RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	A Phase II Trial of Vemurafenib in Combination with Sorafenib to Treat Patients with Advanced KRAS Mutated Pancreatic Cancer. Targeting RAF Dimers to Suppress Oncogenic RAS Signaling (The Dr. Nate Nieto Study)
PROTOCOL NO.:	HRI-Vemurafenib-Sorafenib-001 WCG IRB Protocol #20214754 HonorHealth IRB# 1806109
SPONSOR:	HonorHealth Research Institute
INVESTIGATOR:	Erkut Borazanci, MD 10510 North 92nd Street Scottsdale, AZ 85258 USA
STUDY-RELATED PHONE NUMBER(S):	Erkut Borazanci, MD 480-323-1350 (24 hours)

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you and answer your questions.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand something, ask questions. Ask all the questions you want before you decide.
- The purpose of this research is to determine the clinical efficacy of vemurafenib in combination with sorafenib in patients with KRAS mutated pancreatic cancer.
- We expect that you will take part in this research for 16 weeks or longer depending on how you tolerate treatment.
- If you decide to take part in this research study, the general procedures include obtaining informed consent, physical examinations, vital collection, blood and urine collection, ECGs, imaging assessments, archival or fresh tumor tissue collection.

- The most important risks or discomforts that you may expect from taking part in this research include joint pain, rash, hair loss, fatigue, nausea, low blood counts, changes in electrolytes, and itching. More serious reaction that can occur include skin cancer, severe skin reactions, heart rhythm changes, liver damage, eye inflammation, damage to an unborn child, kidney failure, bleeding from the gastrointestinal system, poor wound healing, and high blood pressure.
- It is not expected that you will personally benefit from this research.
- Possible benefits to others include possible new treatment option for patients with KRAS mutated pancreatic cancer.
- Instead of being in this research, your choices may include chemotherapy, other clinical trials, receiving palliative (comfort) care or receiving no treatment for your disease.
- Other information that may be important for you to consider so you can decide whether to take part in this research is*:*
    - Optional tissue collection for analysis

INTRODUCTION

You are being asked to take part in a clinical trial, a type of research study. A person who takes part in a research study is called a research or study subject. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not understand.

Before you decide to participate in the study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Your participation is entirely voluntary. Research studies include only people who choose to take part. To allow you to make an informed decision as to whether you want to take part in this research, this consent form describes the purpose of the research, your rights and obligations, the procedures that are conducted as part of the research, and the possible benefits and risks of participating, and asks for your consent for the use and disclosure of your health information that will be obtained from you if you take part in the study.

You should read all of this information carefully and discuss your questions and concerns about the research, this form, or your condition with your study doctor or healthcare team. You may take home an unsigned copy of this consent form to think about or discuss your decision with your family, friends and anyone you choose. You should not sign this consent form until all of your questions are answered. Please take your time to make your decision.

Vemurafenib and Sorafenib are FDA approved drugs but have not been approved for the use described in this study by the Food and Drug Administration (FDA). For the purpose of this research study, the use of these two drugs is experimental.

The following is information you should know before deciding to take part in this research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join this study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

- Parts of this study may involve standard medical care. Standard medical care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the study doctor or study staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed, then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

PURPOSE OF THE RESEARCH
The purpose of this research is to determine the benefit of two oral chemotherapy drugs, Vemurafenib and Sorafenib, in individuals with KRAS mutated pancreatic cancer who have progressed on standard chemotherapy.

Who can participate in this research?
This study will include between 7-12 patients with KRAS mutated pancreatic cancer.

PROCEDURES
In order to make sure you are a good candidate for this study, you will need to complete a screening visit.

Screening Visit:
The following assessments will be completed as part of the screening visit within 28 days prior to initiating study treatment:

- Sign the informed consent form
- Complete medical history including concurrent baseline conditions, prior cancer therapy (including documentation of prior surgery, chemotherapy and radiotherapy given before or after surgery)
- ECOG Performance Status (standard way of measuring the ability to perform ordinary tasks)
- Vital Signs (blood pressure, pulse, respiratory rate, and temperature)
- Complete physical examination including height and weight
- Review all medications taken within the last 30 days
- Collect blood for laboratory tests
    - Hematology - complete blood count (CBC) with differential and platelet count
    - Serum chemistries (for hepatic (liver) and renal (kidney) function tests)
    - Lactate dehydrogenase (LDH)
    - Coagulation: PT, INR
    - CA19-9 (or CA 125, or CEA if not expressers of CA 19-9)

  - Serum pregnancy test for WOCBP within 72 hours prior to the first dose of study treatment
  - Correlative analysis

- Electrocardiogram (ECG)
- Computed tomography (CT) / magnetic resonance imaging (MRI) scan to document disease status (including chest, abdomen, pelvis, and other regions as clinically indicated)

  - In addition, brain scan is required to exclude brain metastases if clinically indicated only.
  - If a CT scan was taken within 28 days prior to first dose, a new scan is not necessary.

- Confirm KRAS and BRAF mutation status by tissue biopsy.
- If your mutation status of KRAS and BRAF kinases is not known, you must have an archival tumor specimen (primary or metastatic site) available to submit to confirm KRAS and BRAF status. The results of the mutation status are required for determining your eligibility for this trial.

If you are eligible to participate in this study, you will be assigned a unique ID that will be used to identify you while you are participating in the study.

The following assessments will be completed during each cycle on a specific day of the study:

Day 1 of Each Cycle:

- Directed Physical exam
- Vital Signs (blood pressure, pulse, respiratory rate, and temperature)
- Measurement of weight and body surface area calculation prior to dosing
- ECOG Performance Status
- Collect blood for laboratory tests

  - Hematology: CBC with differential and platelet count
  - Serum chemistries (for hepatic and renal function tests)
  - LDH
  - Coagulation: PT, INR – only required for patients on warfarin
  - Serum Pregnancy Test (if applicable)
  - Correlative analysis (**Cycle 2 and Beyond)**

- ECG **(Cycles 1 through 3, then every 3 cycles 6, 9, 12 etc.)**
- Review any changes to your health since the last visit
- Review any changes to your medications since the last visit
- Receive vemurafenib, sorafenib and use patient diaries

  - Study staff will provide instructions on the completion of the diary and to return on day 1 of each cycle. If there any discrepancies within the diary, study staff will discuss with you and provide further education.

Day 3 (Cycle 1 Only)

- Vital Signs (blood pressure, pulse, respiratory rate, and temperature)
- Review any changes to your health since the last visit
- Review any changes to your medications since the last visit

Days 8, 15 and 22 of Cycle 1 only

- Directed physical exam
- Vital Signs (blood pressure, pulse, respiratory rate, and temperature)
- ECOG Performance Status
- Collect blood for laboratory tests
    - Hematology: CBC with differential and platelet count
    - Serum chemistries (for hepatic and renal function tests)
    - LDH
- ECG (Cycle 1/ Day 15 only)
- Review any changes to your health since the last visit
- Review any changes to your medications since the last visit

Tumor Assessments Every 2 Cycles (Every 8 Weeks)

- Imaging assessments (same method used at screening visit). May be done earlier if your doctor is concerned about your cancer.
- CA19-9 (or CA 125, or CEA if not expressers of CA 19-9) before C3, C5, C7 etc.)

Off Treatment Visit

- Directed physical exam (if applicable)
- Weight
- Vital signs (blood pressure, pulse, respiratory rate, and temperature)
- ECOG performance status
- Collect blood for laboratory tests
    - Hematology: CBC with differential and platelet count
    - Serum chemistries (for hepatic and renal function tests)
    - LDH
    - Coagulation – PT, INR (only required for patients on warfarin)
    - CA19-9 (or CA 125, or CEA if not expressers of CA 19-9)
    - Serum pregnancy (if applicable)
    - Correlative analysis
- Review any changes to your health since the last visit
- Review any changes to your medications since the last visit
- Collect all remaining study drug and patient diaries

- Confirm contact information with study staff for follow-up telephone contact that will be conducted 30 days after last dose of study treatment and every 3 months for survival status

Survival Follow-up
You will be followed for survival every 3 months until study completion (may be done through medical record review or follow-up phone calls). Receipt of second line therapy will be recorded.

RISKS AND DISCOMFORTS

Vemurafenib Risks

Common Side Effects:
- Arthralgia (pain in joint)
- Rash
- Alopecia (hair loss)
- Fatigue (feeling tired)
- Photosensitivity reactions (immune skin reaction triggered by sunlight)
- Nausea
- Pruritus (itchy skin)
- Skin papilloma (wart-like growth on skin)

Rare Side Effects Include:
- New primary skin-type malignancies
- New non-cutaneous squamous cell carcinomas
- Tumor promotion in BRAF wild-type melanoma patients
- Serious hypersensitivity reactions (anaphylaxis and Drug Reaction with Eosinophilia and Systemic Symptoms - DRESS syndrome)
- Stevens-Johnson syndrome and toxic epidermal necrolysis (a life-threatening skin disorder)
- QT prolongation (ECG abnormality)
- Hepatotoxicity (liver damage)
- Photosensitivity (avoid sun exposure)
- Uveitis (eye inflammation)
- Harm to the fetus
- Radiation sensitization and recall
- Renal failure

Sorafenib Risks

Common Side Effects:
- Diarrhea
- Fatigue (feeling tired)

- Infection
- Alopecia (hair loss)
- Hand-foot syndrome (reddening and peeling of palms and soles)
- Rash
- Hypophosphatemia (low level of phosphate in the blood)
- Anemia (low levels of red blood cell in the blood)
- Thrombocytopenia (low level of platelets in the blood)
- Hypocalcemia (low level of calcium in the blood)
- Hypokalemia (low level of potassium in the blood)
- Elevated amylase or lipase
- Weight loss
- Anorexia (loss of appetite)
- Nausea
- Gastrointestinal and abdominal pain
- Hypertension (high blood pressure)
- Hemorrhage (bleeding)

Rare Side Effects:

- Gastrointestinal perforation
- Wound healing complications
- QT interval prolongation
- Hepatic failure and death
- Impairment of thyroid stimulating hormone suppression in patients with Differentiated Thyroid Carcinoma

Reproductive risks

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your doctor must agree on the method of birth control you will use during the entire study. If you think that you may be pregnant at any time during the study, you must tell your study doctor immediately. If you become pregnant, your participation in the study will end.

Men who are in this study should not get a sexual partner pregnant while taking the study drug and for 3 months after the last dose of study drug. The effect of the study drug on sperm is not known.

- Due to potential risk to a fetus woman of child-bearing potential must use effective contraception during treatment and for 6 months after the last dose of treatment.
- Male patients with female partners of reproductive potential or who are pregnant must use effective contraception during treatment and for 3 months after receiving their last dose.
- If a female patient confirms or suspects pregnancy during the study, they should contact their healthcare provider immediately.
- Patients on study treatment should not breastfeed while taking the medication and for 2 weeks after receiving their last dose.

Birth Control Requirements for Male Patients:
The study drugs may have a harmful effect on sperm. This can lead to damage to a fetus or embryo (developing unborn baby). If you are a fertile male, you must not impregnate a female while in this study. If you are sexually active, and able to father a child, you must agree to use two forms of birth control methods listed below:

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Hormonal methods used by your partner, such as birth control pills, patches, injections, vaginal ring, or implants
- Intrauterine device (IUD) used by your partner
- Abstinence (no sex)

You must use birth control for the entire study and for at least 3 months after your last dose of study drug. If your partner becomes pregnant while you are on the study or within 3 months of receiving the last dose of study medication, you will need to report this to your study doctor.

Other Risks

Risks of a Blood Draw: Risks can also occur during blood draws. The risk of blood drawing may include bleeding, pain, lightheadedness, fainting, bruising, clotting, discomfort, and/or infection at the site of the needle stick. Your blood will be drawn weekly during the study. Depending on your condition, your study doctor may wish to perform additional blood draws.

Risks of CT Scans, MRI Scans: CT scanning uses X-rays to create images of tissue below the skin. The risk of X-rays is slight. The amount of X-ray exposure that most people receive in a lifetime is not known to produce any illness. An allergic reaction to the dyes used to perform the CT scans is a possible risk of the procedure. CT dye may cause kidney injury. MRI uses magnetic fields to produce high-quality images of tissue below the skin. Therefore, subjects with metal in their bodies (such as cardiac pacemakers, metal prostheses [artificial body parts] and magnetic clips) will not be imaged. The MRI scanner is an enclosed space that may cause anxiety. The MRI makes a loud noise; you will be given ear protection. If you have kidney failure, MRI dye may cause a serious skin scarring and thickening disorder.

In addition to the risks listed above, there may be side effects that are not known at this time. Your condition may not get better or may get worse during this study. The dose you receive may be too low to have the best effect, or so high that it causes bad side effects.

Only you should take the study drug. It must be kept out of the reach of children or anyone else who may not be able to read or understand the label. Tell your doctor, and research staff, if any study drug is misplaced or lost during the study.

NEW INFORMATION
You will be told about any new information, findings, or changes to the way the study will be performed that might change your decision to be in this study. If there is new information, you may be asked to sign a new consent form.

BENEFITS
This study is for research purposes only.

There may be no direct medical benefit to you from participating in this study. You may gain information about your health from the different tests that are done as part of the study. Information obtained from this study will benefit the sponsor. It might also lead to treatments that help others in the future.

COSTS

- You do not have to pay a fee to take part in this research.
- Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. Make sure you fully understand the costs associated with your study participation before signing this consent form.
- The sponsor pays all the study costs, including study-specific procedures and the study drug associated with conducting the study.

    - Informed consent
    - Collection of medical history and demographics, adverse events and medication review
    - Vital sign collection including height and weight
    - ECOG performance status
    - Laboratories including CBC with differential, CMP, magnesium, inorganic phosphorus/phosphate, creatinine clearance, albumin, LDH, direct bilirubin, PT/INR, pregnancy test (if applicable), tumor markers (CA 19-9, CEA, CA-125)
    - Blood for correlative analysis
    - Confirmation of KRAS/BRAF mutation of archival tumor tissue
    - Pancreas biopsy collection (core of excisional biopsy of a tumor lesion)
    - 12 Lead ECG collection
    - Telephone contact follow-up
    - Bayer will be providing the sorafenib free of charge
    - Genentech will be providing the vemurafenib free of charge

- Your medical insurance may be billed for any standard medical care not being undertaken specifically for this study that you receive during the study.
- You may want to talk with your insurance company about its payment policy for standard medical care given during a research study because insurance companies may not pay for treatment that is part of a research study.
- If your insurance company does not pay, you may be billed for those charges.

PAYMENT FOR PARTICIPATION
You will not be paid to participate in the study.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there are other choices available. These include: chemotherapy, participation in another clinical trial, receiving no treatment. Ask the study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually, this care can be provided at home.

If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

CONFIDENTIALITY OF YOUR INFORMATION COLLECTED DURING THE STUDY
We will do our best to make sure that the personal information obtained about you during the course of this study will be kept private (such as using codes or keeping consent forms separate from data to ensure that the subject's name and identity will not become known or linked with any information they have provided). However, we cannot guarantee total privacy.

Unless required by law, you will not be identified on any electronic study related form by name, social security number, address and telephone number or any other information that can directly identify you. The information shared with the sponsor is protected by the use of a code, which is a number specifically assigned to you. The study doctor is in control of the code needed to connect your data to you, but the study doctor will not send the list with the code to the sponsor. However, the study forms may contain other information about you, such as your age, sex and medical history. It is possible that this other information could be used to identify you even though your name does not appear.

The results of this study may be published by the sponsor, including in a medical journal and shown at medical meetings. You will not be identified (by name or any other means, e.g., photo) in any of these publications or presentations.

Because this research is regulated by the Food and Drug Administration (FDA), the FDA may inspect records related to this research, which may include your protected health information or other information about you derived or maintained as part of this study.

Information derived from this study may be used for research purposes that may include publication and teaching. However, information used for publication and teaching will not disclose your identity.

Research Samples for Exploratory Biomarker Testing
As noted previously, a blood sample for research purposes will be collected at certain visits while you are participating in this study. These research de-identified samples will be used for exploratory biomarker testing. These de-identified samples will be placed in long-term storage until such time they are needed for testing for future research.

If available, your already obtained tumor sample used for diagnosis, will be obtained from the pathology department of the institution where the biopsy was done. These de-identified samples will be placed in long-term storage at HonorHealth until such time they are needed for future research.

COMPENSATION FOR INJURY
It is important that you carefully follow all the instructions given by the study doctor and study staff regarding the study. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you may go to any emergency room or urgent care facility to seek medical treatment. If it is determined that the injury or illness is not related to the research, the costs of this care may be charged to you or to your medical insurance. HonorHealth will not routinely compensate you for a study-related injury or illness. This does not mean that you are giving up any of your legal rights.

The study doctor will provide you medical care if you need it and will also treat you for any complications that may occur during your participation in the study. If you become ill or are injured as a direct result of your participation in this study, you will be provided the reasonable and necessary treatment for that injury or illness. The bills for the injury or illness not caused by study participation may be billed to your medical insurance or to your third party or governmental programs in which you participate.

The sponsor will not routinely reimburse costs for documented medical expenses for care and treatment of injury or illness caused by administration of the study drug and/or the use of medical device in accordance with the study protocol or any properly performed procedures required by the research. This includes a change from the study procedures described in this consent that are necessary to protect your rights, safety or welfare.

The sponsor will not reimburse costs for injury caused by your failure to follow your study doctor's or study staff's instructions for the study or that is the result of your preexisting medical condition or the natural progression of your disease or condition, unless exacerbated by participation in the study. The sponsor will not offer to pay costs of medical care for such an injury or items such as lost wages, expenses, compensation for pain and suffering, discomfort and disability. Please speak with your study doctor to make sure you understand your options regarding compensation for injury.

VOLUNTARY PARTICIPATION OR REMOVAL FROM STUDY
Your participation in this study is voluntary. You are free to decide not to take part or to withdraw from this study at any time without giving a reason. Neither decision will cause any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons, including but not limited to:

- it is in your best interest,
- you fail to follow directions for participating in the study,
- you do not consent to continue in the study after being told of changes in the research that may affect you,
- discontinuation of the study by the sponsor and/or study staff participating in the study prior to completion.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

SOURCE OF FUNDING FOR THE STUDY

TGen Foundation is providing funding support for this investigator initiated clinical trial at HonorHealth Research Institute.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you.

As referenced above, the HIPAA Privacy Rule is designed to protect the confidentiality of your protected health information (PHI). This section of the consent form is called an "Authorization" and explains how your PHI will be used and disclosed (shared) for purposes of the research and describes your rights with respect to such information.

What information will be collected by the study doctor and his research staff for this study?

The study doctor will collect your personal and medical information. This may include:

- Past and present medical records,
- Research records,
- Records about phone calls made as part of this research,
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff conducting the research.

Who will receive your personal and medical information collected?

Information from this study will be given to the study sponsor. The sponsor is the person or entity that initiates the study, provides oversight of activities within the study. Information will also be given to persons or companies that are contracted by the sponsor to have access to the research

information during and after the study. Medical records which identify you and this consent form signed by you will be looked at and collected for research purposes by:

- HonorHealth Research Institute, the sponsor,
- HonorHealth
- HonorHealth Human Subject Research Protection Program
- HonorHealth Research Institute, the study site

Your information may also be shared with the following people or groups:

- The FDA,
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases must be reported,
- WIRB Copernicus Group Institutional Review Board (WCG IRB®)
- HonorHealth Institutional Review Board
- HonorHealth Human Subjects Protection Program
- Genentech
- Bayer
- TGen

If your medical insurance company is billed, then it may also have access to the research records.

Why will this information be used and/or given to others?

- for research purposes as described in this consent form,
- for consideration by the FDA or any governmental agencies in other countries for drug approval,
- to make sure the study was conducted as approved by the IRB.
- to be used for future research purposes

The HonorHealth HSRPP and the HonorHealth Research Institute have the authority to review and monitor all records related to this research.

What will happen if you decide not to give permission to use and give out your private health information?
You cannot be in this research study.

Will you have access to the information collected during the study?
To maintain the integrity of this study, you will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you may request access to your health information that HonorHealth maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at HonorHealth. If it is necessary for your care, your health information will be provided to you or your physician.

Does this authorization expire?
This authorization does not expire unless it is canceled by you in writing. The study staff may need to correct or provide missing information about you even after your study participation is over. The review of your medical records may also take place after the study is over.

Can this authorization be withdrawn or canceled?
You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by the Privacy Rule. Absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

QUESTIONS
Contact Erkut Borazanci, MD at 480-323-1350 (24 hours) for any of the following reasons:

- if you have any questions, concerns, or complaints about the research or your participation in this study, or
- if at any time you feel you have had a research-related injury or a reaction to the study drug,

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may also contact:

WCG IRB
855-818-2289
researchquestions@wcgirb.com

WCG IRB is a group of people who independently review research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. You will need to contact the study doctor at the number above. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers. By signing this consent form, you are stating that you have been fully informed and give your consent to take part in the study.

A signed and dated copy of this consent form will be given to you for your records.

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.

CONSENT
I have read this consent form and understand what has been discussed. All my questions about the study and my part in it have been answered. I voluntarily consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

OPTIONAL: EXPLORATORY BIOMARKER TESTING
My leftover tumor tissue samples collected as part of this study may be kept by the sponsor for future research. I understand that if I check "No," I will still be able to take part in this study with no penalty.

YES ☐ **NO ☐**

_____
Subject Name (printed)

_____ _____
Signature of Subject Date

_____
Name of Person Conducting Informed Consent Discussion (printed)

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

---------- Use this witness section only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the study.

_____ _____

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.