THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Open-label Phase Ib/II Study of Cetuximab Administered in Combination with LY3214996 (ERK 1/2 Inhibitor) or Cetuximab in Combination with LY3214996 and Abemaciclib in Patients with Metastatic, Anti-EGFR-Refractory Colorectal Cancer
2019-1016

Subtitle: Main protocol v19FEB2020

Study Chair: Christine Parseghian

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical trial is to find the most effective dose of LY3214996 when given with cetuximab and abemaciclib in patients with advanced or metastatic colorectal cancer (mCRC).

This study will have two arms (or groups) of patients and the goal is to find the best dose of the investigational drug, LY3214996, in combination with two standard of care drugs: cetuximab and abemaciclib.

This is an investigational study. LY3214996 is not FDA approved or commercially available. Its use in this study is investigational. Cetuximab is FDA approved and commercially available for the treatment of colorectal cancer. Abemaciclib is FDA approved and commercially available for the treatment of breast cancer. The combination of these drugs is considered investigational in the treatment of advanced or metastatic colorectal cancer. The study doctor can explain how the study drugs are designed to work.

Taking the study drug(s) may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you will have a biopsy to decide if you are eligible.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may continue receiving the study drug(s) for as long as the doctor thinks it is in your best interest.

LY3214996, abemaciclib, and cetuximab will be provided at no cost to you while you are on the study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive other chemotherapy. You may choose to receive Lonsurf or Regorafenib outside of this study. You may choose to receive other investigational therapy, if available. The study doctor will discuss the possible risks and benefits of these treatments. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening test will help the doctor decide if you are eligible:

- You will have a physical exam.
- You will have an eye exam by an eye doctor.
- You will have an MRI or CT scan to check the status of the disease.
- Blood (about 3 tablespoons) will be drawn for routine tests and to check how well your blood clots.
- Blood (about 3 tablespoons) will be drawn to check for genetic mutations (changes), circulating tumor DNA (ctDNA), and for biomarker testing, which may include genetic biomarkers. Biomarkers are found in the blood and tissue and may be related to your reaction to the study drug.
- Urine will be collected for routine tests.
- You will have an EKG to check your heart function.
- Leftover tumor tissue, if available, will be collected for genetic and biomarker testing**.**
- You will have an image-guided core needle biopsy for genetic, pharmacogenomic (PGx), and tumor marker testing, to check the status of the disease, and will be used to make cell lines. Genetic and tumor marker testing may help researchers learn about your response to the study drug(s)

and about the status of the disease. PGx testing looks at how someone's genes may influence the study drug's effect on the disease. Cell lines are tissue cells that are grown in a laboratory or in research animals. To perform an image-guided core biopsy, a needle is inserted into the affected area using imaging such as CT, ultrasound, or MRI to collect tissue from an organ, lymph node, or suspected tumor mass. The doctor will use the imaging to guide the needle into the area.

- If you can become pregnant, blood (about 1 teaspoon) will be drawn for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Study Groups

If you are eligible to take part in this study, you will either be placed in Phase 1 or Phase 2 depending on when you join the study.

For both phases, you will be assigned to 1 of 2 groups. The study will start to enroll participants into Group A first. Once Group A is full, Group B will begin to enroll.

- If you are in Group **A**, you will receive LY3214996 and cetuximab.
- If you are in Group **B**, you will receive LY3214996, cetuximab, and abemaciclib.

Phase 1

In Phase 1, the study staff will be looking for the safest dose of LY3214996. If you are in Phase 1, you will receive LY3214996 in combination with either cetuximab or cetuximab and abemaciclib. Up to 2 dose levels of LY3214996 will be tested. Up to 6 participants will be enrolled at each dose level. The first group of participants will receive the highest dose level. If there are serious side effects with the highest dose, the next participants to join the study will receive a lowered dose. If no serious side effects are seen, the highest dose will be used for the Phase 2 part of the study.

Phase 2

If you are in Phase 2, you will receive LY3214996 at the dose found in Phase 1. You will receive LY3214996 in combination with either cetuximab or cetuximab and abemaciclib.

The doses of cetuximab and abemaciclib (if you receive it) will remain the same throughout the study.

Up to 23 participants will be enrolled in Part 1 and 23 in Part 2 of this study. All participants will take part at MD Anderson.

Study Drug Administration

Each study cycle is 28 days.

If you are in Arm A, you will receive LY3214996 daily by mouth, on an empty stomach (meals should not be eaten within 1 hour after taking the drug). You should take this drug at about the same time each day (within about 2 hours) as much as possible. If you miss or vomit a dose, you should skip that dose and wait until the following day.

You will receive cetuximab by vein on Day 1 and Day 15 of each cycle (every 2 weeks). During Cycle 1, cetuximab will be given over 2 hours. After that, if there are no side effects, it will be given over 1 hour.

If you are in Arm B, you will receive LY3214996 daily by mouth, on an empty stomach (meals should not be eaten within 1 hour after taking the drug). You should take this drug at about the same time each day (within about 2 hours) as much as possible. If you miss or vomit a dose, you should skip that dose and wait until the following day.

You will receive cetuximab by vein on Day 1 and Day 15 of each cycle (every 2 weeks). During Cycle 1, cetuximab will be given over 2 hours. After that, if there are no side effects, it will be given over 1 hour.

You will take abemaciclib by mouth twice each day (about every 12 hours) of every cycle. During all cycles, abemaciclib should be taken at about the same time each day. If you miss or vomit a dose, you should skip that dose and wait until the following day.

Instructions for LY3214996 and Abemaciclib:

- Store capsules in the original container.
- Keep out of reach of children at all times.
- Capsules should not be opened, crushed, or dissolved.

At the end of each study cycle or if you stop taking the study drug, you should return any unused drug to the study staff.

Study Visits

On **Day 1 of** every cycle**:**

- Blood (about 6 tablespoons) will be drawn for routine and biomarker testing.
- You will have a physical exam.
- You will have an EKG on Day 1 of Cycle 1 only.
- If you can become pregnant, blood (about 1 teaspoon) will be collected for a pregnancy test.

During Cycles 1 and 2:

- You will have a physical exam on Days 1, 8, and 15.
- You will have blood drawn for routine and biomarker testing on Days 1, 8, and 15.
- You will have an EKG on Days 1 and 15 of Cycle 1 only.

On Day 1 of Cycle 3 and every 8 weeks after that, you will have a CT or MRI to check the status of your disease.

On Day 15 of Cycle 1, you will have an image-guided core needle biopsy to check the status of the disease and to learn if your body has responded to the study drug(s).

If the study doctor thinks it is needed, you may have an eye exam at any time.

You will no longer be able to receive the study drug(s) if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

End of Treatment Visit

Within 30 days after your last dose of study drug, you will have an end-of-treatment visit. The following tests and procedures will be performed:

- You will have a physical exam.
- Blood (about 5 tablespoons) will be drawn for routine and biomarker testing.
- You will have an EKG.
- You will have a CT scan of your chest and a CT scan or MRI of your abdomen and pelvis.
- If the doctor thinks it is needed, you will have an eye exam.
- If you can become pregnant, blood (about 1 teaspoon) will be collected for a pregnancy test.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug/procedures.

LY3214996 and abemaciclib may each cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.

- A low white blood cell count may increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

LY3214996 Side Effects

This is the first study of LY3214996 in humans, so the side effects are not well known. Based on studies in animals and similar drugs, LY3214996 may cause the following side effects:

• headache • dizziness • swelling (arm/leg) • feeling tired • hair loss (partial/total) • skin rash/scabs/irritation • skin sensitivity to sunlight or lamps • abnormal salts, minerals, and/or acids in the blood (possible fatigue/weakness) • itchy skin • nausea	• vomiting • loss of appetite • abnormal taste • abdominal pain/swelling • heartburn • diarrhea • constipation • dehydration • mouth blisters/sores • injury to the ovaries • inability to have children • increase in infection-fighting cells	• low blood cell counts (white/red/platelets) • abnormal liver tests (possible liver damage) • blurry vision • vision problems • damage to the retina (possible vision problems) • abnormal kidney test (possible kidney damage) • kidney damage • cough • shortness of breath

LY3214996 may cause you to develop another type of cancer.

Cetuximab Side Effects

Common (occurring in more than 20% of patients)

• heart attack • fatigue/lack of energy • headache • difficulty sleeping • fever • skin rash (possibly acne-like), peeling, and/or itching • dry skin • nail changes • low blood levels of magnesium (possible weakness and/or seizures)	• weight loss • dehydration • abdominal pain • constipation • diarrhea • mouth blisters/sores (possible difficulty swallowing) • vomiting • nausea • loss of appetite • low white blood cell count	• abnormal liver tests (possible liver damage) • weakness • pain • nerve damage (loss of sensory function) • difficulty breathing • cough • sore throat • infection • severe rash at the site of previous radiation • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Cetuximab may commonly cause a low white blood cell count. A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Occasional (occurring in 3-20% of patients)

• confusion • depression • anxiety • chills/shivering • skin sores • hair loss (partial or total) • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering)	• low blood levels of calcium and/or potassium (possible weakness and/or cramping) • dry mouth • abnormal taste • upset stomach	• painful red eyes • immune reaction • infusion reaction (possible chills and/or hives) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Frequency unknown but occurring in 1-10% of patients

• hair growth

Rare but serious (occurring in fewer than 3% of patients)

• heart attack • stoppage of heart and lung function • decreased blood supply to the heart • low blood pressure (possible dizziness/fainting) • irregular heartbeat • inflammation of the membranes around the spinal cord and brain (possible headache and/or coma)	• shock • loss of consciousness • large skin blisters • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • changes in body salts such as sodium and/or potassium (possible fatigue and/or weakness)	• eye ulcer • kidney failure • lung inflammation (possible difficulty breathing) • difficulty breathing due to narrowing of the airways • blockage in the lung (possible pain, shortness of breath, and/or failure to breathe)

Abemaciclib Side Effects

Common (occurring in more than 20% of patients)

• fatigue • nausea	• upset stomach • diarrhea	• vomiting • loss of appetite

Occasional (occurring in 3-20% of patients)

• irregular heartbeat • fainting • headache • fever • weight loss • dehydration • dry mouth • hair loss • mouth blisters/sores (possible difficulty swallowing)	• abnormal taste • stomach pain • constipation • inflammation of the colon (possible abdominal pain and/or diarrhea) • low blood cell counts (red/white/platelets) • low blood levels of potassium (possible muscle cramps)	• decreased kidney function • abnormal kidney function test (possible kidney damage) • abnormal connections or passageways between organs, intestines, or vessels

Rare but serious (occurring in fewer than 3% of patients)

• heart failure • decreased heart function • fever • fainting • low blood levels of	• inflammation of the intestine • inflammation of the pancreas (possible abdominal pain) • abnormal liver tests	• lung inflammation (possible difficulty breathing) • severe life-threatening blood infection (possible low blood

sodium (possible headache, confusion, seizures, and/or coma) • decreased brain function (possible paralysis and/or coma)	(possible liver damage) • liver failure • weakness • kidney damage • kidney failure	pressure, kidney failure, and/or heart failure) • severe difficulty breathing

Abemaciclib may cause severe difficulty breathing.

Based on studies in animals, abemaciclib may cause the following side effects:

• skin and eye effects or sensitivity to light	• low birth weight • injury to the testes	• inability to have children • heart/bone birth defects

While you are taking abemaciclib, you should avoid the use of tanning beds and, if long exposure to sunlight is expected, you should use sunscreen and wear sunglasses.

Using the study drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

EKGs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may

cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications for Males and Females: If you can become pregnant or father a child, you must use an appropriate method of birth control while on the study and through the follow-up period of 30 days after the last dose of study drug.

Acceptable methods of birth control include: male condom with spermicide, female condom with spermicide, diaphragm with spermicide, cervical sponge, or cervical cap with spermicide. Talk with your study doctor about appropriate methods of birth control.

Tell the doctor right away if you or your partner becomes pregnant or suspects pregnancy. If you are pregnant, you will not be enrolled on this study.

Getting pregnant may/will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Eli Lilly for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Christine Parseghian, at 713-792-2828) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson. It may be dangerous to suddenly stop study treatment, and the study doctor can discuss ways to safely withdraw.

   The study staff may ask if they can continue collecting the results of routine care

from your medical record.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

   Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers may contact you to let you know what they have found.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: MD Anderson and Eli Lilly (supplier of drug).

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and Eli Lilly and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research. Leftover samples stored by Eli Lilly may be used in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Genetic research may include whole genome sequencing, which is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers

learn how changes in the ordering of genes may affect a disease or response to treatment.

Financial Interest Disclosure

Outside relationships are disclosed to and approved by the Conflict of Interest Committee, which reviews these relationships for compliance with institutional policy. This review helps the IRB to assure that financial relationships do not have an impact on the conduct of this study. The following members of the study staff have disclosed compensation from the funding source(s) of this study:

- Dr. Scott Kopetz (Co-Investigator)
- Dr. Michael Overman (Co-Investigator)

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Eli Lilly, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form
   - Any future sponsors and/or licensees of the study technology

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

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

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____	_____	_____
NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)