Informed Consent/Authorization for Participation in Research

Title of Research Study: A Phase 2 Study Evaluating Olutasidenib in combination with Hypomethylating Agents in patients with IDH1-mutated Higher-Risk Myelodysplastic Syndromes, Chronic Myelomonocytic Leukemia, or Advanced Myeloproliferative Neoplasms

Study Number: 2024-0515

Principal Investigator: Kelly Chien, MD

_____ _____
Participant's Name Medical Record Number

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you have Higher-Risk Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukemia (CMML), or Advanced Myeloproliferative Neoplasms (MPN), and the disease has an IDH1 mutation.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this clinical research study is to learn if olutasidenib when combined with

azacitidine, which is a drug called a hypomethylating agent (HMA), can help to control MDS, CMML, and/or MPN. The safety of the drug combination will also be studied.

This is an investigational study. Olutasidenib is FDA approved for the treatment of acute myeloid leukemia (AML), but not for the diseases being tested in this study. Azacitidine is FDA approved for the treatment of MDS and CMML. It is investigational to give azacitidine for the treatment of MPN. It is investigational to give azacitidine in combination with olutasidenib to patients with MDS, CMML, and/or MPN. The test to detect IDH1 mutations is investigational.

How long will the research last and what will I need to do?

You are expected to be in this research study for as long as the study doctor thinks it is in your best interest.

You will be asked to take the study drugs and attend several study visits, at which you will have various tests and procedures performed to check your health and for research purposes.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

The most common side effect of olutasidenib is abnormal liver tests, which may indicate liver damage. Another serious side effect to be particularly aware of is differentiation syndrome, symptoms of which include fever, difficulty breathing, swelling, altered mental status and/or kidney failure. Other side effects include buildup of fluid in the area around the heart, lung inflammation, low blood pressure, and weight gain.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

It cannot be promised that there will be any benefits to you or others from your taking part in this research. However, the study drugs may help to control the disease. Future patients may benefit from what is learned.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, your choices may include: standard of care treatment with azacitidine or other HMAs. Other clinical trials may also be available. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits, with you.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-745-7584.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics 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 cannot reach 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.

How many people will be in this study?

It is expected about 45 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

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 tablespoons) will be drawn for routine tests.
- You will have an EKG to check your heart function.
- You will have a bone marrow aspirate/biopsy to check the status of the disease and for research tests. On this study, research tests will include biomarker testing, including genetic biomarkers. Biomarkers are found in blood/tissue and may be related to your reaction to the study drug.

- If you can become pregnant, you will have a blood (about 1 teaspoon) or urine 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 Drug Administration
Study cycles will be 28 days long.

You will take capsules of **olutasidenib** 2 times each day while you are on study. Each dose should be taken about 12 hours apart at least 1 hour before or 2 hours after a meal. Do not break, open, or chew the capsules. If a dose of olutasidenib is vomited, do not take a replacement dose; wait until the next scheduled dose is due. If a dose of olutasidenib is missed or not taken at the usual time, take the dose as soon as possible as long as it is at least 8 hours prior to the next scheduled dose. Return to the normal schedule the following day.

Azacitidine will be given on Days 1-7 of each cycle either by vein over about 15 minutes or as an injection under the skin.

If you show signs of differentiation syndrome, you may be treated with hydroxyurea and a corticosteroid such as dexamethasone 2 times a day until symptoms improve. Additional treatment may be required. The study doctor can tell you more about this.

Study Visits

You will have study visits each week during Cycles 1 and 2, and then on Day 1 of every cycle after that. On **Day 1 of each cycle**:

- You will have a physical exam.
- Blood (about 2 to 3 tablespoons) will be drawn for routine and, at some cycles, research tests. The research tests will be optional. You can choose whether or not to have these tests later in this document.
- You will have a bone marrow aspirate/biopsy to check the status of the disease and for research tests on Day 1 of Cycle 2 and then every 3 cycles after that until Cycle 13. After that, you will have these every 12 cycles. The research tests will be optional. You can choose whether or not to have these tests later in this document.

On **Days 8, 15, and 22 of Cycles 1 and 2**, blood (about 2 to 3 tablespoons) will be drawn for routine tests.

End-of-Dosing
After you stop receiving the study drugs:

- You will have a physical exam.
- Blood (about 2 to 3 tablespoons) will be drawn for routine and, at some cycles, research tests. The research tests will be optional. You can choose whether or not to have these tests later in this document.
- You will have a bone marrow aspirate/biopsy to check the status of the disease and for research tests. The research tests will be optional. You can choose whether or not to have these tests later in this document.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study team about any symptoms or side effects you have, follow study directions, and come to all study appointments (or contact the study team to reschedule).
- Tell the study doctor/study staff about all medications that you are taking or plan to take, including prescription and over-the-counter medications, supplements, vitamins, and herbal remedies.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the study doctor so that the study doctor can help you safely withdraw. 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.

Is there any way being in this study could be bad for me? (Detailed 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.

Olutasidenib Side Effects

Common (occurring in more than 20% of patients)

• skin rash • 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) • constipation	• abnormal digestive blood test (possible inflammation of the pancreas) • nausea • mouth blisters/sores (possible difficulty swallowing) • increase in infection-fighting cells • abnormal liver test (possible liver damage)	• fatigue/lack of energy • joint pain • abnormal kidney test (possible kidney damage) • difficulty breathing • fever • fatigue

Occasional (occurring in 3-20% of patients)

• swelling • high blood pressure • abnormal EKG • abdominal pain • loss of appetite • diarrhea	• vomiting • painful spasm or blockage of the gall bladder • blockage of the bile tract (possible body yellowing and/or abdominal pain)	• differentiation syndrome (fever, difficulty breathing, swelling, altered mental status and/or kidney failure) • headache • cough

The drug may cause an increased risk of infection, such as pneumonia. This infection may occur anywhere. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

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 • lesions due to skin infection • abnormal blood acid/base balance (possible organ damage) • dehydration • gallbladder inflammation (possible abdominal pain) • digestive system bleeding	• tarry stool • enlarged spleen • bone marrow failure • liver failure • kidney failure • build-up of bodily waste products in the blood (possible kidney problems) • 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	• 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 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) • differentiation syndrome (fever, difficulty breathing, swelling, altered mental status and/or kidney failure)

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

Azacitidine may 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 increases your risk of infection (such as pneumonia, infection of the mouth/throat/skin, urinary tract infection, and/or severe blood infection [possible low blood pressure, decreased kidney function, and/or heart failure]). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Hydroxyurea Side Effects

Hydroxyurea may **commonly** cause low white blood cell counts. 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.

Rare

• low sperm count • liver damage	• lung damage (possible difficulty breathing) • lung inflammation	• breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

Frequency unknown

• destruction and/or irritation of small blood vessels • swelling • dizziness • weakness • chills • hallucinations (seeing or hearing things that are not there) • confusion • headache • fatigue/lack of energy • seizure • nerve damage (possible numbness, pain, and/or loss of motor function) • hair loss (partial or total) • facial redness • skin redness • eczema (skin inflammation)	• skin rash, bumps, and/or sores • darkening of the skin • decay of body tissue • nail changes • skin thinning, peeling, scaling, and/or sores • inflammation of the fatty layer under the skin • mouth blisters/sores (possible difficulty swallowing) • loss of appetite • digestive system irritation • constipation • diarrhea • nausea • vomiting • inflammation of the pancreas (possible abdominal pain)	• difficult and/or painful urination • enlarged red blood cells • low blood count (red and/or platelet) • liver failure • abnormal kidney test (possible kidney damage) • decreased kidney function (possible kidney failure) • high blood levels of uric acid (possible painful joints and/or kidney failure) • difficulty breathing (possibly due to narrowing of the airways) • bone marrow failure

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

The usual side effects of short-term **dexamethasone** treatment (days/weeks) include weight gain, psychological disorders, high blood sugar, and failure of hormone-producing organs.

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 **bone marrow aspirates/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.

The test being used to check for detect IDH1 mutations is investigational, so there is a chance of either a **false positive or false negative** result:

- A “false positive” result means the test found IDH1 mutation, but it is actually not present in the tumor. As a result, you would be considered eligible to move forward with screening for the main study and could be exposed to potential risks of the study drug without receiving any potential benefit.
- A “false negative” result means the test did not find IDH1 mutation, but it is actually present in the tumor. As a result, you would not be considered eligible to move forward with screening for the main study that may benefit you.

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.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

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 90 days after treatment if you are sexually active. Talk to the study doctor about birth control options.

Females: 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.

Getting pregnant will result in your removal from this study.

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

Will it cost anything to be in this study? Will I be paid to be in this study?

Olutasidenib will be provided at no cost to you on this study. You and/or your insurance provider will be responsible for the cost of azacitidine.

You and/or your insurance provider will not have to pay for certain research exams and procedures done that are covered by the study. You and/or your insurance provider will be responsible for the costs of routine clinical services (such as diagnostic/therapeutic procedures, drugs, devices, laboratory assays, and other services that would ordinarily be ordered for medical care, regardless of whether or not you are participating in a study). There may be extra costs that are not covered by your medical plan that you will have to pay yourself.

Taking part in this study may result in added costs to you (such as transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the clinic/hospital more often than if you were not participating in this study.

If you have insurance, talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data or samples be used for 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.

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

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Some of your specimens and genetic and/or health information might also be placed into one or more external publicly-accessible scientific databases. Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include worsening of the disease or intolerable side effects.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. Chien, at 713-745-7584) or 713-792-2121 (24 hours)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson 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.

What else do I need to know?

This research is being funded by Rigel Pharmaceuticals, Inc.

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

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

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 will not contact you to let you know what they have found.

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members, or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Please contact the study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

Part of your care may be provided outside of MD Anderson by your home doctor(s). Some of your study visits may be performed at home or via telemedicine. The study team will tell you more about this possibility.

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:

- Courtney DiNardo (Co-Investigator)

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: If you agree, blood (up to 2-3 tablespoons) will be collected for research tests on Day 1 of Cycle 1, at the end of Cycle 1, then every 3 cycles through Cycle 12, then every 12 cycles after that. This will also be done if at any time the disease gets worse.

Optional Procedure #2: If you agree, bone marrow will be collected for routine tests on Day 1 of Cycle 1, at the end of Cycle 1, then every 3 cycles after that. This will also be done if at any time the disease gets worse.

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.

Having **bone marrow aspirates/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.

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 have blood collected for research tests?

YES NO

Optional Procedure #2: Do you agree to have bone marrow collected for research tests?

YES NO

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
   - Rigel Pharmaceuticals, Inc., who is a supporter of this study, and/or any future sponsors/supporters of the study, 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 do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

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

By signing the consent form, the witness attests that the consent information was accurately explained to and appears to have been understood by the participant and that informed consent was freely given by the participant.

_____ _____
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

By signing the consent form, the investigator or delegated investigator site staff attests that the informed consent was freely given by the participant and the consent information was accurately explained to and appears to have been understood by the participant.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT