



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Phase I Trial of Adjuvant Pembrolizumab After Radiation Therapy for
Lung-Intact Malignant Pleural Mesothelioma
2015-0856

Subtitle: MPM

Study Chair: Matthew Ning

Participant's Name

Medical Record Number

This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. You may choose not to take part in this study.

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 study is to assess the safety of pembrolizumab (also called MK-3475) after radiation therapy (with or without surgery and/or chemotherapy) in patients with MPM.

This is an investigational study. Radiation therapy is delivered using FDA-approved and commercially available methods for local control of metastatic and primary tumors. Pembrolizumab is FDA approved and commercially available for the treatment of unresectable or metastatic melanoma, and for lung cancer. Its use in this study is investigational.

Treatment on this study 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, prolonged stay out of town, and time commitment. If you take part in this study, you may experience side effects, which may be life threatening

or fatal.

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

You may continue taking the study drug for up to 2 years.

Pembrolizumab will be provided at no cost to you. You and/or your insurance company will be responsible for the costs of radiation.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard photon radiation therapy outside of this study. You may choose to receive other investigational therapy, if available. The study doctor will discuss 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 screening tests will help the doctor decide if you are eligible to take part in this study. If you have had some of these tests or procedures done recently, they may not need to be repeated:

- You will have a physical exam.
- You will have a computed tomography (CT) scan and/or positron emission tomography (PET) scan to check the status of the disease.
- Blood (about 4 teaspoons) and urine will be collected for routine tests.
- If you are able to become pregnant, blood (about ½ teaspoon) or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.
- You may have a pulmonary function test (PFT) to check your lung function. The PFT involves breathing into a machine that measures how much air you breathe.
- You may have a nuclear medicine study that determines how much blood is flowing to each lung and kidney, to determine how well you may tolerate the treatment in this study.

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 1 of 2 groups. Your doctor will decide which group you are in. Up to 12 participants will be enrolled in each group.

If you are enrolled in Group A, you will have already received at least 2 cycles of chemotherapy and possibly lung-sparing surgery. You will then receive radiation therapy to one side of your chest, or thorax, a technique called “hemithoracic radiation.” You will then receive pembrolizumab.

If you are enrolled in Group B, you may or may not have had chemotherapy or immunotherapy. You will not have received surgery. You will receive radiation therapy over a course of 1-3 weeks to a region that does not include the entire side of your chest, or thorax. You will then receive pembrolizumab.

Up to 24 participants will take part in this study. All will be enrolled at MD Anderson.

Study Drug Administration

In both groups, you will receive pembrolizumab by vein over about 30 minutes on Day 1 of each 3-week cycle after radiation therapy, for up to 2 years.

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

Study Visits

When you are not receiving radiation, you will have these visits about every 3 weeks while you receive immunotherapy:

- You will have a physical exam.
- Blood (about 1-2 tablespoons) will be drawn to check your immune system, for side effects, and to check the status of the disease.

You will have a CT and/or PET scan to check the status of the disease before radiation therapy, at Cycle 4, and then every 3 cycles thereafter. If the doctor thinks it is needed, you may have extra imaging.

You will have a PFT to check your lung function at Cycle 7 and then every 6 cycles.

End-of-Study Visit

When you stop receiving the study drug:

- You will have a physical exam.
- Blood (about 1-2 tablespoons) will be drawn to check your immune system, for side effects, and to check the status of the disease.
- You will have a PFT to check your lung function.

Treatment Beyond Progression

If the disease appears to be getting worse or the tumors appear to be getting larger, you may still be able to receive the study drug if you and your doctor decide it is in your best interest. Sometimes the disease appears to get worse but the study drug is actually working.

However, there are risks of continuing to receive the study drug because the disease may actually be getting worse. You are still at risk for side effects due to the study drug. This could also delay starting other treatments. The disease may get worse to the point that you are no longer able to receive other treatments.

If you choose to receive the study drug after the disease gets worse, you will continue to have study visits as described above. The study doctor will discuss this option with you.

Follow Up

About 30 days after your last dose of study drug, you will have a physical exam.

About every 12 weeks after your last dose of pembrolizumab:

- You will have a physical exam.
- You may have CT or PET scans to check the status of the disease.
- If your doctor thinks it is needed, blood (about 1 tablespoon) may be drawn for routine tests.
- At Weeks 12 and 24, you will have PFTs performed.

If you are unable to make these visits, you will be contacted by phone to check your health.

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

Other Information

You are not allowed to receive any types of vaccinations while receiving the study drug.

You should not take certain drugs or herbal products while you are receiving the study drugs, such as medications known to produce QT prolongation.

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 drug/procedures.

Radiation Therapy Side Effects

Common (occurring in more than 20% of patients)

<ul style="list-style-type: none"> • skin redness • dry skin • hair loss 	<ul style="list-style-type: none"> • inflammation of the esophagus • cough 	<ul style="list-style-type: none"> • difficulty breathing • lung damage
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Radiation therapy may cause you to develop another type of cancer. Side effects may not occur for up to 6 months after radiation therapy is over. Side effects will vary depending on what part of the body is receiving radiation therapy.

Radiation to the chest may cause low blood cell counts (white blood cells, red blood cells, and platelets). This means that during and after you receive radiation therapy, there is more of a chance of getting an infection, including pneumonia. You may become anemic and/or have problems with bleeding, bruising, fatigue, and/or shortness of breath. You may need a blood transfusion.

Pembrolizumab Side Effects

Common (occurring in more than 20% of patients)

<ul style="list-style-type: none"> • fatigue • fever • skin rash and/or itching • 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"> • high blood sugar (possible diabetes) • high blood levels of fat (possible heart disease and/or stroke) • nausea • constipation • loss of appetite • diarrhea • abdominal pain 	<ul style="list-style-type: none"> • abnormal liver test (possible liver damage) • pain • abnormal kidney test (possibly kidney damage) • cough • difficulty breathing
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Pembrolizumab may cause low blood cell counts (red, white, and/or platelets):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood 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.
- 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.

Occasional (occurring in 3-20% of patients)

<ul style="list-style-type: none"> • swelling (face/arm/leg) • inflammation of the tissue around the heart (possible chest pain) • irregular heartbeat • headache • confusion • patches of skin color loss • underactive thyroid gland (possible weight gain, heart failure, and/or constipation) 	<ul style="list-style-type: none"> • overactive thyroid gland (possible weight loss, diarrhea, mood swings, difficulty sleeping, heart rate changes, and/or sweating) • low blood sugar • weight loss • fluid in the abdomen • vomiting • blood in the urine • abnormal liver tests (possible yellowing of the skin and/or eyes) 	<ul style="list-style-type: none"> • weakness • nerve damage (possible numbness, pain, and/or loss of motor function) • difficulty breathing (possibly due to lung inflammation) • flu-like symptoms • infusion reaction (possible dizziness, low blood pressure, nausea, pain, and/or difficulty breathing)
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Frequency Unknown

<ul style="list-style-type: none"> • heart failure • heart attack • build-up of fluid around the heart (possible heart failure) 	<ul style="list-style-type: none"> • abnormal connections or passageways between organs or vessels • bleeding in the rectum and/or uterus 	<ul style="list-style-type: none"> • blockage in the lung (possible pain and/or shortness of breath) • nosebleed • coughing up blood
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Rare but serious (occurring in fewer than 3% of patients)

<ul style="list-style-type: none"> • low blood pressure (possible dizziness/fainting) • heart inflammation • build-up of fluid in the tissue around the heart • blood vessel inflammation (possible bleeding, skin rash, numbness/weakness, fever, weight loss, fatigue, and/or bruising, depending on where the inflammation occurs) • seizure • immune system damage to the nervous system (causing 	<ul style="list-style-type: none"> • low hormone blood levels (possible weakness, bone changes, and/or cramping) • hormonal deficiency that affects the body's ability to control blood pressure and react to stress • pituitary gland inflammation (possible headaches) • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • inflammation of the 	<ul style="list-style-type: none"> • inflammation inside the eye (possible vision problems) • kidney inflammation (possible kidney damage/failure) • kidney failure • build-up of fluid around the lungs • immune response that causes the body to attack itself (possible organ damage) • immune response (causing muscle weakness) • multi-organ disease causing lesions, most often in the lungs
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<p>numbness and/or paralysis)</p> <ul style="list-style-type: none"> • spinal cord inflammation (possible pain, weakness, loss of feeling or movement, and/or paralysis) • brain inflammation (possible paralysis and/or coma) • shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids) • large skin blisters • very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract) 	<p>thyroid gland (possible tenderness in the neck)</p> <ul style="list-style-type: none"> • diabetes requiring insulin • severe high blood sugar due to uncontrolled diabetes • inflammation of the pancreas (possible abdominal pain) • inflammation of the intestines (possibly with a hole in the intestines, which may lead to contents leaking into the abdomen) • anemia due to destruction of red blood cells • liver damage (hepatitis) • inflammation/scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver), which may cause liver damage, stomach pain, yellowing of the skin/eyes, fatigue, and/or itching 	<p>(sarcoidosis)</p> <ul style="list-style-type: none"> • immune system reaction (possible fever, jaundice, liver/spleen enlargement, irritability, and/or seizures) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • Vogt Koyanagi Harada syndrome -- pigmented tissue (possible eye pain/swelling and changes in vision, hearing loss, and/or white patches on the skin)
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If you have a stem cell transplant from a donor after you receive pembrolizumab, you may have an increased risk of complications, such as severe graft-versus-host disease (when transplanted donor tissue attacks the recipient's organs such as skin, liver, and/or intestines) and/or clotting of blood within the liver. Deaths have been reported in patients who received a stem cell transplant from a donor after pembrolizumab therapy. If you decide to receive a stem cell transplant from a donor, please tell your transplant doctor that you received pembrolizumab in the past.

If you have a solid tumor type and you have an organ transplant, pembrolizumab may increase your risk for the transplant to be rejected by your body.

Pembrolizumab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue.

Other risks

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

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.

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 flushing, 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.

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.

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**.

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:

Females: While on study, you should use birth control pills, an intrauterine device (IUD), or implantable or injectable birth control (NorplantR or Depo-ProveraR started at least 3 months before joining the study). These must be used with a barrier method, such as a condom or diaphragm, for a total of 2 methods of birth control before starting radiation therapy and through 120 days after the last dose of study drug.

Males: You should use an adequate method of birth control before starting radiation therapy through 120 days after the last dose of study therapy.

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. MD Anderson will contact you at least every month to check the status of the pregnancy. The supporter will ask for information about the pregnancy. Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, blood (about 2 teaspoons) will be drawn at screening, before radiation therapy, at the end of radiation therapy, Cycle 3, at the End-of-Study visit, and if the disease gets worse. This will continue for up to 2 years. This blood will be stored in a research bank at MD Anderson for future research related to cancer.

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:

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, which may create a need for blood transfusions.

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 allow extra blood to be drawn and stored in a research bank for future research related to cancer?

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 Merck 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.

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. Matthew Ning, at 713-563-2300) 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. Your participation in this research study is strictly voluntary. 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, Merck, 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: Merck.
10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s). If you have any questions about this, you may call the IRB at 713-792-2933.

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 Merck 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. Leftover samples stored by Merck may be used in future research.

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.

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.

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
- Merck, 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.

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 of MD Anderson at 713-745-6636. If you withdraw your authorization, the data collected about you up to that point can be used and included in data analysis, but no further information about you will be collected.
- E. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

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

SIGNATURE OF PARTICIPANT

DATE

PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2015-0685**.

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