THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Phase II Study of 5-Azacytidine (AZA) + Venetoclax as Maintenance Therapy in Patients with AML in Remission
2019-0226

Subtitle: Genentech IIR

Study Chair: Tapan Kadia

_____ _____
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 research study is to learn if the combination of azacitidine and venetoclax can help control the disease when given to patients with acute myeloid leukemia (AML) that is in remission.

This is an investigational study. Azacitidine is FDA approved and commercially available for the treatment of myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML). Venetoclax is FDA approved for the treatment of chronic lymphocytic leukemia (CLL) and acute myeloid leukemia (AML). Using this study drug combination as a maintenance therapy during remission is investigational.

The study drugs 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 may experience low blood cell counts.

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

You may receive the study drug combination for up to 24 cycles (about 2 years).

Venetoclax will be provided to you at no cost while you are on this study by the study supporter, Genentech. You and/or your insurance provider will be responsible for the cost of azacitidine.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard therapy. The study doctor will discuss the possible risks and benefits of these treatments. You may choose to receive other investigational therapy, if available. 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 Visit

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be performed within 14 days of signing this consent to help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 2 tablespoons) will be drawn for routine tests within 4 days before your first dose of study drugs.
- You will have a bone marrow aspiration and/or biopsy performed to check the status of the disease and for cytogenetic testing within 28 days before your first dose of study drug. To collect a bone marrow aspirate and/or biopsy, an area of the hip is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle. Cytogenetic testing looks at how genetic changes to cells may affect how the disease may react to the study drugs.
- If you can become pregnant, you will have blood (included in the routine blood test listed above) or urine collected for a pregnancy test within 10 to 14 days after enrolling in the study. 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 options will be discussed with you.

Up to 50 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

Each cycle is 28 days.

You will receive azacitidine as an injection under the skin or by vein over about 1 hour on Days 1-5 of each cycle.

You will take venetoclax by mouth every day on Days 1-14 of each cycle. You should take it with a meal and water at about the same time each day. Do not chew, crush, or break the tablets. Each dose should be swallowed whole.

If you are taking certain drugs (such as antifungal medicines) that may affect how your body processes the study drug, your dose of venetoclax may be lowered. Depending on how your body reacts to venetoclax during Cycle 1, your doctor may choose a different dose and schedule for you to take for the rest of the study. This will be discussed with you.

If you miss a dose of venetoclax by less than 8 hours, take the missed dose right away. Take your next dose the following day as usual. If you miss a dose and it has been more than 8 hours since the scheduled dosing time, do not take the dose that day. Take the next dose as scheduled. If you vomit after taking a dose, do not "make up" the dose. Wait and take the next dose as scheduled.

You may receive fluids or other medications to help reduce the risk of side effects. The study doctor will discuss this with you.

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

Study Visits

At least 1 time each week during Cycle 1, then every 2-4 weeks during Cycles 2-6, then every 4 weeks as long as you are on study, blood (about 2-4 tablespoons) will be drawn for routine tests.

On **Day 28 of Cycles 1-3, then every 3 months (Cycles 6, 9, and 12), then every 6 months (Cycles 18 and 24):**

- You will have a physical exam.
- Depending on the status of the disease**,** you may have a bone marrow biopsy and/or aspiration to check the status of the disease

Follow-Up Phone Call

About 30 days after your last dose of the study drugs, the study staff will call you to ask how you are doing. This phone call should last about 5 minutes

Long-Term Follow-Up

About every 6-12 months after your last dose of study drugs, you will have a study visit if you are not enrolled in a leukemia department long-term follow-up study. At this visit, blood (about 1-2 teaspoons) will be drawn for routine tests and you will have a physical exam.

Other Information

While taking part in this study, you should not take part in any other research study without checking with the study doctors of each study.

It is very important that you tell your study doctor what prescription and non-prescription drugs, vitamins, nutritional, and herbal supplements you are taking.

Do not receive a live vaccine within 4 weeks before your first dose of venetoclax, during treatment with venetoclax, and after treatment until the study doctor tells you it is okay to receive a vaccine. If you are not sure if a vaccine is live or not, please talk to the study doctor. These vaccines may not be safe and/or may not work as well during treatment with venetoclax. The study doctor will provide further information on non-live vaccines you can receive on the study.

Certain non-live COVID-19 vaccines may be given during the study. However, they may not be as effective since venetoclax lowers the number of infection-fighting cells in your body. The study doctor will discuss this with you, if needed.

Do not drink grapefruit juice or eat grapefruit, Seville oranges or marmalades, or starfruit while taking venetoclax. These products may increase the amount of venetoclax in your blood.

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 product/procedures.

Venetoclax and azacitidine may each cause a low blood cell count (red, 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 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.

Venetoclax Side Effects

Common (occurring in more than 20% of patients)

• fatigue • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• diarrhea • constipation nausea/vomiting	• loss of appetite • low blood cell counts (red, platelets, white)

Occasional (occurring in 3-20% of patients)

• low blood pressure (possible dizziness/fainting) • dizziness • headache • weakness • swelling (arm/leg) • fever • headache	• abdominal pain • weight loss • mouth blisters/sores (possible difficulty swallowing) • gall bladder inflammation (possible abdominal pain) • back pain • joint pain • high blood levels of uric acid (possible painful joints and/or kidney failure)	• abnormal kidney tests (possible kidney damage) • upper respiratory infection • urinary tract infection • pneumonia • cough • difficulty breathing • nosebleeds • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

You should wear ear plugs or other hearing protection when involved in a loud activity.

If you notice any rash, hives, itching, or other signs of an allergic reaction such as swelling, wheezing, or you are having a hard time breathing, tell your doctor right away.

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

• tumor lysis syndrome (TLS)--breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

TLS is a problem that can occur when cancer cells break down rapidly and the body has to get rid of the broken up cell parts. Sometimes your body, especially the kidneys, cannot remove the cell parts quickly enough, so the level of some of these cell products in your blood, such as salts and acids, can rise. This can happen

especially in participants with large tumors or a high number of cancerous white cells in the blood. TLS can lead to serious problems, such as effects on your kidneys and heart (including abnormal heart rhythms), seizures, or even death.

If you develop TLS, your urine may look dark, thick, or cloudy. You may have fever, chills, nausea/vomiting, diarrhea, confusion, shortness of breath, irregular heartbeat, fatigue, muscle pain, joint discomfort, and/or seizure. If you notice any of these, tell your doctor or nurse right away. Your study doctor will closely watch and treat you as needed to lower the risk of any serious changes in your blood or other complications of TLS. You may need to have extra blood tests or EKGs to check for signs of TLS.

Serious Infections
Infections, including serious infections and some infections leading to death, have been reported in patients taking venetoclax. Your doctor may advise you to take medicines to help prevent some common infections for which you may be at risk. Your doctor may also advise you to take other measures to reduce your chance of developing an infection. If you notice fever or other symptoms of infection, tell your doctor or nurse right away.

Other Cancers
Some patients who have received several previous chemotherapy treatments may develop another cancer. It is unknown if venetoclax has contributed since these types of cancers can happen in people who have not received venetoclax.

Side effects seen in pre-clinical studies
Side effects that have been seen in studies in animals are reported below. Some of these side effects have been also seen in studies where patients with cancer have been treated with venetoclax. It is not clear, at this time, if venetoclax treatment is causing the side effects to happen or if they are caused by other medical conditions that the patients were having at the same time or had in the past.

- Decrease in sperm cells in male dogs. It is unknown how long this decrease may last. It could be permanent. This may affect the ability of a man taking venetoclax to father a child. If you are a man who is planning to have children in the future, you should consider sperm banking before receiving treatment on this study.
- Areas of hair color change (to white or gray) without changes in the skin or eye color.

The meaning of these findings in animal studies to humans is unclear. You will be watched closely for signs of these and other potential side effects.

Azacitidine Side Effects

The following side effects have been reported when azacitidine is given either by vein or as an injection under the skin:

Common (occurring in more than 20% of patients)

• fever • fatigue/lack of energy • headache • nausea • vomiting	• diarrhea • constipation • loss of appetite • low blood cell counts (red, white, platelets) • weakness	• pain • shivering • cough • difficulty breathing • injection site redness and/or pain

Occasional (occurring in 5-20% of patients)

• chest pain • pale skin • swelling (arm/leg) • abnormal heart sound • fast heartbeat • low blood pressure (possible dizziness/ fainting) • high blood pressure • fainting • dizziness • anxiety • depression • difficulty sleeping • numbness • hives and/or skin redness • skin bump/sores/rash • dry skin and/or itching • sweating	• low blood levels of potassium (possible weakness /or muscle cramps) • weight loss • abdominal pain, tenderness, and/or swelling • bleeding gums • tongue sores • bleeding in the mouth • mouth blisters and/or sores (possible difficulty swallowing) • upset stomach • hemorrhoids • difficulty swallowing • difficult and/or painful urination • blood in the urine • sore throat	• muscle cramps • nosebleed • stuffy and/or runny nose • abnormal breath sounds • wheezing • build-up of fluid around the lungs • lymph node swelling • infection • hardened tissue/inflammation/skin discoloration at the injection site • injection site swelling, itching, and/or rash • increased risk of bleeding after a procedure/surgery • reaction to a blood transfusion

Rare but serious (occurring in fewer than 5% of patients)

• irregular heartbeat • heart failure • bleeding in and/or around the brain • seizures • skin condition with fever and skin lesions • decay of body tissue	• tarry stool • enlarged spleen • bone marrow failure • liver failure • kidney failure • build-up of bodily waste products in the blood (possible kidney problems)	• allergic reaction, which may be life-threatening (such as difficulty breathing, low blood pressure, and/or organ failure) • severe life-threatening infection (possible low blood pressure, kidney

• lesions due to skin infection • abnormal blood acid/base balance (possible organ damage) • dehydration • gallbladder inflammation (possible abdominal pain) • digestive system bleeding	• coughing up blood • lung inflammation (possible difficulty breathing) • tissue death at the injection site caused by drug leakage • bleeding in the eye • catheter site bleeding • infection at the injection site	failure, and/or heart failure) • breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

Azacitidine may cause you to develop another type of cancer (such as leukemia, a type of blood cancer).

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

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

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.

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 or for 30 days after the last dose of study drug. You must use birth control during the study if you are sexually active.

Birth Control Specifications:

If you or your partner/spouse are able to become pregnant, you must agree to use 2 effective methods of birth control while you are on this study and for 30 days after the last dose of study drug.

Effective methods of birth control include:

- Hormonal birth control such as pills, vaginal rings, or patches (hormonal methods must be used with a barrier method, such as a condom)
- Bilateral tubal occlusion (getting your “tubes tied”)
- Intrauterine device (IUD) or intrauterine hormone-releasing system (IUS)
- Vasectomy of yourself or your only male partner (with confirmation that vasectomy surgery was a success)

If you can father a child, you must use a condom during sexual activity, even if you have had a successful vasectomy, during the study and for 30 days after the last dose of study drug.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

If your partner/spouse becomes pregnant while you are enrolled in this study or within 30 days after the last dose of study drug, the study sponsor (Genentech) would like to collect information about the pregnancy. The study sponsor's contact information will be made available so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

Females: If you are pregnant, you will not be enrolled on this study.

If you become pregnant or suspect that you are pregnant while you are enrolled in this study, or within 30 days after the last dose of study drug, you must tell your doctor right away. The sponsor will ask for information about the pregnancy.

Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure #1: You will be asked to have additional blood (about 1-2 teaspoons) drawn at the screening visit for antibody testing. Antibodies are created by the immune system and may attack foreign cells or substances, such as the study drug.

Optional Procedure #2: You will also be asked to have additional blood (about 1-2 teaspoons) drawn for antibody testing weekly during Cycle 1 and on Day 28 of Cycles 3, 6, and 12.

Optional Procedure 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.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to allow additional blood (about 1-2 teaspoons) to be drawn at the screening visit for antibody testing?

YES NO

Optional Procedure #2: Do you agree to allow additional blood (about 1-2 teaspoons) to be drawn weekly during Cycle 1 and on Day 28 of Cycles 3, 6, and 12 for antibody testing?

YES NO

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 Genentech/Roche 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. Tapan Kadia, at 713-563-3534) 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 who can help you safely stop study treatment. It may be dangerous to suddenly stop study treatment. The study doctor will also decide if you need to have any visits or tests to check on your health. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Genentech/Roche, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

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.

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: Genentech/Roche.

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

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

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.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or 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 samples are used for future research. If this 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 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 this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic 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. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

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.

Conflict of Interest

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. Elias Jabbour (Collaborator)
- Dr. Nitin Jain (Collaborator)
- Dr. Naval Daver (Collaborator)

Outside Care

Part of your care may be provided outside of MD Anderson by your home doctor(s).

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
- Genentech/Roche, 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

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. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

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.)