the cancer tissue will occur 1-5 days after receiving your panitumumab-IRDye800 study infusion. On the day of your surgery, we will:

- Review current medications and record any adverse events.
- Blood draw for lab safety tests and for research tests (pharmacokinetics) (approximately 2 teaspoons).
- Surgical imaging and resection of cancer tissue – You will have the same surgery you would receive if you were not part of a research study. The details of this surgery will be part of your regular medical care and will be determined by your surgeon based on your medical condition.
    - Prior to, and once the surgeon has removed as much cancer as per the surgical plan using standard methods, the investigator will use additional special cameras (fluorescence cameras) to take extra images of the tumor for the study.
    - Prior to, and once the surgeon has removed the lymph nodes from the neck per the surgical plan using standard methods, the investigator will use additional special cameras (fluorescence cameras) and gamma probe to take extra images and measurements of the lymph nodes for the study.
- Pathology evaluations – after removal, tumor and lymph node tissues will be sent to the pathology laboratory as standard practice.
    - The research imaging and evaluations will not affect the routine diagnostic pathology tests that will be performed on your tissues.

FOLLOW UP VISITS: DAY OF DISCHARGE and DAY 30 AFTER STUDY INFUSION -
We may collect a blood sample for research tests on the day you are discharged from the hospital after your surgery.
If you are scheduled to return to Stanford for a post-operative follow-up visit as per your standard of care and the visit falls within the study window for Day 30 follow-up, we would like to collect the following data for the study at the visits:

- Performance status;
- Review medications and record any adverse events;
- Blood draw for lab safety tests and research tests (pharmacokinetics and immunogenicity) (approximately 2 teaspoons);

If you are not scheduled to return to Stanford for a post-operative follow-up visit within the window for these follow-up time points, we may ask you to return to clinic to collect these assessments for the study.

<u>Women of Childbearing Potential</u>
If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in

this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk as the effects of panitumumab-IRDye800 on an unborn child have not been studied.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study if of childbearing potential. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception while you are participating in the study and for at least 15 days after the study infusion. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant.

Tissue Sampling for Research

Research using tissues is an important way to try to understand human disease. As part of this study, we may want to store some of the tissue and blood collected from you during your surgery for future research on cancer. The future research may be conducted by Dr. Fred Baik, or other members of his research staff or other researchers at or outside of Stanford that obtain IRB approval for their research. With these samples, researchers will study other means of fluorescent imaging of human cancer tissues; examine tumor and adjacent normal tissues from the head and neck region to identify and characterize proteins and genes that may contribute to the development and progression of cancer; and/or other research projects. There are several things you should know before allowing your tissues to be studied.

Any of your samples which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of samples do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Your samples may be sent outside of Stanford for research and analysis.

Your tissues will be stored in a research lab at Stanford University. Your tissue samples will be processed and the resulting materials stored for an indefinite period of time. Samples will be labeled with a code and will not carry information that personally identifies you. Dr. Baik's study staff will keep the list that links research code to your name confidential. Your name or other

public identifiers will not be included with any data shared with other investigators or outside collaborators. Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Results of any future research will not be given to you or your doctor.

If you agree, up to five 10 mL tubes of blood (approximately 3.5 tablespoons) may be obtained prior to, or during surgery. These blood samples will be store at -80°C for future analysis and research.

Tissue Sampling for Genetic Testing
As part of the analysis on your samples, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Information from analyses of your coded samples and your coded medical information may be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research. These databases will be accessible by the Internet. Only anonymous information from the analyses will be put in a completely public database, available to anyone on the internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the

security of the computer systems used to store the codes linking your genetic and medical information to you.

The scientific results by analysis of your samples may be published in scientific journals and will not reveal the identity of the subjects. Patient information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, has the right to inspect research records and, therefore, could learn your identity if you are involved in any study performed under FDA jurisdiction. Confidentiality will be insured by maintaining the specimens in a locked laboratory with access only to authorized personnel.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

You have the right to refuse to allow your tissues to be saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research. However, investigators may keep data generated before you withdrew consent. You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

Please initial one choice below:

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Ask questions as you think of them.

- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Fred Baik at [redacted] or after hours at (650)-498-6000.

If you withdraw from the study, or the study medication is stopped for any reason, you will be asked to return for a safety visit 30 days after receiving panitumumab-IRDye800. You should notify Dr. Fred Baik if you also withdraw consent for investigators to use your tissue samples for research.

The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You become pregnant or start breast feeding.
- Severe infusion reaction to panitumumab-IRDye800 dose requiring stopping the infusion.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Because Panitumumab-IRDye800 is investigational, you may experience side effects not yet known, or in greater severity than those listed below. We will tell you if we learn any new information that may affect your health, welfare, or decision to stay in this study. You should talk to your study doctor about any side effects that you have while taking part in the study.

Panitumumab (VECTIBIX ®) Risks

Many of the reported adverse events are associated with repeat administration of panitumumab, rather than the single dose that you will receive as part of this study. The total dose of panitumumab that you will receive will be lower than the usual total dose that is given to patients receiving it as treatment for cancer.

The most common side effects patients have experienced when receiving panitumumab primarily include skin reactions (including acne-like rash, dry or itchy skin, cracking of skin around your nail beds, skin infections, and dry eyes), fatigue, nausea, and diarrhea. Monitor skin reactions carefully to prevent serious or life-threatening complications. Exposure to sunlight may make skin reactions worse; limit exposure by using sunscreen and protective clothing.

Infusion reactions, including fever, chills, difficulty or labored breathing, and low blood pressure, occurred in 4% of patients taking panitumumab. These reactions are most likely during or immediately following panitumumab infusion. Severe infusion reactions occurred in 1% of patients. You may be given a drug in your IV prior to the panitumumab infusion to help prevent these types of reactions. This will be determined by your study doctor. The most common drug that is given is an antihistamine called diphenhydramine (Benadryl). Based on your study doctor's routine practice, he or she may decide to give other drugs, such as steroids, if it's felt necessary to treat a reaction. ***Tell your doctor or nurse immediately if you experience any of the symptoms of an infusion reaction.***

Patients receiving repeated doses of panitumumab occasionally had progressively decreased magnesium and/or other minerals in the blood. Your blood chemistry levels will be monitored closely during this study, and electrolyte replacement will be given if necessary.

There have been rare reports of patients experiencing fatal and non-fatal lung disease after treatment with panitumumab. You should notify your study doctor if you have ever had lung disease. Notify your study doctor immediately if you experience sudden or worsening breathing troubles.

Panitumumab-IRDye800 Risks

The study drug has been tested in over 60 humans with head and neck cancer so far with no observed side effects or related adverse events. We do not believe that the study drug will increase your chances of experiencing known side effects from treatment with panitumumab; however, we do not know this for sure. Despite extensive efforts to assure your safety, other unexpected side effects could occur.

Animals given this study drug did not experience any severe side effects. There were heart rhythm changes during the infusion; however, the animals did not experience any physical problems during the infusion or during the monitoring period for 2 weeks after the infusion. Nevertheless, these heart rhythm changes are considered abnormal heart rhythms and could indicate serious side effects resulting in death.

Reproductive Risks
Based on data from animal studies, panitumumab may cause fetal harm (organ damage, death) when administered to pregnant women.

Risks Associated Lymphoseek (Applicable to Cohort 1 Only)
As of today, Lymphoseek has been evaluated and validated >550 patients with breast cancer, melanoma and/head-and-neck cancer. None of the patients studied with either experienced serious adverse reactions. The side effects injection site irritations (0.7% (4 patients)) and pain (0.2% (1 patient) were reported.

Lymphoseek might pose a risk of hypersensitivity reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs). Please notify the investigator about previous hypersensitivity reactions to drugs, in particular dextran and modified forms thereof.

Radiation Risk Sentinel Node Biopsy Procedure: Any radiation-emitting product may increase risk for cancer. We will adhere to the dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to you, your family or health care workers. This procedure would be performed in routine care regardless of a patient's participation in this study.

Study Procedure Risks
Blood Draw/IV: Inserting a needle into your arm for drawing blood, or an IV catheter for infusion, can cause slight discomfort or bruising at the puncture site. Lightheadedness or fainting may occur. Rarely, an infection at the puncture site may occur.

ECG: The adhesive pads used during this procedure may cause mild skin irritation or pull out some hairs when removed.

Injection Sentinel Node Tracer: Insertion of a needle in the oral cavity (i.e. tongue or floor of mouth), can cause discomfort. Lightheadedness or fainting may occur. Rarely, an infection at the puncture site may occur.

Sentinel Node Imaging: When performing imaging, movement restrictions apply as such to gather the best images possible. For acquisition of the low-dose CT scan you will be positioned in a small tunnel, this might lead to slight claustrophobic feelings.

POTENTIAL BENEFITS

You may not benefit directly from taking part in this study. However, information obtained from your participation in this study may benefit other people with cancer in the future, and help determine if Panitumumab-IRDye800 can be used as an alternative for the current standard treatments (sentinel node biopsy, neck dissection) for detection of tumor tissue in the lymph

node(s). We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

You do not have to participate in this study. The alternative to participating in this study is to undergo your planned surgical procedure without the additional injection of radiotracer or panitumumab-IRDye800 and the study related imaging and follow-up visits.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction. The purpose of this research study is to obtain data or information on the safety and effectiveness of panitumumab-IRdye800; the results will be provided to the sponsor, the FDA and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to evaluate the effectiveness of Panitumumab-IRDye800 in head and neck cancer patients. Your health information will be used to verify the study conduct and data entry, assess the study treatment effects, and prepare regulatory documents for submission to Stanford institutional review, the FDA, and/or other national regulatory agencies for marketing approval. Your coded information may also be used in research related to the study drug, your cancer and related diseases, and/or diagnostics to inform treatment.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the

research use or disclosure of your health information in this study, you must write to:

Dr. Fred Baik
875 Blake Wilbur Drive
Stanford, California 94305

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your personal information (such as name, address, telephone number, date of birth); demographics (e.g. gender, race, ethnicity); medical history (especially cancer and surgical history); information from laboratory tests, imaging procedures, physical exams and other study tests or procedures; and information learned during research office visits.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Dr. Fred Baik
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration
- The National Cancer Institute
- Northern California Cancer Registry

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31st 2067, or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

If authorization is to be obtained from a legally authorized representative -- e.g., parent(s), legal guardian or conservator

_____ _____

Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____

Print Name of LAR

_____

LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

FINANCIAL CONSIDERATIONS

Payment

You will not be paid to participate in this research study. You may be reimbursed for travel expenses. If you are interested in knowing more details, please ask a member of the study team.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits.

You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Sponsor

The National Institutes of Health are providing some financial support for the study and for the facility and staff where part or all of the study is taking place.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints:
If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Fred Baik at [redacted] or after hours at (650)-498-6000.

Injury Notification:
If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Fred Baik at [redacted].

Independent Contact:
If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team [redacted] toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- 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.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

When consent is obtained from a legally authorized representative (LAR) or representatives (e.g., parent(s), guardian or conservator):

_____ _____
Signature of Legally Authorized Representative (LAR) (e.g., parent, guardian or conservator) Date

_____ _____
Print Name of LAR LAR's Authority to Act for Participant (e.g., parent, guardian or conservator)

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____ _____
Print Name of Other Parent or Guardian Authority to Act for Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____

Signature of Witness Date

_____

Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form (referred to as the "Summary Form" in the regulations):
  - Must be signed by the witness AND the Person Obtaining Consent (POC).
  - The non-English speaking participant/LAR does not sign the English consent.
  - The non-English speaking participant/LAR should not sign the HIPAA participant line
  - If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.