THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A Phase II Study of Vibecotamab (XmAb14045) for MRD-Positive AML and MDS after Hypomethylating Agent Failure

2021-1124

Study Chair: Nicholas Short, MD

_____ _____
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). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

STUDY SUMMARY

The goal of this clinical research study is to learn if vibecotamab can be used to control acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) that has not responded to standard therapies. The safety of this drug will also be studied.

This is an investigational study. Vibecotamab is not FDA approved or commercially available. It is currently being used for research purposes only. The study doctor can describe how the study drug is designed to work.

The study drug 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 challenges related to the cost of staying in Houston, travelling to the clinic for treatment, and not being eligible for other studies or therapies.

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

Depending on the group you are enrolled in, you will receive vibecotamab for up to 4 cycles (about 4 months) or for as long as the study doctor thinks it is in your best interest. 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.

Vibecotamab will be provided to you at no cost while you are on this study. You and/or your insurance provider will be responsible for the costs of the study drug infusions.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard treatment for AML or MDS, which may include a combination of chemotherapy drugs or stem cell transplantation. The study doctor will discuss the possible risks and benefits of these treatments. You may choose to receive other drugs, or supportive care alone (including transfusions). 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 Tests

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

- You will have a physical exam.
- Blood (about 2-3 teaspoons) will be collected for routine tests.
- Blood (about 6 teaspoons) will be drawn for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.
- You will have a bone marrow aspirate to check the status of the disease and for biomarker and genetic testing. The genetic testing will look for genetic mutations (changes) in the DNA found in the bone marrow. To collect a bone marrow aspirate, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow is withdrawn through a large needle.
- If you can become pregnant, urine will be collected 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 options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be assigned to a study group based on your disease type: AML or MDS. Each group has 2 cohorts: Cohort 1 and Cohort 2.

If you are in **Cohort 1** of the AML or MDS group, you will receive vibecotamab for up to 4 cycles.

If you are in **Cohort 2** of the AML or MDS group, you will receive vibecotamab for as long as the study doctor thinks it is in your best interest, until the disease comes back or gets worse.

The study doctor will tell you the group and cohort you are assigned to.

Up to 80 participants (20 in each cohort) will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

Each study cycle is 28 days.

You will receive vibecotamab by vein (IV) over about 2 hours.

If you are in **Cohort 1** of the AML or MDS group, you will receive vibecotamab on Days 1, 3, 5, 8, 15, and 22 of Cycle 1 and then on Days 1, 8, 15 and 22 of Cycles 2-4.

If you are in **Cohort 2** of the AML or MDS group, you will receive vibecotamab on Days 1, 3, 5, 8, 15, and 22 of Cycle 1 and then on Days 1, 8, 15 and 22 of Cycles 2 and beyond.

You will be hospitalized for the first 4 doses, and you will be monitored for 4 hours after each dose. You and/or your insurance provider will be responsible for the costs of this hospitalization. If you tolerate the first 4 doses well, then the rest of the doses may be given as an outpatient, and you will be monitored for 2 hours after each dose.

You will be given the following standard drugs to help decrease the risk of side effects:

- Dexamethasone by vein over about 60 minutes before the dose
- Acetaminophen [Tylenol®] by mouth about 30-60 minutes before the dose
- Diphenhydramine [Benadryl®] either by mouth or vein about 30-60 minutes before the dose

Study Visits

On **Days 1, 3, 5, 8, 15, and 22 of Cycle 1** before receiving vibecotamab:

- Blood (about 2-3 teaspoons) will be drawn for routine tests.
- On Day 1 only, you will have a physical exam.
- On Day 1 only, if you can become pregnant, urine will be collected for a pregnancy test.

On **Days 1, 8, 15, and 22 of either Cycles 2-4 (if you are in Cohort 1) or Cycles 2 and beyond (if you are in Cohort 2)**, before receiving vibecotamab:

- Blood (about 2-3 teaspoons) will be drawn for routine tests.
- On Day 1 only, if you can become pregnant, urine will be collected for a pregnancy test.

On **Day 28 of Cycles 1 and 4, then every 3-4 cycles after that , and at any time the study doctor thinks the disease may have returned:**

- You will have a bone marrow aspirate to check the status of the disease, for biomarker testing, and/or for cytogenetic testing. Cytogenetic testing looks at how genetic changes to cells may affect how the disease may react to the study drug. You may have this procedure done more or less often depending on how the disease responds to the study drug.
- Blood (about 4-6 teaspoons) will be drawn for biomarker testing.

On **Day 28 of Cycles 2 and 3,** blood (about 4-6 teaspoons) will be drawn for biomarker testing.

If your body begins to make antibodies that attack the study drug, blood (about 2-3 teaspoons) will be drawn for immune system testing. Antibodies are created by the immune system and may attack foreign cells or substances, such as the study drug.

End-of-Dosing visit and Follow-up

After you stop receiving the study drug, 30 days after the last dose, and then every 6 months after that until the study closes, you will be called and asked about your health and any side effects you may be having. Each call should last about 5-10 minutes.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. 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.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

Vibecotamab and diphenhydramine may cause low blood cell counts (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.

Vibecotamab (XmAb14045) Side Effects

This is an early study of vibecotamab in humans, so the side effects are not well known. Based on early human studies, vibecotamab may cause the following side effects:

• abnormal EKG • swelling (arms/legs) • low blood pressure (possible dizziness/fainting) • high blood pressure • fast heartbeat • chills • fever • fatigue • difficulty sleeping • headache • dizziness • confusion • anxiety • fainting • increased sweating • change in skin color due to bruising • dry skin • high blood sugar (possible diabetes) • abnormal salts, minerals, and/or acids in the blood (possible	• mouth blisters/sores (possible difficulty swallowing) nausea/vomiting • diarrhea • loss of appetite • constipation • abdominal pain • abdominal swelling • abnormal amount of protein in urine • blood in urine • increased risk of bleeding • low oxygen level in the blood (possible lightheadedness) • abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes) • muscle weakness • pain	• nerve damage (possible numbness, pain and/or loss of motor function) • decreased kidney function (possible kidney failure) • stuffy nose • shortness of breath • cough • fast breathing • severe life-threatening blood infection (possible low blood pressure, kidney failure, and/or heart failure) • drug leakage from the infusion site • infusion reaction (possible chills and/or hives) • immune reaction (possible loss of drug function and/or

weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• walking/balance problems (possible falling)	increase the seriousness of listed risks)

Vibecotamab may cause cytokine release syndrome. This involves a release of a large amount of proteins into the blood stream. This may cause changes in blood pressure and heartbeat, flu-like symptoms (nausea, fever, and chills), and/or affect your lung/liver/kidney function. It may also cause certain brain-related symptoms, such as dizziness, weakness, confusion, difficulty speaking, and/or decreased brain function (possible paralysis and/or coma).

Vibecotamab may cause neurologic (brain-related) problems, such as confusion, disorientation, difficulty speaking, or tingling or numbness in the body during or soon after infusions. Because of the possibility of this happening, you should not drive or operate heavy machinery while receiving vibecotamab and for 30 days after receiving the last dose of vibecotamab.

Vibecotamab may cause build-up of fluid in the lungs (which may cause difficulty breathing), trouble breathing, or other lung side effects, or swelling in other parts of the body.

Vibecotamab may cause problems with your heart, including heart failure, inflammation of the membrane around the heart, and/or build-up of fluid in the tissue around the heart. Any or all of these can cause shortness of breath, swelling of ankles, tiredness, and/or chest pain.

Dexamethasone Side Effects

It is not well known how often the following side effects may occur.

• high blood pressure • irregular, fast, and/or slow heartbeat • enlarged heart • heart failure • tearing of the walls of the heart (post-heart attack) • blood vessel inflammation (possible bleeding and/or bruising) • blood clots in a vein (possible pain, swelling, and/or redness) • blood clots in the arteries • swelling (such as tissue and/or abdominal swelling) • dizziness • shock • fainting • headache • increased pressure in the skull or between the skull and brain (possible headache, vision changes, and/or mental status changes) • seizure • depression • fatigue and anxiety • mood swings • personality changes • mental disorders • euphoria (unusual feelings of happiness or well-being) • difficulty sleeping • fatigue/lack of energy • darkening and/or lightening of the skin • tiny dots on the skin • impaired wound healing	• decreased ability to process carbohydrates • high blood sugar (possible diabetes) • diabetes • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • abnormal blood acid/base balance (possible organ damage) • low blood levels of potassium (possible weakness and/or muscle cramps) • high blood levels of sodium (possible weakness and/or swelling) • sugar in the urine • body-wide loss of proteins (possible weakness and/or swelling) • build-up of fat in abnormal areas • weight gain • increased appetite • digestive system bleeding • small red or purple spots in the mouth • esophageal sore • hole in the intestines (possibly leaking contents into the abdomen) • nausea • itching near the anus • inflammation of the pancreas (possible abdominal pain) • stomach ulcer	• inflammation of nerves (possible pain and/or loss of motor or sensory function) • joint disease (possible pain) • pain or loss of function of the hips or shoulders due to bone death • broken bones • loss of muscle • muscle damage causing weakness • nerve damage (loss of motor or sensory function) • loss of bone strength (possible broken bones) • abnormal sensation (such as pins and needles) • tendon tear • collapse of bones in the spine • enlarged liver • abnormal liver tests (possible liver damage) • bulging eye • increased pressure in the eye (possible vision loss, pain, and/or blurry vision) • cataracts (clouding of the lens of the eye) • hiccups • fluid in the lung (possible difficulty breathing) • breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage) • infection

• skin rash, redness, and/or dryness • fragile and/or thinning skin • skin test reaction impaired (due to a lowered immune system) • stretch marks • hives • acne-like rash • hair loss (partial or total) • hair growth • sweating • tissue death • Cushing's syndrome (possible weakness, diabetes, and/or bone weakness)	• changes to the menstrual cycle • problems with production of sperm • bruising • muscle weakness	• allergic reaction (such as skin reaction) • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Dexamethasone may cause you to develop another type of cancer.

Dexamethasone may cause a false-positive or false-negative skin test (such as a test for tuberculosis [TB]). If you need to have a skin test performed, tell the doctor that you are taking dexamethasone.

Stopping dexamethasone suddenly may cause withdrawal symptoms (such as fever, muscle/joint pain, and fatigue). This is because dexamethasone affects your adrenal glands and may cause your body's hormone levels to change. The study doctor will help you stop dexamethasone safely, if you want to stop taking the study drug. Do not just stop taking dexamethasone.

Acetaminophen Side Effects

An overdose of acetaminophen may cause damage to the liver.

Diphenhydramine Side Effects

It is not well known how often the side effects of diphenhydramine may occur.

• chest tightness • extra heartbeats • low blood pressure (possible dizziness/ fainting) • irregular/fast heartbeat	• difficulty sleeping • sweating • loss of appetite • constipation • diarrhea	• abnormal sensation (such as pins and needles) • inflammation of nerves (possible pain and/or

• chills • confusion • seizures • loss of coordination • dizziness • headache • euphoria (unusual feelings of happiness or well-being) • unusual excitement • irritability • nervousness • restlessness • sedation • fatigue or sleepiness	• dry mucous membranes • abdominal pain • nausea • throat tightness • vomiting • dry mouth • changes to the menstrual cycle • difficult and/or frequent urination • inability to urinate • low blood cells (white and platelet) • anemia due to destruction of red blood cells • tremor	loss of motor or sensory function) • blurry and/or double vision • inflammation of part of the ear that controls balance • ringing in the ears • stuffy nose • increased thickness of secretions in the lung • wheezing • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Diphenhydramine may cause low blood cell counts (white and/or platelet):

- 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/or difficulty breathing.

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.

<u>Other Risks</u>

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

Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you

compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

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 and for at least 4 weeks after your last dose of study drugs, if you are sexually active.

Birth Control Specifications: The study doctor or staff will discuss the birth control methods with you.

Males: Do not donate sperm while on study and for 4 weeks after your last dose of study drug. Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. If your partner/spouse becomes pregnant while you are on this study, the sponsor 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: Do not donate eggs while on study and for 4 weeks after your last dose of study drug. If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, 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.

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 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.

If you become injured or ill as a direct result of taking part in this study, the sponsor may pay for the treatment of the injury or illness. MD Anderson cannot determine at this time what you may be reimbursed for. A financial counselor will be made available to you after the injury or illness is reported.

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. Nicholas Short, at 713-792-8760) 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. The study staff may ask if they can continue collecting the results of routine care from your medical record. 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, Xencor, Inc., 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, if you are unable to follow study directions, or if the study is stopped.

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: Xencor, Inc.

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 Xencor, Inc. 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 Xencor, Inc. may be used 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 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 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 will 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.

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
   - Xencor Inc., who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Any future sponsors and/or licensees of the study technology
   - 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.

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.)