THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Phase 1 Dose Escalation Study of CPX-351 alone or in Combination with Venetoclax for Patients with Int-2 or High risk IPSS Myelodysplastic Syndromes and Chronic myelomonocytic leukemia after failure to hypomethylating agents
2018-0911

Study Chair: Guillermo Montalban Bravo

_____ _____
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 the MD Anderson Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to find the highest tolerable dose of CPX-351 that can be given alone or in combination with venetoclax to patients with myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML). Researchers also want to learn more about the safety and effects of the drug and drug combination.

This is an investigational study. CPX-351 is FDA approved and commercially available for the treatment of acute myeloid leukemia (AML), but not for the treatment of MDS or CMML. Its use in this study is investigational. Venetoclax is FDA approved and commercially available for the treatment of AML and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). It is considered investigation to give CPX-351 alone or in combination with venetoclax to patients with MDS or CMML.

The study doctor can explain how CPX-351 and venetoclax are designed to work.

The study drug(s) may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study. If you have newly diagnosed MDS, you will be forgoing approved therapies with known benefit to participate 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.

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

If you receive CPX-351 alone, you may continue taking the study drug for up to 14 cycles (each cycle is 28 days long), as long as the doctor thinks it is in your best interest. If you receive CPX-351 with venetoclax, you may receive up to 4 cycles of CPX-351 and receive venetoclax for as long as the doctor thinks it is in your best interest.

CPX-351 will be provided at no cost to you while you are on study. You and/or your insurance provider will be responsible for the cost of venetoclax.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard-of-care treatments for MDS or CMML outside of this study. Your study doctor will talk to you about other treatments or therapies that are available and their benefits and risks. You may choose to receive other investigational therapy, if available. You may choose not to have treatment 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.
- You will have an EKG and either a MUGA scan or echocardiogram (ECHO) to check your heart function.
- Blood (about 2 teaspoons) will be drawn for routine tests.
- You will have a bone marrow biopsy and aspirate to check the status of the disease, cytogenetic testing, molecular mutation tests (tests to look for changes in DNA [the genetic material in cells]), and biomarker testing. Cytogenetic testing looks at how genetic changes to cells may affect how the disease may react to the study drug. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. To collect a bone marrow biopsy/aspirate, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.

- If you can become pregnant, urine or blood (about 1 teaspoon) 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 treatment 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 (Cohort 1, 2, 3, 4, or 5) based on when you join this study and/or the type of disease you have. The study doctor will discuss your study group assignment with you.

Up to 57 participants will be enrolled in this study. All will take part at MD Anderson.

CPX-351 Alone
If you are assigned to Cohort 1 or 2, you will receive CPX-351 alone.

If you are in Cohort 1, the dose of CPX-351 you receive will depend on when you join this study. The first group of participants will receive the lowest dose level of CPX-351. Each new group will receive a higher dose of DRUG than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of CPX-351 is found.

If you are enrolled in Cohort 2, you will receive CPX-351 at the recommended dose that was found in Cohort 1.

CPX-351 with Venetoclax
If you are assigned to Cohort 3, 4, or 5, you will receive CPX-351 with venetoclax.

If you are in Cohort 3, you will receive CPX-351 at the recommended dose that was found in Cohort 1 and 2. The dose of venetoclax you receive will depend on when you join this study. The first group of participants will receive the starting dose level of venetoclax. If intolerable side effects are seen in the first group of participants, the next group will receive a lower dose level of venetoclax. If no intolerable side effects were seen in the first group of participants, the next group will receive the same starting dose level of venetoclax.

If you are enrolled in Cohort 4 or 5, you will receive CPX-351 at the recommended dose that was found in Cohort 1 and 2 and venetoclax at the recommended dose that was found in Cohort 3.

Study Drug Administration
Each study cycle is 28 days.

Cohorts 1-2: CPX-351 Alone

You may receive up to 14 cycles of CPX-351 alone. CPX-351 is given by vein over about 90 minutes (about 1½ hours).

You will receive CPX-351 on Days 1, 3, and 5 of Cycle 1 (called an Induction Cycle). If the disease does not get better after Cycle 1, you may receive CPX-351 on Days 1 and 3 of another Induction Cycle (Cycle 2). If the disease gets worse, you will no longer take part in this study.

If the disease gets better after the Induction Cycle(s) and the study doctor thinks it is in your best interest, you may receive CPX-351 on Days 1 and 3 for up to 12 more cycles (called Consolidation Cycles).

Cohorts 3-5: CPX-351 with Venetoclax
You may receive up to 4 cycles of CPX-351 and venetoclax for as long as the study doctor thinks it is in your best interest. CPX-351 is given by vein over about 90 minutes (about 1½ hours). You will take venetoclax by mouth. Take venetoclax with a glass of water (about 1 cup) and within 30 minutes before or after a meal.

You will receive CPX-351 on Days 1, 3, and 5 and venetoclax on Days 1-7 of Cycle 1 (called an Induction Cycle). If the disease does not get better after Cycle 1, you may receive CPX-351 on Days 1 and 3 and venetoclax on Days 1-7 of another Induction Cycle (Cycle 2). If the disease gets worse, you will no longer take part in this study.

If the study doctor thinks it is in your best interest, you may then receive CPX-351 on Days 1 and 3 and venetoclax on Days 1-7 for up to 2 more cycles (Cycles 3 and/or 4; called Consolidation Cycles).

After Cycles 3 and/or 4, you may either have a stem cell transplant as part of your standard care outside of this study or you may receive maintenance therapy as part of this study. If you receive maintenance therapy, you will receive venetoclax on Days 1-7 and azacitidine (given by vein over about 15-30 minutes or as an injection under the skin) on Days 1-5 of each Maintenance Cycle. You will continue to receive maintenance therapy until you have a stem cell transplant as part of your standard care or the study doctor thinks it is no longer in your best interest.

Azacitidine is FDA and approved and commercially available for the treatment (maintenance) of AML. You and/or your insurance provider will be responsible for the cost of azacitidine.

All Participants
Depending on your age and health, you may be admitted to the hospital during the first cycle. The study doctor will tell you more about this.

You may be given standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

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

Study Visits

Before **each cycle**:

- You will have a physical exam.
- Blood (about 2 teaspoons) will be drawn for routine tests.

At least **every week** during each Induction Cycle, blood (about 2 teaspoons) will be drawn for routine tests. **Every 2-4 weeks** during each Consolidation Cycle, blood (about 2 teaspoons) will be drawn for routine tests. If the study doctor thinks it is needed, this will be done more often.

On Day 28, you will have a bone marrow aspirate and/or biopsy to check the status of the disease, biomarker testing, and for cytogenetic testing. If the study doctor thinks it is needed, you may have a bone marrow aspirate and/or biopsy **between cycles** to check the status of the disease.

Follow-Up

About 30 days after your last dose of study drug(s), and then about every 6 months after that, you will be called by a member of the study team and asked how you are feeling. Each call should last about 10 minutes.

Other Research

The study staff may ask you to take part in another MD Anderson clinical research study (LAB01-473 and/or PA19-0345) for immune system and molecular studies. You will be given a separate informed consent document that describes this study that you will need to sign if you want to participate.

Other Information

While on study, avoid grapefruit, Seville (sour) oranges, and star fruit, including juices and products containing these fruits. Tell the study doctor/study staff about all medications (including prescription and over-the-counter), herbal remedies, supplements, and vitamins you are taking or plan to take while on study.

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.

CPX-351, venetoclax, and azacitidine may each cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia, severe fungal infection, and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

CPX-351 Side Effects

Common (occurring in more than 20% of patients)

• swelling • irregular heartbeat • heart damage • low blood pressure (possible dizziness/fainting) • headache • fatigue • difficulty sleeping • chills	• skin rash • diarrhea • nausea • inflammation of the intestines • mouth blisters/sores (possible difficulty swallowing) • constipation • abdominal pain	• loss of appetite • vomiting • low blood cell counts (red, platelets, white) • bacteria in the blood • muscle and/or bone pain • cough • difficulty breathing

Occasional (occurring in 3-20% of patients)

• high blood pressure • chest pain • fever • dizziness • delirium (loss of contact with reality) • anxiety • hallucinations (seeing or hearing things that are not there) • itching • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood	• hemorrhoids • upset stomach • abnormal liver test (possible liver damage and/or yellowing of the skin and/or eyes) • eye dryness, pain, irritation, inflammation, redness, and/or swelling • deafness • decreased kidney function • low oxygen level in the blood (possible lightheadedness)	• build-up of fluid around the lungs • lung inflammation (possible difficulty breathing) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • injection site swelling, pain, and/or heat

pressure, organ failure, heart problems, changes in mental status, and/or seizure)		

At this time, there are no known side effects that **occur in fewer than 3% of patients**.

You may continue to have low white blood cell counts after you stop taking CPX-351, putting you at risk for infection even after you stop taking the drug.

Venetoclax Side Effects

Common (occurring in more than 20% of patients)

• swelling (arm/leg) • fatigue • high blood sugar (possible diabetes) • 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 • nausea • low blood counts (red, platelets, and white) • abnormal liver tests (possible liver damage)	• muscle and/or bone pain • upper respiratory tract infection • cough

Occasional (occurring in 3-20% of patients)

• fever • headache • dizziness • skin rash • vomiting • constipation	• abdominal pain • mouth blisters/sores (possible difficulty swallowing) • joint pain • pneumonia	• difficulty breathing • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

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

• tumor lysis syndrome (TLS)

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.

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.

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	• 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	• 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

• difficulty sleeping • numbness • hives and/or skin redness • skin bump/sores/rash • dry skin and/or itching • sweating	• hemorrhoids • difficulty swallowing • difficult and/or painful urination • blood in the urine • sore throat	• 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).

<u>Study Drug Combination Side Effects</u>

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

Other Risks

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

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

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

MUGA scans may cause allergic reactions to the radioactive tracer, injection site soreness, and/or swelling. They may cause damage to cells or tissue from being exposed to the radiation used in the scan. These side effects may occur in less than 10% of patients.

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

This study may involve unpredictable risks to the participants.

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

Birth Control Specifications: If you can become pregnant or father a child, you must use acceptable methods of birth control while you are on study. Male participants must use condoms. Female participants must use birth control patches, pills, or injections, intrauterine device [IUD], double-barrier method [spermicidal jelly or foam with condoms or diaphragm], or surgical sterilization.

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

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 may result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Jazz Pharmaceuticals for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 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.

Additional Information

4. You may ask the study chair (Dr. Guillermo Montalban Bravo, at 713-794-3604) 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 713-792-2933 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 continue to 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 at any time by the study chair, Jazz Pharmaceuticals, 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, including the results of all of your standard tests performed as part of this research, 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: Jazz Pharmaceuticals.

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 713-792-2933.

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.

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

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

Genetic Research

Any 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.

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:

- Elias Jabbour and Courtney DiNardo (Collaborators)

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
- Jazz Pharmaceuticals, 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.)