THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Study of Erdafitinib in Castration-Resistant Prostate Cancer Patients Evaluating Markers of Bone Remodeling and FGF Signaling in Plasma and Bone Marrow

2020-0953

Study Chair: Paul G. Corn

_____ _____
Participant's Name Medical Record Number

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

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

STUDY SUMMARY

The goal of this clinical research is to learn if erdafitinib can help to control advanced prostate cancer.

This is an investigational study. Erdafitinib is FDA approved and commercially available to treat urothelial (bladder) cancer. It is considered investigational to give erdafitinib to patients with prostate cancer. The study doctor can explain how the study drug is designed to work.

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

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience fatigue, low blood pressure, abnormal salts and minerals, or infection. If you are not from the Houston area, travel to the clinic may be a burden.

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

You will receive erdafitinib for as long as the doctor thinks it is in your best interest.

Erdafitinib will be provided at no cost to you while on this study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive a standard approved treatment for the disease, such as androgen deprivation therapy (Lupron, for example). You may choose to receive other investigational therapy, if available. The study doctor will discuss with you the possible risks and benefits of these treatments. 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 tests/procedures will help the study doctor decide if you are eligible. Some of the below tests will need to be performed within 30 days before your first dose of study drug, and some will need to be performed within 14 days before your first dose.

- You will have a physical exam.
- You will have an eye exam by an eye doctor and an Amsler Grid test to check your vision. During the Amsler Grid test, you will be asked to cover each eye separately and look at a grid to track any changes in your vision.
- Blood (about 2 ½ to 3 ½ tablespoons) will be drawn for tests including:
    - Routine tests
    - Circulating tumor cell (CTC) testing - CTC testing measures the amount of tumor cells in the blood
    - Tests to check your bone marrow, kidney, and liver function
    - Tests to measure your prostate specific antigen (PSA) and testosterone levels
    - Bone alkaline phosphatase (BAP) testing – BAP testing helps the doctor check the status of the disease by measuring the levels of an enzyme called alkaline phosphatase, which is produced by the skeletal system.
    - Samples for correlative studies – these studies are other clinical research studies performed at MD Anderson. Samples collected for correlative studies during this study will be used for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.
- You will have an EKG to check your heart function.

- You will have imaging scans to check the status of the disease. This may include a bone scan and an x-ray, CT scan, PET-CT scan, and/or MRI of your chest, abdomen/pelvis, and/or brain, if the doctor thinks it is needed. The study doctor will discuss what kind of imaging scans you will have and what areas will be scanned.
- You will have a bone marrow aspirate/biopsy for biomarker testing in correlative studies. To collect a bone marrow aspirate/biopsy, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and/or bone is withdrawn through a large needle.
- Archival (leftover) tissue from a previous procedure, if available, will be collected for biomarker testing in correlative studies.

If the screening tests show that you are not eligible, you will not be able to take part in the study. Other treatment options will be discussed with you.

Up to 40 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration
You will take erdafitinib by mouth 1 time a day each day in this study. After you have received the study drug for 14 days, your dose may be increased depending on how well you tolerate it and results of certain blood tests. The study doctor will discuss this with you.

You should take the study drug, with or without food, at about the same time each day with a glass (about 8 ounces) of water. The capsules should be swallowed whole; do not crush, chew, or dissolve them in water. If you miss a dose, you may make up the dose up as soon as possible on the same day only. If more than a day has passed, do not make up the missed dose. Only take the dose you are scheduled to take that day. If you vomit after taking a dose, do not make up the dose; wait and take the next dose as scheduled.

Take the study drug as instructed. Do not give the study drug to anyone else, and keep the study drug out of reach of children. You should bring all empty packaging and unused study drug with you to each study visit.

You will no longer be able to take the study drug if the study doctor decides that the disease has gotten worse, if you have intolerable side effects, if you are unable to follow study directions, if you choose to withdraw from the study, or if the study ends.

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

Study Visits
Each cycle is 21 days.

On **Day 1 of Cycle 1,** you will have a physical exam.

On **Day 14 of Cycle 1,** blood (about ½ teaspoon) will be drawn for routine tests.

On **Day 1 of Cycles 2, 4, 6, and 7:**

- You will have a physical exam.
- You will have an Amsler Grid test to track changes in your vision. At any time in this study, if your Amsler Grid test shows an abnormality, the study doctor may refer you to an eye doctor.
- Blood (about 4 teaspoons) will be drawn for routine tests.

On **Day 1 of Cycles 3 and 5:**

- You will have a physical exam.
- You will have an eye exam by an eye doctor.
- You will have an Amsler Grid test to track changes in your vision.
- Blood (about 2 tablespoons) will be drawn for routine tests, PSA testing, and biomarker testing.
- You will have the same imaging scans described in screening to check the status of the disease.
- During Cycle 3 only, you will have a bone marrow biopsy/aspirate for biomarker testing in correlative studies.

On **Day 1 of Cycles 8 and beyond:**

- You will have a physical exam.
- You will have an Amsler Grid test to track changes in your vision.
- Blood (about 4 teaspoons) will be drawn for routine tests.
- Every 3 cycles (Cycle 8, 11, 14, and so on), blood (about 1-2 tablespoons) will be drawn for biomarker testing in correlative studies.
- Every 2 cycles for the first 6 months, then every 3 cycles for 9 months after that, blood (about 1-2 tablespoons) will be drawn for PSA testing, CTC testing, and BAP testing. This test may be repeated any time the doctor thinks it is needed.
- Every 2 cycles for the first 6 months, then every 3 cycles for 9 months after that, you will have the same imaging scans described in screening to check the status of the disease. These scans may be repeated any time the doctor thinks it is needed.

End-of-Treatment Visit

Within 30 days after your last dose of erdafitinib, you will have an End-of-Treatment Visit. The following tests and procedure will be performed:

- You will have a physical exam.
- You will have an Amsler Grid test to track changes in your vision.
- Blood (about 1 ½ - 3 tablespoons) will be drawn for routine tests, PSA testing, CTC testing, BAP testing, and biomarker testing in correlative studies.
- You will have the same imaging scans described in screening to check the status of the disease.

Long-Term Follow-Up Visits

If you stopped taking the study drug because the disease got worse, you will have a follow-up visit about every 16 weeks for 1 year, then every 6 months after that. At these visits, the study team will check on how you are doing, including any side effects are you experiencing. If you cannot come to the clinic for these visits, the study team will contact you by phone, video call, or email, to check on your health.

If you stopped taking the study drug for any reason other than the disease getting worse, you will continue to follow the schedule for the PSA, CTC, and BAP blood draws and imaging scans described in study visits (every 2 cycles for the first 6 months, every 3 cycles for 9 months after that, and any time the doctor thinks it is needed after that). These visits will continue unless the disease gets worse and/or your side effects resolve, if applicable.

Other Information

- During this study, for your safety, you should come to all study visit appointments and give accurate information about your medical history and current medical condition.
- Erdafitinib is cleared from the body by the liver and may interact with other drugs that are cleared in the liver. Because of this, it is very important that you do not take any additional drugs, including over-the-counter or prescription drugs or herbal remedies, during the study without first checking with the study team.
- Do not have immunizations with live vaccines (such as vaccines for rubella, mumps, measles, and so on) while receiving the study drug and for 3 months after your last dose.
- Do not take any other anti-cancer treatments while taking part in this study.
- You should not take part in any other medical research studies that are intended to treat your bladder cancer or symptoms.
- During the COVID-19 pandemic or in the event of a natural disaster, the study visits described above may be performed remotely using a video call platform and some tests (such as blood tests or imaging scans) may be performed at a lab closer to your home. The study doctor will discuss this with you if needed.

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.

Erdafitinib Side Effects

Very Common (occurring in more than 35% of patients)

• fatigue • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• dry mouth • abnormal taste • loss of appetite • diarrhea • mouth blisters/sores and/or pain in the mouth (including cheeks, tongue, or lips, possible difficulty swallowing)	• abnormal liver tests (possible liver damage) • abnormal kidney tests (possible kidney damage)

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.

Common (occurring in 10-35% of patients)

• fever • dry/cracking skin • hair loss (partial or total) • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering) • separation of the nail from the nail bed • nail discoloration	• infection of the fingernails/toenails • weight loss • abdominal pain • nausea/vomiting • constipation • low blood cell counts (red/platelets/white) • pain (including muscle, joint, bone, mouth, and/or throat)	• dry eyes • blurry vision • detached retina (possible partial blindness) • damage to the retina (possible vision loss) • partial or total loss of vision • inflammation inside the eye • blood in the urine

Erdafitinib may cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause shortness of breath 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.

Uncommon (occurring in 5-10% of patients)

• itching • high blood sugar (possible diabetes) • dry nose	• nosebleed • painful/dry throat	• eye disorders (red/irritated eyes, possible watery/itchy eyes) • teary eyes • difficulty breathing

Erdafitinib may cause nail changes (including brittleness, peeling, ridging, and breakage). It may also cause changes in the thickness, color, or strength of the nails.

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.

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

During the **eye exam**, your pupils will be dilated with eye drops to allow a good view of the back of the eye. This will result in some blurred vision lasting for a few hours. You will not be able to drive during this time.

Having **bone marrow biopsies/aspirations** 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.

A **standard bone scan** exposes you only to the radiation that comes from injecting the standard radioactive imaging solution for bone imaging.

X-rays send a small amount of radiation though the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

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.

A PET scan may cause you to 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 technicians will give comfort, or the scanning will be stopped. The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

During an **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.

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. There will be no personal identifying information connected to your health information and your questionnaire answers.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn baby, so you must use birth control during the study and for 3 months after your last dose of erdafitinib if you are sexually active.

Birth Control Specifications: If you can father a child, you must use a condom with spermicide during this study and for 3 months after your last dose. Your partner must also use a recognized form of birth control unless they are surgically sterile. If you have had a vasectomy (and it was confirmed to be successful), you do not need to use a condom for birth control.

Males: Do not donate or store sperm during this study and for 3 months after your last dose. Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. If your partner/spouse becomes pregnant while you are on this study, the sponsor would like to collect information about the pregnancy. The study sponsor's contact information will be made available so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you will have a bone marrow biopsy/aspirate for biomarker testing during your End-of-Treatment Visit.

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. 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 procedure.

Optional Procedure Risks

Having **bone marrow biopsies/aspirations** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the 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 a bone marrow biopsy/aspirate at your End-of-Treatment Visit?

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 Janssen Scientific Affairs, LLC for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

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

Additional Information

4. You may ask the study chair (Dr. Paul Corn, at 713-563-7208) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can then decide if you need to have any visits or tests to check on your health. If you withdraw from this study, you can still choose to be treated at MD Anderson.

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

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Janssen Scientific Affairs, LLC, 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 may be stopped include if the study doctor decides that the disease has gotten worse, if you have intolerable side effects, if you are unable to follow study directions, if you choose to withdraw from the study, or if the study ends.

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: Janssen Scientific Affairs, LLC (a pharmaceutical company of Johnson & Johnson).

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

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

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research. Janssen Scientific Affairs, LLC will not have access to any leftover 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 or data at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

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

Genetic Research
Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

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

Ana Aparicio (Collaborator) has received compensation from Janssen as a Consultant. The financial interests are within the limits of the conflict of interest policy.

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
   - Janssen Scientific Affairs, LLC, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   After your encoded health information is disclosed to the sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The study sponsor and people who work with the study sponsor may use the results of this study for other research purposes, including:
      - Reviewing the safety or effectiveness of the study drug and other products or therapies;
      - Evaluating other products or therapies for patients;
      - Developing a better understanding of disease; or
      - Improving the design of future clinical trials

   You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you agree that you will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time, you may ask to see the study doctor's files related to your participation in the study, and you may ask the study doctor to correct any study-related information about you that is wrong.

   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

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 **2020-0953**.

_____ _____
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 DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION