Are you participating in any other research studies? _____ yes _____no

LAY TITLE

A research study to evaluate the effectiveness and safety of adding an antibody therapy (bevacizumab) to standard chemotherapy (capecitabine and carboplatin) in the treatment of advanced cancers of the lower esophagus and stomach.

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug or device's safety and its effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study of capecitabine, carboplatin and bevacizumab in the treatment of advanced cancers in the lower esophagus and stomach. At Stanford, we currently use capecitabine and carboplatin for the treatment of these diseases and would like to study the addition of bevacizumab to this standard treatment.

Bevacizumab (commercially marketed as Avastin) is currently approved by the Food and Drug Administration (FDA) for the treatment of colon, breast and lung cancer.

This study is experimental because, while we know that capecitabine, carboplatin, and bevacizumab can be helpful in these other cancers, we do not yet know if this combination is helpful and safe when given to patients with cancers in the lower esophagus and stomach.

This study aims to establish the safety and tolerability of the combination of capecitabine, carboplatin, and bevacizumab in patients with cancers in the lower esophagus and stomach. We also want to find out what possible benefit this combination of drugs might have of treating your cancer.

You were selected as a possible candidate because you have an advanced cancer of the lower esophagus and stomach.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are **free to withdraw** your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. [redacted] or [redacted].

This research study is looking for 35 people with advanced cancers of the lower esophagus or stomach. Stanford University expects to enroll all of the research study subjects.

DURATION OF STUDY INVOLVEMENT

We think you will be in the study for at least 9-18 weeks. If the treatment appears beneficial to you, you may continue to receive it for a longer time. If you go off the study for any reason, we would like to keep track of your medical condition for approximately 3 years. If you receive treatment longer than 3 years, we will continue to monitor you.

TREATMENT AND PROCEDURES

If you choose to participate, [redacted] and the research study staff will ask you to sign this informed consent.

Study Treatment (please see attached calendar, APPENDIX A)

This study is a Phase II study, which means that we will evaluate safety and effectiveness. All patients enrolled will receive standard doses of capecitabine, carboplatin, and bevacizumab.

During the study treatment period, you will be given two intravenous (through a vein in your arm) drugs on Day 1 and take pills on Days 1 through 14 over a 21 day period. A 21 day period is called one "cycle." These cycles will be repeated as long as your cancer is responding to treatment and you are tolerating chemotherapy without serious side-effects.

- **Capecitabine** is a pill that is swallowed twice daily for the first 14 days of every 21 day cycle.
- **Carboplatin** is an intravenous drug given over 30-60 minutes on the first day of every 21 day cycle.
- **Bevacizumab** is an intravenous (given through a vein in your arm) drug given over 30-90 minutes on the first day of every 21 day cycle.

Laboratory and Imaging Procedures: Please note that participation in the research CT Perfusion portion of your standard CT is optional; a separate consent form is available. If you have had a previous reaction to contrast agents, or a history of severe allergies or kidney disease, please inform the person obtaining your consent.

Before entering the study:

- Physical exam and medical history
- Routine blood (approx 3 teaspoons) and urine tests (considered standard clinical care)
- CT scans
- Pregnancy test (for women of childbearing potential)
- An additional 2 teaspoons of blood will be drawn and stored for future tests\
- Research CT Perfusion (optional) which will be incorporated into regular CT scan. You will only have one scan and we will get both standard and perfusion images together.

During the study:

- Physical exam and medical history on the first day of cycle
- Blood (approx 3 teaspoons) and urine tests on the first day of each cycle
- CT scans (chest, abdomen and pelvis) every 3 cycles
- An additional 2 teaspoons of blood will be drawn on the first day of each cycle and stored for future tests
- Research CT Perfusion (optional) after 3 cycles only and incorporated into regular CT scan.

End of study:

You will be asked to return to the clinic approximately 30 days after the last dose of medication for the following procedures:

- Physical examination and medical history
- Blood (approx 3 teaspoons) and urine tests.
- CT scans

After the study:

After the end-of-treatment visit, you will enter the long-term follow-up period of the study. We would like to follow you for at least 3 years after discontinuing the study. You will be followed in the clinic at least every year. All of the following tests and procedures are routine, considered standard of care for evaluating cancer therapy:

- Physical exam and medical history
- CT scans

Description of Laboratory and Imaging Procedures

The collection of a **blood sample** requires your blood (approximately 3 teaspoons) be removed by inserting a needle into a vein in your arm. The side effects of taking a blood sample include pain or bruising at the site of the needle puncture of your skin. The collection of a **urine sample** requires that your urine (approximately 2 tablespoons) be collected in a standard specimen jar. There are no side effects of collecting a urine sample.

A **Computed Tomography (CT) scan** uses special X-ray equipment to take multiple images from different angles around the body. A computer then processes the information from the images and produces an image that shows a cross section of the area being examined. To help visualize the process, imagine looking at one end of a loaf of sliced bread. If you pull a slice out of the loaf, you can see the entire surface of that slice, from the outer crust to the center. The body is seen on CT scan "slices" in a similar way, from the outer skin to the central part of the body. The exam produces multiple slices showing multiple views of the area being examined. The "slices" can be displayed on a video monitor and saved on film for analysis. The image can be made even clearer by using a special contrast agent, which can be swallowed as a liquid, injected into a vein, or given as an enema. If you have had a previous reaction to contrast agents or a history of severe allergies, please notify the operator/investigator.

TISSUE SAMPLING FOR GENETIC TESTING, OTHER TESTING, OR BANKING FOR FUTURE RESEARCH

Introduction.
Research using tissues (in this study-blood and urine) is an important way to try to understand human disease and/or the role genes play in disease. You have been given this consent form because the investigators want to include your blood and urine in a research project, or because they want to save such samples for research. In addition to the blood and urine samples collected as part of standard clinical care we will be collecting additional blood samples for future research studies.

Subject Identification.
Your tissues will be stored and assigned a unique identifier. Your name or other public identifiers will not be included with any data shared with other investigators.

Risks.
Disease testing raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety. A possible risk of not knowing includes being unaware of the need for treatment.

Reporting Results to a Subject.
Even with special precautions, there is no absolute protection against discrimination on the basis of disease. For this reason, the investigator will use the results of this study as research only and not include them in your medical record. Generally, you will not be told the results, even if there might be some potential benefit to you.

Right to Withdraw.
You have the right to refuse to allow your tissues to be studied now or 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.

Completion of Your Research.
The samples will not be destroyed at the end of the study. These samples may also be stored for use in research to be conducted at a future date.

I agree to have my tissues stored for future research: ☐ Yes ☐ No _____
Initials

Family Members.
Disease information from tissue research can sometimes apply to family members. The investigator will not provide information about you to your family members.

Follow Up Contacts.
Investigators in this study may try to recontact you in the future. If you are recontacted and want to know what the investigators have learned about your tissue samples, you should understand the following possibilities:

- Information may be too sketchy to give you particular details or consequences.
- You may be determined to carry a gene for a particular disease that can be treated.
- You may be determined to carry a gene for a particular disease for which there is no current treatment.
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene. Genetic counselors can help sort out the various options in such a case.

Use in Commercial Development of Products.
Any tissues you have donated 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 tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests, or discoveries.

MEN AND WOMEN OF CHILDBEARING POTENTIAL

Because the drugs in this study can affect a fetus, you should not become pregnant or father a baby while on this study. Men and women must use an effective method of birth control while taking part in this study and for up to 60 days after the last administration of the trial medication. You must agree to use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation in order to prevent exposing a fetus to a potentially dangerous agent with unknown risk. 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 or your partner becomes pregnant, either of which may result in your being withdrawn from the study. If you are a woman, 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.

If you are a woman, 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 you are pregnant or currently breast feeding, you may not participate in this study.

SUBJECT'S RESPONSIBILITIES

You should:

- Take the study drug as instructed.
- 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.
- Keep the study drug in a safe place, away from children and for your use only.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.

- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.
- Follow the instructions of the protocol Director and study staff.

While participating in this research study, you should not take part in any other research project without approval from all of the Protocol Directors. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, the possible interaction(s) of research drugs, or other similar hazards.

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 withdraw from the study, or the study medication is stopped for any reason, you will still be asked to return to the clinic. You may be asked to undergo a physical exam or blood laboratory tests. If you experienced any side effects from the study medication, you will be followed once a week for 4 weeks, and subsequently at 4 week intervals for 3 years until the side effect resolves. These visits are important to make sure that there are no lingering side effects of having taken the study medications. All study-related supplies, including unused study drug, must be returned.

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:

- The cancer worsens.
- New information on treating cancers of the lower esophagus and stomach becomes available.
- Failure to follow the instructions of the Protocol Director and/or 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.

While on the study, you are at risk for side effects from capecitabine, carboplatin, and bevacizumab. They may cause some, all or none of the side effects listed. The drug combination may cause unknown side effects. Many side effects go away shortly after treatments are stopped, but, in some cases, side effects can be serious or long lasting or permanent. In addition there is always the risk of a very rare or previously unknown side effect (or even death) occurring. If any of these side effects occur, you must tell your doctor who may prescribe medications to ease the discomfort you may experience. In addition, if a severe reaction to the drug occurs, your doctor may discontinue the study treatment.

Possible Risks from Capecitabine

The common side effects of capecitabine are:

- Fatigue
- Pain, swelling, numbness, tingling, or redness of the hands or feet
- Skin infection
- Skin discoloration
- Diarrhea,
- Nausea, vomiting, stomatitis (mouth sores)
- Numbness, tingling in hand and foot area

Rare side effects:

- Lowering of the white blood cells and red blood cells
- Other abnormal blood tests
- Fever
- Headache, dizziness, difficulty sleeping
- Loss of hair
- Eye irritation, vision abnormal
- Difficulty breathing
- Chest pain
- Abdominal pain, stomach or intestinal discomfort or bleeding,
- Constipation
- Loss of appetite, dehydration, taste disturbance
- Swelling in hands, feet, abdomen
- Back pain, joint pain
- Mood alteration, depression

- Blood clots in deep vein

Possible Risks from Carboplatin

The common side effects of carboplatin are:

- Lowering of the white blood cell and red blood cells
- Low platelets with risk of bleeding and decreased ability for clotting
- Fatigue, weight loss
- Loss of appetite
- Nausea, vomiting
- Mouth sores, taste disturbances
- Abnormal blood tests

Rare side effects:

- Decreased hearing, mild ringing in the ears, problems with balance
- Alteration in the rhythm of the heartbeat
- High blood pressure
- Inflammation or blood clots in a vein
- Fever
- Pain, swelling, numbness, tingling, or redness of the hands or feet
- Injection site reaction
- Rash
- Constipation
- Diarrhea, dehydration
- Trouble sleeping, depression
- Pain: abdominal, joint, bone, chest, headache, muscle pains
- Eye irritation, abnormal vision
- Inability to pass urine, renal failure
- Cough, difficulty breathing, hiccoughs
- Loss of hair

Possible Risks from Bevacizumab

The common side effects of bevacizumab are:

- Chills
- Rash
- Mild elevation in blood pressure
- Mild occasional nose bleeding

Rare side effects:

- Fever
- Infection
- Mouth ulceration

- Headache
- Severe high blood pressure
- Blood clot formation: which can include heart attack, stroke, or pulmonary emboli (blood clots that have been carried through the blood into the pulmonary artery, the main blood vessel from the heart to the lung, or one of its branches, plugging that vessel).
- Severe bleeding or hemorrhage
- Kidney damage
- Colon wall perforation (Formation of a hole in the intestine)
- Gallbladder perforation
- Heart failure
- Problem healing wounds
- Ovarian failure and impaired fertility in premenopausal women

RARE BUT SERIOUS:

- Reversible Posterior Leukoencephalopathy Syndrome (RPLS) or similar leukoencephalopathy syndrome: RPLS is a medical condition related to leakiness of blood vessels in the brain and can cause confusion, blindness or vision changes, seizure and other symptoms, as well as changes in brain scans. This condition is usually reversible if treated promptly, but in rare cases, it is potentially life-threatening or permanent and may have long-term effect on the brain function.
- Fistulae formation (abnormal connection or passageway between two epithelium-lined organs or vessels that normally do not connect).

Possible Risks from Blood Draws

The blood samples taken for this study are also associated with risks and discomforts that may include redness, warmth, redness, pain, bruising or infection at the site from which blood is taken.

Possible Risk of CT contrast

Although rare, the intravenous (IV) contrast material involved in some CT scans causes medical problems or allergic reactions in some people. Most reactions are mild and result in hives or itchiness. In rare instances, an allergic reaction can be serious and potentially life-threatening. Make sure to tell your doctor if you've ever had a prior reaction to contrast material during medical tests.

POTENTIAL BENEFITS

We hope this study will help you and others, but we cannot say that it will help you directly. Your condition may remain the same or may worsen due to ineffective treatment. No benefit can be guaranteed by taking part in this study, and the chance

of benefit from this investigational treatment cannot be accurately predicted. Tumor shrinkage associated with treatment may make one feel better or live longer than might have been the case without treatment.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

There are other experimental and non-experimental treatments besides the one described in this study at this or other institutions. You may choose to receive other investigational drugs (if available). All alternative experimental and nonexperimental therapies have similar or increased risks and side effects.

You may also decide not to have any further treatment. In this case, you would receive supportive care to make you as comfortable as possible. You should discuss the alternatives with your doctor before you make your decision about taking part in this study.

SUBJECT'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 still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

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.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

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 study treatment; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

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 investigate the safety and tolerability of the combination of capecitabine, carboplatin, and bevacizumab in patients with cancer of the lower esophagus and stomach. We also want to find out what possible benefit this combination of drugs might have of treating your cancer.

Your identity will be kept as confidential as possible as required by law, but absolute confidentiality cannot be guaranteed. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required, including IRB, Genentech, and representatives or designees. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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 contact: Dr. George Fisher at [redacted]

What Personal Information Will Be 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, information obtained from procedures to determine your eligibility to participate in the trial, routine medical history, physical exam, vital signs, blood and urine tests, x-rays, MRIs, PET or CT scans and any other procedures performed during the study.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, or other identifying information. Your name will not appear anywhere on the study forms.

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. George A. Fisher)
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.
- The research team, the study coordinators
- Stanford Cancer Clinical Trials Office

Who May Receive / 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
- National Cancer Institute (NCI)
- Food and Drug Administration (FDA)
- Genentech

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 expire on December 31, 2105.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health

information if it was used to make medical or billing decision about you (e.g., if included in your official medical record).

_____ _____

Signature of Subject Date

FINANCIAL CONSIDERATIONS

PAYMENT

You will not be paid to participate in this research study.

COSTS

You will not be charged for the study treatment drug bevacizumab. The costs of carboplatin and capecitabine will be billed to your medical insurance. Costs related to research blood samples, and data management of the study will not be charged to you.

You and/or your insurance company will be responsible for the standard of care costs. During your treatment on this study, these costs may include charges for insurance co-payments and deductibles, office visits, blood and laboratory tests, X-rays, CT/MRI scans, medications to control side effects, routine costs associated with treating your cancer, hospitalization and doctor's fees. Costs associated with disease progression or your underlying medical condition will be the responsibility of you and/or your insurance company.

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

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

SPONSOR

Genentech is providing financial support and material for this study.

CONTACT INFORMATION

- Appointment Contact: If you need to change your appointment, please contact [redacted]
- 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 contact [redacted] You should also contact him/her at any time if you feel you have been **hurt by being a part of this study**.
- Injury Notification: If you need immediate assistance please contact the Stanford page operator and ask for the "Medical Oncologist on Call" 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 at [redacted] You can also write to the Stanford IRB, Stanford University, Stanford, CA 94305-5401.

COMPENSATION

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, care will be provided to you. You will **not** be responsible for any of these costs.

Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a human subject you have the following rights. These rights include but are not limited to the subject'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.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____ _____

Signature of Adult Participant Date

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

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- Translated short form must be signed and dated by both the participant (or their LAR) and the witness.
- The English consent form (summary form) must be signed by the witness and the POC. The non-English speaking participant does not sign the English consent.
- The non-English speaking participant should not sign the HIPAA participant line

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____ _____

Signature of Person Obtaining Consent Date