INFORMED CONSENT FORM

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

Concise Summary: We are seeking consent for a research study in which we evaluate whether the combined use of ^{89}Zr-panitumumab and panitumumab-IRDye800 can be used to identify head and neck cancer that has spread to the 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 two investigational imaging agents (^{89}Zr-panitumumab and panitumumab-IRDye800). You will return to clinic on Day 0 to Day Before Surgery to have ^{89}Zr-panitumumab PET/CT imaging. Your surgery to remove the cancer tissue will occur 2-5 days after receiving the investigational imaging agents. You will be asked to return to clinic once 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 your medical history and current medications; physical examination, electrocardiogram (ECG), and blood draws for lab safety tests and research tests.

There are risks, discomforts, and inconveniences associated with any research study. ^{89}Zr-panitumumab and panitumumab-IRDye800 both contain the panitumumab antibody. Panitumumab 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 known 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 total dose that is given to patients receiving it as treatment for cancer, and you will only 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 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.

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 investigational study agents.

PURPOSE OF RESEARCH

You are invited to participate in a research study to examine whether the combined use of ^{89}Zr-panitumumab and panitumumab-IRDye800 can be used to identify head and neck cancer that has spread to the lymph nodes (metastatic lymph nodes). ^{89}Zr-panitumumab and panitumumab-IRDye800 are both investigational agents, meaning they are not approved by the US Food and Drug Administration for use outside of clinical research studies.

Currently, to identify the presence of metastatic lymph nodes during the 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 the combined use of ^{89}Zr-panitumumab and panitumumab-IRDye800 can help surgeons to identify metastatic lymph nodes prior to and during the surgical procedure with equal or better accuracy than the current methods.

^{89}Zr-panitumumab is an investigational imaging agent that contains a small amount of radiation, which makes it visible in positron emission tomography (PET) scans. Panitumumab-IRDye800 is an investigational imaging agent that contains a dye molecule that surgeons and researchers can image using light waves both during surgery and after the surgery on removed tissues.

If you decide to terminate your participation in this study, you should notify [redacted].

This research study is looking for 14 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

Your participation in this research study is expected to take approximately 60 days, with up to 30 days for screening to see if you are eligible to participate and approximately 30 days on study.

PROCEDURES

If you choose to participate, Dr. Eben Rosenthal and his research team will perform the procedures listed below 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.

The following procedures will occur during screening:

- Review your medical history and current medications.
- Physical exam, including height, weight, and vital signs (blood pressure, heart rate, respiratory rate, and temperature).
- 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).
- 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.
- Obtain a copy of results from an ^{18}F-FDG PET/CT or ^{18}F-FDG PET/MRI scan that was part of your standard of care pre-operative tests.

Day 0

If you meet all the requirements to participate, you will come to clinic on Day 0 to receive the two investigational imaging agents. The following procedures will occur:

<u>Prior to administration of Study Agents</u>

- Physical exam and performance status; these may be skipped if done for Screening within 21 days of Day 0.
- Blood draw for lab safety tests (approximately 1 teaspoon); this may be skipped if done for Screening within 21 days of Day 0.
- Urine pregnancy test, if you are a woman who could have children; this may be skipped if done for Screening within 72 hours (3 days) of Day 0.
- Record vital signs.
- Review any current medications.
- ECG.
- Blood draw for research samples (approximately 2 teaspoons) to measure:
    - Levels of panitumumab-IRDye800 and ^{89}Zr-panitumumab (pharmacokinetics).

- Immune response to study agents (immunogenicity).

Administration of panitumumab-IRDye800: The first study agent will be infused through an intravenous (IV) tube into a vein in your arm. The infusion will take 15 minutes. You will be observed for 30 min for any side effects.

- Record vital signs immediately after study agent administration.

Administration of ^{89}Zr-panitumumab: The second study agent will be given as a single dose given all at once through the IV tube into a vein in your arm.

- Record vital signs immediately after study agent administration.

Observation (1 hour): Safety monitoring for 1 hour after the end of the study agents administration to watch for side effects. Your study doctor may prescribe other medications to treat or prevent side effects. 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 to measure panitumumab-IRDye800 and ^{89}Zr-panitumumab pharmacokinetics (approximately 1 teaspoon), at end of 1 hour observation period.
- ECG, at end of 1 hour observation period.
- Record any side effects or medications given, at end of 1 hour observation period.

Day 0 to Day Before Surgery

On Day 0 to Day of Surgery, depending on schedule availability, you will come to clinic to have ^{89}Zr-panitumumab PET/CT imaging. The following procedures will occur:

- Blood draw to measure panitumumab-IRDye800 and ^{89}Zr-panitumumab pharmacokinetics (approximately 1 teaspoon).
- PET/CT imaging: During image collection, study doctors will collect both PET images, which detect the small amount of radiolabeled ^{89}Zr-panitumumab imaging agent, and CT images, which uses X-rays, to look at your tissues and organs. You will be asked to lie on a long narrow couch for about 20 minutes while the machine gathers data.
- Record any side effects and review current medications.
- If possible, based on your tumor location, study doctors may collect images with a handheld fluorescence imaging system. This imaging uses a narrow band of (non-visible) light to activate the dye in panitumumab-IRDye800 imaging agent. Your study doctor can tell you if this is applicable to you.

Day 2 to 5

Based on your availability and hospital scheduling, your surgery to remove the cancer tissue will occur 2-5 days after receiving ^{89}Zr-panitumumab and panitumumab-IRDye800. On the day of surgery, the following procedures will occur:

- Record vital signs prior to surgery.

- Blood draw for lab safety tests (approximately 1 teaspoon).
- Blood draw to measure panitumumab-IRDye800 and ^{89}Zr-panitumumab pharmacokinetics (approximately 1 teaspoon).
- 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.
- Record any side effects and review current medications
- 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 (Day 15)
You will be asked to return to clinic once after surgery for safety follow up and to check how you are feeling. The following procedures will occur:

- Physical exam and performance status.
- Record vital signs.
- Blood draw for lab safety tests (approximately 1 teaspoon), if past lab values were not in the normal range.
- Blood draw for research samples (approximately 2 teaspoons) to measure:
    - Panitumumab-IRDye800 and ^{89}Zr-panitumumab pharmacokinetics.
    - Immunogenicity.
- ECG.
- Record any side effects and review current medications.

DAY 30
Your study doctor or research study staff will contact you by telephone or review your electronic medical record 30 days after study drug infusion to check for any side effects related to study participation.

After all necessary clinical information is obtained from tissues, additional optical imaging of archived tissues will be performed in a research laboratory at Stanford University to assess location of panitumumab-IRDye800 within the tissues.

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.

OPTIONAL Tissue Storage for Future Research
Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to save your tissue samples for future research. There are several things you should know before allowing your tissues to be studied.

Your tissues will be stored in a research laboratory at Stanford University. Samples will be labeled with a study ID code number that does not personally identify you. The key linking the study ID code with your personal information will not be shared with researchers. Your samples may be sent outside of Stanford for research and analysis.

You have the right to refuse for 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. 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.

Identifiers will 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.

Allowing the use of your data for future research is optional. You can refuse to participate in future research and still take part in the main study.

Please mark one choice:

_____ I consent to my samples being saved for future research

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

OPTIONAL Saving Images for Future Research
Investigators would like to save the images and data from your PET/CT scans and fluorescence imaging for future research projects. Your data will be de-identified (removing your name and medical record number), coded for confidentiality, and stored at Stanford in a secure, password protected computer. Your name and other personal identifiers will not be included in any data shared with other researchers.

Allowing the use of your data for future research is optional. You can refuse to participate in future research and still take part in the main study.

Please mark one choice:

_____ I consent to the use of my scan data for future research.

_____ I do not consent to the use of my scan data 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 [redacted].

If you withdraw from the study, or administration of either study agent is stopped for any reason, you will be asked to return to the clinic approximately one month from Day 0 for a safety follow up appointment (will be coordinated where possible with a routine visit).

The Protocol Director may also withdraw you from the study and administration of the study agents 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.
- Pregnancy

- 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. The investigational study agents, ^{89}Zr-panitumumab and panitumumab-IRDye800, may include risks which are not yet known or unforeseeable.

Potential Risks of Panitumumab (VECTIBIX ®)

^{89}Zr-panitumumab and panitumumab-IRDye800 both contain the panitumumab antibody. Panitumumab is approved by the US FDA for treatment of certain types of advanced colorectal cancer at dosage of 6 mg/kg given every 14 days. 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. Based on your study doctor's routine practice, he or she may decide to give other drugs, such as an antihistamine called diphenhydramine (Benadryl) or 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.

Potential Risks of Panitumumab-IRDye800
Panitumumab-IRDye800 has been tested in 64 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.

Potential Risks of ^{89}Zr-panitumumab
^{89}Zr-panitumumab has been tested in 5 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. The most common dose-independent side effects associated with panitumumab are infusion reaction or allergic reactions, described in the panitumumab risk section above. ^{89}Zr-panitumumab is radioactive, so you will exposed to a small amount of radiation from the study drug. The radiation risks are discussed in a separate section below.

Potential Risks of Deferoxamine (DFO, Desferal ®)
Deferoxamine is a component of ^{89}Zr-panitumumab. Deferoxamine is approved by the US FDA and throughout much of the world for the treatment of acute iron intoxication and of chronic iron overload due to transfusion-dependent anemias. Deferoxamine is a metal chelator, meaning it binds to a metal atom (in this case, Zirconium-89). The most likely possible side effects of deferoxamine include localized reactions at the site of IV placement, including irritation, pain; burning; swelling; induration (hardening of the skin); itching; redness; rash or scabbing of the skin.

In addition to injection site reactions, deferoxamine can also cause an allergic or hypersensitivity reaction in your body. Symptoms of a systemic (whole body) allergic reaction include rash, hives, anaphylactic reaction, swelling or tightness of the face or throat, nausea, vomiting, diarrhea, dizziness or fainting, fast heartbeat, and/or low blood pressure. ***Tell your doctor or nurse immediately if you experience any of the symptoms of an allergic reaction.***

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

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 and within 72 hours receiving study agents. 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 for 30 days after study drug administration. 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.

Potential 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.

Radiation Risks
This research study involves exposure to radiation from one ^{89}Zr-panitumumab whole body PET/CT scan. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation exposure is about 17.2 mSv, which is approximately equal to 34% of the limit that radiation workers (for example, a hospital x-ray technician) can receive in one year. This amount of radiation involves minimal risk and is necessary to obtain the research information desired.

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 ^{89}Zr-panitumumab and/or 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 imaging with investigational study agents.

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 ^{89}Zr-panitumumab and panitumumab-IRDye800; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as child abuse and neglect, or harm to self or others.

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?

This is a clinical research study to evaluate the safety and efficacy of ^{89}Zr-panitumumab and panitumumab-IRDye800 imaging agents when used together. Your health information will be used to verify the study conduct and data entry, assess the study agents effects, and prepare regulatory documents for submission to Stanford institutional review, FDA, and/or other funding agencies. Your coded information may also be used in research related to the study agents, 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 assessments. 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. Eben Rosenthal, 875 Blake Wilbur Drive, MC 5739, 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); personal and family medical history (past, present and future); information from laboratory tests, blood and urine tests, physical exams and other study tests or procedures; and information learned during office visits done as part of this research study. Researchers will collect results from certain laboratory tests and PET imaging performed as part of your normal care from your medical record.

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 and Investigational New Drug (IND) holder, Dr. Eben Rosenthal
- 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
- Staff at the Stanford Cyclotron & Radiochemistry Facility preparing the ^{89}Zr-panitumumab
- Massachusetts General Hospital
- Stryker Corporation
- The National Cancer Institute
- Northern California Cancer Registry
- The Food and Drug Administration
- National Institution of Health (NIH)

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 31, 2068 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
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/Reimbursement

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 is providing financial support and/or material for this study. Stryker Corporation is also providing financial support and/or material for this study.

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, Complaints, or Injury: 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. Eben Rosenthal. You should also contact him if you feel you have been hurt by being a part of this study. [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 at (650)-723-5244 or 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.

May we contact you about future studies that may be of interest to you? ☐ **YES** ☐ **NO**

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

_____ _____
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)

_____ _____
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 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.*