



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Phase 1b Study of ALRN-6924 in Combination with Paclitaxel in Wild-type TP53 Advanced or Metastatic Solid Tumors including Estrogen-Receptor Positive Breast Cancer
2018-0561

Subtitle: Main Informed Consent

Study Chair: Ecaterina E. Dumbrava

Participant's Name

Medical Record Number

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

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

STUDY SUMMARY

There are 2 parts to this clinical research study: Part 1 (dose escalation) and Part 2 (dose expansion).

The goal of Part 1 of this clinical research study is to find the highest tolerable dose of ALRN-6924 in combination with paclitaxel that can be given to patients who have advanced solid cancers with a specific normal protein, p53. The p53 protein helps control the growth of cancer cells.

The goal of Part 2 of this study is to learn if the dose of ALRN-6924 in combination with paclitaxel found in Part 1 can help to control advanced cancer in patients who have a specific mutation (genetic change).

The safety of this drug combination will also be studied.

ALRN-6924 is not FDA approved or commercially available. It is currently being used for research purposes only. Paclitaxel is FDA approved and commercially available

for the treatment of many types of cancer, including the type of cancer you have. It is considered investigational to combine ALRN-6924 and paclitaxel. Its use in this study is investigational. The study doctor can explain how the study drugs are designed to work.

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

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You can read a full list of potential side effects below in the Possible Risks section of this consent.

You may continue taking the study drugs for as long as the doctor thinks it is in your best interest.

While you are on this study, ALRN-6924 will be provided at no cost to you. You and/or your insurance provider will be responsible for the cost of paclitaxel.

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

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be performed within 28 days before your first study drug dose to help the doctor decide if you are eligible.

- You will have a physical exam.
- You will have 3 EKGs in a row to check your heart function.
- Blood (about 10 teaspoons) will be drawn for routine tests and biomarker testing, including genetic biomarkers. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drugs.
- Urine will be collected for routine tests.
- You will have a CT scan, MRI, or a bone scan to check the status of the disease.
- If you are being screened to participate in Part 2, you will have a tumor biopsy for biomarker testing (including genetic biomarkers). The type of tumor biopsy you have will depend on the type and location of the tumor. The study staff will discuss this with you.
- If the doctor thinks it is needed, blood (about 1 teaspoon) will be drawn for tumor marker testing. Tumor markers may be related to the status of the disease.

- If you have a history of hepatitis B, hepatitis C, and/or HIV, additional blood (about 2 teaspoons) will be drawn to check the amount of virus in your blood and your immune function.
- If you can become pregnant, blood (about 1 teaspoon) will be drawn for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other 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 when you join this study. Up to 3 dose levels will be tested in Part 1. It is not known at this time how many participants may be enrolled in each dose level. Up to 15 participants will be enrolled in Part 2.

If you are enrolled in Part 1, the dose of ALRN-6924 you receive will depend on when you join this study. The first group of participants will receive the lowest dose level of ALRN-6924. Each new group will receive a higher dose of ALRN-6924 than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of ALRN-6924 is found.

If you are enrolled in Part 2, you will receive ALRN-6924 at the highest dose that was tolerated in Part 1.

All participants will receive the same starting dose of paclitaxel. However, if you have side effects and the doctor thinks it is needed, your dose may be lowered.

The study doctor will let you know what study group and which part of the study you are participating in.

Study Drug Administration

Each study cycle is 28 days.

You will receive paclitaxel by vein over about 1 hour on Days 1, 8, and 15 of each cycle. About 2 hours after the paclitaxel infusion, you will receive ALRN-6924 by vein over 1 hour on Days 1, 8, and 15 of each cycle.

You may also 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. The study doctor also may lower the dose of paclitaxel or ALRN-6924 to try to decrease side effects.

Your doctor may stop you from taking part in this study without your consent and 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.

Your participation in this study will be over after follow-up.

Study Visits

On Day 1 of Cycle 1:

- You will have a physical exam.
- You will have 3 EKGs in a row before the dose of study drugs.
- Blood (about 6 teaspoons) will be drawn for routine tests.
- Blood (about 1-2 teaspoons each time) will be drawn for testing on cytokines (proteins that may affect the immune system) within 1 hour before the dose of ALRN-6924 and again 3 hours after your dose of ALRN-6924.
- If you can become pregnant, urine will be collected for a pregnancy test.

On **Day 2 of Cycle 1**, blood (up to 10 teaspoons) will be drawn for cytokine testing.

On Days 8, 15, and 22 of Cycle 1:

- You will have a physical exam.
- Blood (about 6 teaspoons) will be drawn for routine tests.

Between Days 8-10 of Cycle 1, if you are in Part 2, you will have a tumor biopsy collected for biomarker testing (including genetic biomarkers).

On Day 1 of Cycles 2 and beyond:

- You will have a physical exam.
- Blood (about 6 teaspoons) will be collected for routine tests and to test how well your blood clots.
- You will have an EKG before the dose of study drugs.
- Blood (about 4 teaspoons) will be drawn for genetic biomarker testing.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test.

On **Days 8 and 15 of Cycles 2 and beyond**, blood (about 2-6 teaspoons) will be drawn for routine testing.

Every 8 weeks, you will have a CT scan, MRI, or bone scan to check the status of the disease. If the doctor thinks it is needed, blood (about 1 teaspoon) will be drawn for tumor marker testing.

If the doctor thinks it is needed, the study tests may be repeated or additional tests may be performed (such as scans, blood draws, and other tests).

End-of-Study Visit

Within 30 days after your last dose of study drugs:

- You will have a physical exam.
- You will have an EKG.
- Blood (about 8 teaspoons) will be drawn for routine testing and biomarker testing (including genetic biomarkers).
- You will have a CT scan, MRI, or bone scan to check the status of the disease. If you had one within the last 6-8 weeks, this does not need to be repeated.

- If the doctor thinks it is needed, blood (about 1 teaspoon) will be drawn for tumor marker testing.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test.

Long-Term Follow-Up

For 1 year after the end-of-treatment visit, about every 2 months, the study staff will call you and ask how you are doing. After 1 year, the study staff will call you every 3 months for as long as the study is open. The calls should take about 10-15 minutes.

Other Information

It is important that you tell the study doctor about all prescription and non-prescription drugs, herbal preparations, and nutritional supplements you are taking or planning to take. ALRN-6924 may interfere with other drugs you are taking for high blood pressure, high cholesterol, or other conditions.

There are certain types of medications that you are not allowed to take while on study. It is very important that you discuss with the study staff all medications that you are taking or plan to take. You will be told if you can or cannot continue taking these.

2. POSSIBLE RISKS

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

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

ALRN-6924 and paclitaxel may cause low blood cell counts (red blood cells, platelets, and 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.

ALRN-6924 Side Effects

This is an early study of ALRN-6924 in humans, so the side effects expected are not yet well known. Based on early studies in humans, ALRN-6924 may cause the following side effects:

<ul style="list-style-type: none"> • low blood pressure (possible dizziness/fainting) • fatigue (reduced activity/movement) • headache • weakness • facial swelling (possible difficulty breathing) • 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) 	<ul style="list-style-type: none"> • loss of appetite • nausea/vomiting • constipation/diarrhea • upset stomach • low red blood cell counts • abnormal liver tests (possible yellowing of the skin and/or eyes) • difficulty breathing • injection site pain, swelling, redness, and/or changes in skin color 	<ul style="list-style-type: none"> • infusion reaction (possible fever, chills, swelling and/or hives) • inflammation of the vein and tissue at/around the injection site • breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, other organ damage, and/or death)
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ALRN-6924 may cause tissue swelling (angioedema). If you experience tissue swelling, please call the study doctor or study staff.

Paclitaxel Side Effects

Common (occurring in more than 20% of patients)

<ul style="list-style-type: none"> • abnormal EKG • swelling • flushing • hair loss (partial or total) • mouth blisters/sores (possible difficulty swallowing) 	<ul style="list-style-type: none"> • nausea/vomiting • diarrhea • low blood cell counts (red/platelets/white) • abnormal liver tests (possible liver damage) • pain (muscle/joint) 	<ul style="list-style-type: none"> • nerve damage (possible numbness, pain, and/or loss of motor function) • abnormal kidney test (possible kidney damage) • allergic reaction • infection
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Occasional (occurring in 3-20% of patients)

<ul style="list-style-type: none"> • low blood pressure (possible dizziness/fainting) • slow heartbeat 	<ul style="list-style-type: none"> • skin rash • abdominal pain • abnormal liver tests (possible yellowing of the skin and/or eyes) 	<ul style="list-style-type: none"> • weakness • injection site reaction (possible redness, swelling, skin discoloration)
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Rare but serious (occurring in fewer than 3% of patients)

<ul style="list-style-type: none"> • fast/irregular heartbeat • blood clots in a vein (possible pain, swelling, and/or redness) • heart failure • heart attack • decreased blood supply to the heart • high blood pressure • fainting • decreased brain function (possible paralysis and/or coma) • decreased brain function due to liver damage • seizure • severe sunburn-like rash at site of previous radiation (called radiation recall) • death of skin • worsening of existing scleroderma (severe hardened skin, which can cause difficult movement) 	<ul style="list-style-type: none"> • inflammation at the site of previous tissue death • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • inflammation of the pancreas (possible abdominal pain) • inflammation of the intestines • dehydration • hole in the intestines (possible leaking contents into the abdomen) • decreased blood flow to part of the bowel (possibly causing death of tissue) • paralysis of the intestines 	<ul style="list-style-type: none"> • intestinal blockage • difficulty walking • liver damage and/or failure • hearing loss • decreased kidney function • blockage in the lung (possible pain and/or shortness of breath) • lung inflammation and/or damage (possible difficulty breathing) • blood clots in the lung (possible failure to breathe) • difficulty breathing • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) • tissue death at the injection site caused by drug leakage
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Using the study drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

Other Risks

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

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

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

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

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

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

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

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 6 months after your last study drugs dose if you are sexually active.

Birth Control Specifications: Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

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 will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree and you are in Part 1, you will have a tumor biopsy at screening and between Days 8-10 of Cycle 1 for biomarker testing (including genetic biomarkers). The study doctor will explain what type of biopsy you will have and its risks.

Optional Procedure #2: If the disease gets worse and if you agree, you will have a tumor biopsy for biomarker testing (including genetic biomarkers). The study doctor will explain what type of biopsy you will have and its risks.

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 Risks:

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

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

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

Optional Procedure #1: If you are in Part 1, do you agree to have tumor biopsies at screening and between Days 8 and 10 of Cycle 1 for biomarker testing?

YES NO

Optional Procedure #2: Do you agree to have a tumor biopsy for biomarker testing if the disease gets worse?

YES NO

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Aileron Therapeutics, Inc 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.

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

Additional Information

4. You may ask the study chair (Dr. Ecaterina E. Dumbrava , at 713-563-1930) 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. If you withdraw from this study, you can still choose to be treated at MD Anderson.
6. This study or your participation in it may be changed or stopped at any time by the study chair, Aileron Therapeutics, Inc, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.
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: Aileron Therapeutics, 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 713-792-2933.

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

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.

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.

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

- Aileron Therapeutics, 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.

Aileron Therapeutics, Inc. will provide the study drugs and support this study. MD Anderson is the sponsor of the study.

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

- B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.
- C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

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

- D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.
- E. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

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

SIGNATURE OF PARTICIPANT

DATE

PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SIGNATURE OF LAR

DATE

PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2018-0561**.

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

DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

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 below.)

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

DATE

PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION