THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Phase I/II Study to Evaluate the Safety and Clinical Efficacy of Atezolizumab (aPDL1) in Combination with Temozolomide and Radiation in Patients with Newly Diagnosed Glioblastoma (GBM)
2016-0867

Subtitle: Genentech: ML39558

Study Chair: Shiao-Pei Weathers

_____ _____
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 study: Part I and Part II.

The goal of Part I of this clinical research study is to study the safety and tolerability of atezolizumab in combination with radiation therapy and temozolomide.

The goal of Part II of this study is to learn if atezolizumab combined with radiation therapy and temozolomide can help to control glioblastoma.

The safety of this combination will also be studied.

This is an investigational study. Atezolizumab is FDA approved and commercially available for the treatment of several types of cancer, but not glioblastoma. Temozolomide is FDA approved and commercially available for the treatment of

glioblastoma. The radiation therapy used in this study is being delivered using FDA-approved and commercially available methods.

It is considered investigational to use atezolizumab in combination with temozolomide and radiation therapy to treat glioblastoma.

The study doctor can describe how the study drugs and radiation are designed to work.

The study drugs and radiation therapy 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, hospitalization, potential expenses, and time commitment/prolonged stay out of town.

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

You may receive temozolomide and atezolizumab for up to 12 cycles. You may receive radiation therapy for up to 6 weeks.

Atezolizumab 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 radiation therapy and temozolomide.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive temozolomide and/or radiation therapy without taking part in this study. 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

Up to 60 participants will be enrolled in this study. All will take part at MD Anderson.

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 and a neurological exam. For the neurological exam, you will be asked how well you are able to perform tasks like remembering, communicating, and following instructions. This should take about 20 minutes to complete.

- Blood (about 4 teaspoons) and urine will be collected for routine tests. This will also include a pregnancy test, if you can become pregnant. To take part in this study, you must not be pregnant.
- Blood (about 4 tablespoons) will be drawn for biomarker testing, including genetic biomarkers. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.
- Blood (about 1 teaspoon) will be drawn for T-SPOT.TB test to check if you have tuberculosis (TB).
- Stool will be collected for microbiome testing. The microbiome is the collection of small organisms (like bacteria or fungi) that are present in the human body.
- You will have a brain MRI to check the status of the disease
- If available, tumor tissue leftover from previous procedures will be collected and used for biomarker testing, including genetic biomarkers.

If you have had these tests performed in the last 14 days, they may not have to be repeated.

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 phase based on when you join the study. The first 10 participants enrolled will take part in Part I of the study. Up to 50 additional participants will take part in Part II of the study.

All participants will receive the same dose of atezolizumab, temozolomide, and radiation therapy.

Study Drug Administration

Treatment will be given in 2 phases: Concurrent Phase and Adjuvant Phase.

Concurrent Phase

There are 42 days (about 6 weeks) in the concurrent phase.

You will take temozolomide capsules by mouth every day. Do not open the capsules. If the capsules are accidentally opened or damaged, you should avoid inhaling or coming into contact with the contents of the capsule.

You will also receive atezolizumab by vein over about 60 minutes on Day 1. If you tolerate the drug well, it may be given over about 30 minutes after that on Days 15, 29, and 42 (about every 2 weeks).

You will receive radiation therapy Monday through Friday every week as part of your standard care. You will sign a separate consent form for the radiation therapy that explains this treatment and its risks in more detail.

After you finish radiation therapy, you will have a break or "rest period" for about 21-28 days in which you do not take temozolomide or atezolizumab.

Adjuvant Phase
Each study cycle in the adjuvant phase is 28 days.

You will take temozolomide by mouth on Days 1-5 of each cycle. You will receive atezolizumab by vein over about 30 minutes on Days 1 and 15 of each cycle.

You will not receive radiation therapy during the adjuvant phase of the study.

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

Concurrent Phase

On **Days 1, 8, 15, 22, 29, 35 and 42:**
- Blood (about 1 teaspoon) will be drawn for routine tests.
- You will have a physical exam, including a neurological exam.
- On Day 1 only, if you can become pregnant, blood (about ½ teaspoon) will be drawn for a pregnancy test.
- Stool will be collected for microbiome testing (Day 42 only).

Adjuvant Phase

On **Day 1 of each cycle:**
- You will have a physical exam, including a neurological exam.
- Blood (about 2 teaspoons) will be drawn for routine tests. This sample will also be used for a pregnancy test, if you can become pregnant.
- Blood (about 4 tablespoons) will be drawn for biomarker testing (Cycles 1 and 3 only).
- During odd-numbered cycles (Cycles 1, 3, 5 and so on) only, you will have an MRI.
- Stool will be collected for microbiome testing. (Cycle 7 only).

On **Day 21 of each cycle**, blood (about 1 teaspoon) will be drawn for routine tests.

At any time during the study, extra tests may be performed if the doctor thinks they are needed. The study doctor will tell you more about any extra tests that may be needed.

End-of-Treatment Visit

Within 30 days after your last dose of study drugs:

- You will have a physical exam, including neurological exam.
- Blood (about 3 teaspoons) will be drawn for routine tests. This sample will also be used for a pregnancy test, if you can become pregnant.
- You will have an MRI.

If the disease gets worse at any time while you are on study, blood (about 4tablespoons) will be drawn for biomarker testing. If you have surgery as part of your standard care, additional tumor tissue will be collected for biomarker testing, including genetic biomarkers.

Follow-Up

About every 3 months after your last dose of study drugs, the study staff will call you or check your medical records to learn how you are doing. If you are called, the call should take about 5-10 minutes.

If you stop taking the study drug and the disease has not gotten worse, you will have the following as often as the doctor thinks is needed:

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

The study doctor will discuss with you how often these tests may be performed. If the disease gets worse or the study ends, you will no longer have these tests for the study.

Other Information

Tell your doctor about all drugs you may be taking. You may be required to stop certain drugs, herbs and supplements before you receive the study drugs. Do not change any of your drugs or start any new drugs without checking with your study doctor.

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 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.

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.

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

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia, urinary tract 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.

Temozolomide Side Effects

Common (occurring in more than 20% of patients)

• fatigue • headache • seizure	• hair loss (partial or total) • nausea • vomiting	• constipation • loss of appetite • low white blood cell counts

Occasional (occurring in 3-20% of patients)

• swelling (arm/leg) • weakness on one side of the body • fever • dizziness • memory loss • difficulty sleeping • sleepiness • difficulty walking • paralysis • anxiety • depression • confusion • skin rash • itching/skin redness	• high level of steroid in the body (possible mood changes and diabetes) • breast pain • diarrhea • mouth blisters/sores (possible difficulty swallowing) • abdominal pain • difficulty swallowing • abnormal taste • weight gain • low blood cell counts (red, platelets)	• loss of bladder control • weakness • abnormal sensation (such as pins and needles) • pain (back/joint/muscle) • vision changes (such as blind spots, double vision, and/or blurry vision) • sore throat • cough • difficulty breathing • infection

• dry skin	• frequent urination	• allergic reaction

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

• hallucinations (seeing or hearing things that are not there) • very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract) • hormonal deficiency that causes you to urinate often • low blood levels of potassium (possible weakness and/or muscle cramps)	• high blood sugar (possible diabetes) • blockage of the bile tract (possible body yellowing and/or abdominal pain) • liver damage/failure (possibly causing decreased brain function) • jaundice (yellowing of skin and/or eyes) • gallstones • nerve damage (possible numbness, pain, and/or loss of motor or sensory function)	• lung inflammation and/or damage (possible difficulty breathing) • radiation injury • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Temozolomide may rarely cause you to develop another type of cancer (such as myeloid leukemia, a type of blood cancer.

If you are receiving radiotherapy, temozolomide may cause an increased risk of infection, such as pneumocystis carinii pneumonia (PCP). This infection may occur anywhere, but especially in the lungs. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Atezolizumab Side Effects

Common (occurring in more than 20% of patients)

• fatigue • fever • 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)	• nausea • loss of appetite • constipation • diarrhea • immune reaction that may cause loss of drug function	• abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes) • pain • infection

Occasional (occurring in 3-20% of patients)

• swelling (arm/leg) • difficulty sleeping • skin rash/itching • underactive thyroid gland (possible weight gain, heart failure, and/or constipation)	• vomiting • abdominal pain • inflammation of the intestines • blood in the urine	• abnormal kidney test (possible kidney damage) • lung inflammation (possible difficulty breathing) • difficulty breathing • cough

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

• heart inflammation • inflammation of the membrane around the spinal cord and brain (possible headache and/or coma) • damage to the nervous system (causing numbness and/or paralysis)	• severe high blood sugar due to uncontrolled diabetes • hormonal deficiency that affects the body's ability to control blood pressure and react to stress • inflammation of the pancreas (possible abdominal pain)	• overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating) • nerve damage causing muscle weakness • inflammation of the liver • inflammation inside the eye • build-up of fluid around the lungs

Exact frequency unknown:

• blood clots in a vein (possible pain, swelling, and/or redness) • blood vessel inflammation (possible bleeding and/or bruising) • confusion • skin blistering shedding, scaling • death of skin • high blood sugar (possible diabetes) • pituitary gland inflammation (possible	• decreased production of adrenal hormones (possible weakness and/or low blood pressure • difficulty swallowing • intestinal and/or urinary tract blockage • low blood cell counts (red, platelets, and/or white)	• kidney failure • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • low oxygen level in the blood (possible lightheadedness) • infusion reaction (possible chills and/or hives)

headaches)		

Atezolizumab may cause birth defects. It is not known how often this may occur.

In rare situations, when atezolizumab is combined with other drugs, an excessive immune response can occur. This side effect, called systemic immune activation, can result in inflammation, infection, and/or organ failure. Symptoms of systemic immune activation may include low blood pressure, high-grade fever, cough, difficulty breathing, severe dizziness, confusion, weakness, kidney failure, liver failure, very low blood cell counts, and/or bleeding within the organs.

If you experience any of these symptoms, you should notify your doctor right away as you may need drugs or other treatment and possible hospitalization.

Atezolizumab works by boosting the immune system. This may result side effects that have not been seen yet, such as inflammation and inflammation-related side effects in any organ or tissue.

If you need a vaccination, you must receive it at least 4 weeks before receiving atezolizumab. If you know that you will need a vaccination during the study or within 5 months after the last dose of atezolizumab, please tell your doctor.

It is important to tell your doctor the last time you took any drug that stimulates the immune system. It is also important that you do not take any other drugs that may change your immune system (such as interferons or interleukin-2) for 10 weeks after your last dose of atezolizumab.

Using the study drugs together and/or with radiation therapy 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.

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.

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.

Giving a **stool stample** may make you feel uncomfortable.

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, you must use 2 methods of birth control. If you can father a child, you must use at least 1 method of birth control.

Talk to the study doctor about the most appropriate method for you, as well as methods that are not approved for use in this study.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy while you are on study or within 5 months after the last dose of study drugs.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant during the study or 5 months after the last dose of study drugs, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

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

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

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

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

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

Additional Information

4. You may ask the study chair (Dr. Shiao-Pei Weathers, at 713-792-2883) 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 at any time by the study chair, STRATEGIC ALLIANCE: Genentech, 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: STRATEGIC ALLIANCE: Genentech, Inc.

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

Future Research

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.

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

Before being 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.

Genetic 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

Dr. John de Groot (Study Co-Chair) has received compensation from Genentech as a Scientific Advisor. 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
- STRATEGIC ALLIANCE: Genentech, Inc., 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.

To protect your identity, the data and samples collected from you will be labeled with a unique number instead of your name or other identifying information. Only the study doctor or study staff will have access to the code that can link you to your data and samples.

Study data will be sent to Kristin R Swanson, Ph.D. at Mayo Clinic, Phoenix, AZ for data analysis.

Blood samples and study data will be sent to John Wiencke, Ph.D. at UCSF Neuro and Molecular Epidemiology Laboratory, San Francisco, CA for research analysis.

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 2016-0867.

_____ _____
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