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

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, 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, temozolomide, and bevacizumab in the treatment of advanced pancreatic neuroendocrine tumors.

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. Shagufta Shaheen at [redacted]

This research study is looking for 30 people with advanced pancreatic neuroendocrine tumors. Stanford University expects to enroll 20 research study subjects. Other subjects will be enrolled at and Moffitt Cancer Center.

Capecitabine (commercially marketed as Xeloda) is currently approved by the FDA for the treatment of colon and breast cancer.

Temozolomide (commercially marketed as Temodar) is currently approved by the FDA for the treatment of brain cancer.

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

We hope to establish the safety and tolerability of the combination of capecitabine, temozolomide, and bevacizumab in patients with neuroendocrine tumors. This triplet combination has not been previously been studied. We also

want to find out what possible benefit this combination of drugs might have of treating your cancer.

We also hope to learn more about the value of CT perfusion for characterizing these cancers and predicting their response to treatment. We hope to learn whether the baseline perfusion characteristics of your cancer, as characterized by CT perfusion studies, can predict tumor response to treatment.

This study is experimental because, while we know that capecitabine, temozolomide, 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 neuroendocrine tumors.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 18 months to enroll all 30 patients at 3 sites. You will be in the study for at least 6 months. If the treatment appears beneficial to you, you may continue to receive it for a longer amount of time. If you go off the study for any reason, we would like to keep track of your medical condition every 6 months till disease progression .

PROCEDURES

If you choose to participate, Dr. Shaheen and her research study staff will ask you to sign this informed consent.

Study Treatment

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, temozolomide, and bevacizumab.

During the study treatment period, you will be given an intravenous (through a vein in your arm) drug on Days 1 and 15, take pills on days 1-14 over a 28-day period. A 28-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 28 day cycle.
- **Temozolomide** is a pill that is swallowed once daily on days 10-14 of every 28 day cycle.
- **Bevacizumab** is an intravenous drug given over 30-90 minutes on days 1 and 15 of every 28 day cycle.

Study Calendar:

Before entering the study:

- Vital signs, including blood pressure.
- Medical history, physical exam and assessment of performance status.
- Blood: Complete blood count (about 3 teaspoons) with differential, comprehensive metabolic panel, Chromogranin A, other neuroendocrine markers at the investigator's discretion, and serum (about 2 teaspoons) banked for future studies.
- Urine: Urinanalysis (pH, specific gravity, glucose, protein, ketones and blood) OR urine dipstick are allowed. Pregnancy test for women of childbearing potential.
- Tissue: MGMT deficiency (centrally tested at Stanford)
- Imaging: Radiographic imaging, multi-phasic CT or MRI preferred, of measurable disease for assessment by RECIST criteria (standard clinical care). This must be done within 30 days of starting on study. CT Perfusion will be performed at baseline as a correlative study (optional).

During the study:
First day of each cycle

- Vital signs, including blood pressure.
- Medical history, physical exam and assessment of performance status.
- Blood: Complete blood count (about 3 teaspoons) with differential, comprehensive metabolic panel, Chromogranin A, other neuroendocrine markers at the investigator's discretion, and serum (about 2 teaspoons) banked for future studies.
- Urine: Urinanalysis (pH, specific gravity, glucose, protein, ketones and blood) OR urine dipstick are allowed.
- Imaging: Multi-phasic CT or MRI scans with measurement of target lesions by RECIST criteria will be done at the conclusion of every 3 cycles. CT Perfusion will be performed after 2 weeks and after 3 cycles as a correlative study (optional).

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:

- Medical history, physical exam and assessment of performance status.
- Vital signs, including blood pressure.
- Blood: Complete blood count (about 3 teaspoons) with differential, comprehensive metabolic panel, Chromogranin A, other neuroendocrine markers at the investigator's discretion, and serum (about 2 teaspoons) banked for future studies.

- Imaging: Multi-phasic CT or MRI scans with measurement of target lesions by RECIST criteria and CT Perfusion (OPTIONAL) as a correlative study will be performed if not done within 4 weeks prior to withdrawal from study. Additional imaging will be at the investigator's discretion per standard of care.

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 1 year after discontinuing the study. You will be followed every six months by phone call or in the clinic . All of the following tests and procedures are routine, considered standard of care for evaluating cancer therapy:

- Physical exam and medical history
- CT scan

Description of Laboratory and Imaging Procedures

The collection of a **blood sample** requires that your blood 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.

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.

Prior to your CT scan, you will need to have your blood drawn to check your creatinine level. Your doctor may want additional lab values drawn as well. An intravenous line will be placed and contrast will be administered. Then you will undergo a modified, contrast-enhanced CT scan, including a perfusion scan.

A CT scan is routine, considered part of standard of care for cancer treatment. This study includes an additional component, called a CT perfusion scan, for research purposes. Perfusion is the process by which

blood passes from the blood vessels to an organ or a tissue. Perfusion CT allows for visualization of this passage of blood flow which, in turn, is recorded and quantified.

_____ I consent for the perfusion CT scan

_____ I do not consent for the perfusion CT scan

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

MEN AND WOMEN OF CHILDBEARING POTENTIAL

Women of Childbearing Potential

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. 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.

Men of Childbearing Potential

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 12 weeks after taking your last dose of study medication. 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 GENETIC TESTING, OTHER TESTING, OR BANKING FOR FUTURE RESEARCH

Tissue Sampling 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 study your tissues as part of this research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

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

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.

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.

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.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future 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, and 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.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

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

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study. 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 1 year 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
- 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.

This study requires you to travel to Stanford University for regular study-related visits, which may be inconvenient for you.

While on the study, you are at risk for side effects from capecitabine, temozolomide, 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

Common side effects:

- 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 or taste disturbance
- Swelling in hands, feet or abdomen
- Back pain, joint pain
- Mood alteration, depression
- Blood clots in deep vein

Possible Risks from Temozolomide

Common side effects:

- Headache
- Nausea, vomiting
- Loss of appetite
- Constipation
- Diarrhea
- Fatigue

Rare side effects:

- Sores on lips, mouth or throat
- Loss of hair
- Seizures
- Rash, itching, swelling, dizziness, trouble breathing

- Swelling of hands, feet, ankles, or lower legs
- Vision changes
- Weight gain
- Skin discoloration
- Nose bleeds
- Confusion, anxiety
- Difficulty sleeping
- Urinary incontinence
- Breast pain in women
- Infection
- Fever, chills, cough, sore throat, body aches
- Bleeding, bruising, weakness
- Liver damage which may cause yellowing of eyes and skin, swelling and may result in liver failure.

Possible Risks from Bevacizumab

Common side effects:

- 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)
- Heart failure
- Problem healing wounds
- Ovarian failure and impaired fertility in premenopausal women

Rare but serious side effects:

- 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).
- Duodenal Ulceration: a medical condition characterized by a sore that occur in the upper area of the small intestine.
- Blood disorders, such as a qualitative defect in platelet function, unmasked by bevacizumab. If this occurs, bleeding can arise.

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 Risks from CT Scans

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.

This research study involves exposure to radiation from up to 3 optional perfusion CT scans should the participant choose to participate. Your radiation exposure from the 3 scans will be about 8.4 rems. This amount of radiation has an estimated risk of fatal cancer of about 0.42 percent. If randomly selected members of the general population were exposed to the radiation exposure from this research, the extra lifetime risk of dying from fatal cancer may be about 4.2 in 1,000. Statistics represent averages and do not predict what is going to happen to you. They do not take into consideration individual risk factors including lifestyle (smoking, diet, exercise, etc), family history (genetics) or radiation exposure. The majority of cancers occur later in life and the average lifetime risk of dying from cancer is 25% (1 in 4).

Any of these medications and procedures may involve risks to you that are currently unforeseeable.

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 non-experimental 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.

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 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 capecitabine, temozolomiude and bevacizumab for advanced pancreatic neuroendocrine tumors. The results will be provided to the sponsor, the Food and Drug Administration 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 investigate the safety and tolerability of the combination of capecitabine, temozolomide, and bevacizumab in patients with advanced pancreatic neuroendocrine tumors. We also want to find out what possible benefit this combination of drugs might have of treating your cancer.

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. Shagufta Shaheen at 875 Blake Wilbur Drive Stanford, CA 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 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. Shagufta Shaheen
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff
- The Stanford Scientific Review Committee
- The Stanford Data Safety Monitoring Committee
- Stanford Cancer Clinical Trials Office

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
- National Cancer Institute (NCI)
- Food and Drug Administration (FDA)
- Genentech
- Merck

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 September 1, 2111 or when the research project ends, whichever is earlier.

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 a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____

Signature of Participant Date

FINANCIAL CONSIDERATIONS

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

Costs
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 and Merck are providing financial support and 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, 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. Shagufta Shaheen at [redacted] You should also contact her at any time if you feel you have been hurt by being a part of this study.

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] or toll free at 1-[redacted] You can also write to the Stanford IRB, Stanford University, El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact the main Cancer Center number at [redacted] .

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.

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

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

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)

- 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