THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Phase I Study of NBTXR3 activated by Radiotherapy for Locally Advanced or Borderline-Resectable Pancreatic Ductal Adenocarcinoma 2019-1001

Study Chair: Eugene Koay

_____ _____
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 study has been reviewed and approved by an Institutional Review Board (IRB – a committee that reviews research studies). The IRB is a committee made up of doctors, researchers, and members of the community. The IRB is responsible for protecting the participants involved in research studies and making sure all research is done in a safe and ethical manner.

STUDY SUMMARY

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

The goal of Part 1 of this clinical research study is to find the recommended dose of NBTXR3 that can be given in combination with radiation therapy to patients with pancreatic cancer.

The goal of Part 2 is to learn if the dose NBTXR3 found in Part 1 can help to control the disease.

This is an investigational study. NBTXR3 is not FDA approved or commercially available. It is currently being used for research purposes only. Radiation therapy is delivered using FDA-approved and commercially available methods. The study doctor can explain how the study drug and radiation therapy is designed to work.

NBTXR3 may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may experience side effects that may be severe or fatal.

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

Your active participation in this study will last for up to 3 months.

NBTXR3 will be provided at no cost to you. You and/or your insurance provider may be responsible for the cost of radiation therapy.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive the standard of care treatment. The study doctor will discuss these options with you, including their risks and benefits. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

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

- You will have a physical exam.
- You will have an MRI or CT scan that will include your chest, abdomen, and pelvis to check the status of the disease.
- About 7 days before the first dose of study drug:
    - Blood (about 4 tablespoons) will be drawn for routine tests and 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.
- If you can become pregnant, urine will be collected for pregnancy testing. If the test is positive, blood (about ½ tablespoon) will be drawn to confirm the result. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be assigned to a study group based on when you join this study. Up to 24 participants (12 in Part 1

and 12 in Part 2) will be enrolled in this study. All participants will take part at MD Anderson.

If you are enrolled in Part 1, the dose of NBTXR3 you receive will depend on when you join this study. The first group of participants will receive the lowest dose level of NBTXR3. The new group will receive a higher dose of NBTXR3 than the group before it, if no intolerable side effects were seen. This will continue until the recommended dose of NBTXR3 is found.

If you are enrolled in Part 2, you will receive NBTXR3 at the highest dose that was tolerated in Part 1.

All participants will receive standard of care radiation therapy.

Study Drug Administration

Twelve (12) and 2 hours before the injection, you will receive **prednisone** to help decrease the risk of side effects. You will also be given other standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

You will receive **NBTXR3** as an injection directly into the tumor 1 time on Day 1 of the study. To inject the drug into the correct area, a long, thin, hollow tube with a lighted camera on one end (called an endoscope) will be inserted into your abdomen and will be guided using ultrasound imaging to the location of the tumor. The injection needle will be passed through the tube and NBTXR3 is then injected into the tumor. You will be given general anesthesia (made to sleep) before this procedure.

When the procedure is finished, you will be brought to a recovery area where you will lay in bed until you are awake. Your vital signs will continue to be monitored during this time. When you are awake, you will be given something to drink and eat. The recovery period usually lasts between 20 minutes to 1 hour. You will be observed for at least 2 hours after the injection procedure for side effects. If the study doctor thinks it is needed, you may stay in the hospital overnight. You and/or your insurance provider will be responsible for the cost of this stay. This will be discussed with you.

From Days 15-43, you will have radiation therapy every Monday-Friday (no therapy on weekends or holidays). The study staff will discuss your radiation therapy dosing schedule with you in more detail.

Study Visits

On **Day 1**:

- You will have a physical exam.
- Blood (about 4 tablespoons) will be drawn for routine and biomarker testing.
- Blood (about ½ teaspoon each time) will be drawn before and immediately after the dose, and then 3 more times over the next 2 hours after the NBTXR3

dose to measure how much study drug is in the body. Urine will also be collected the first and second time you urinate after the NBTXR3 dose for this measurement.
- You will have a tumor biopsy to check the status of the disease. During the procedure that you are already having to inject the study drug, a tool will be passed though the endoscope tube and a tissue sample will be taken before you are given the NBTXR3 injection.

On **Day 3**, you will have a CT scan to check the status of the disease and plan where you will receive the study drug injection.

Every day you have radiation therapy:
- You will have a physical exam.
- Blood (about 2 tablespoons) will be drawn for routine testing 1 time each week.

End of Treatment

Four (4) weeks after your last dose of radiation therapy:
- You will have a physical exam.
- Blood (about 4 tablespoons) will be drawn for routine and biomarker testing.
- You will have an MRI and/or CT scan that will include your chest, abdomen, and pelvis to check the status of the disease.

If the study doctor thinks it is in your best interest based on the tests above, within 4-13 weeks after your last dose of radiation therapy, you will have surgery to remove the tumor. You will sign a separate consent form that describes the risks of the surgical procedure. If you are scheduled to have surgery, 14 days before the procedure:
- You will have a physical exam.
- Blood (about 2 tablespoons) will be drawn for routine testing.

During the surgery:
- Blood (about 2 tablespoons) will be drawn for biomarker testing.
- You will have a tumor biopsy to check the status of the disease.

If you are not eligible for surgery, you will have a CT and/or MRI scan 8 weeks after your last dose of radiation therapy. Then, 11-13 weeks after your last radiation dose:
- You will have a physical exam.
- Blood (about 4 tablespoons) will be drawn for routine and biomarker testing.
- You will have an MRI and/or CT scan that will include your chest, abdomen, and pelvis.
- You will have a tumor biopsy using an endoscope tube inserted into your abdomen.

Follow-up Visits

For all participants, every 3 months after the End of Treatment Visit for up to 1 year:

- You will have a physical exam.
- Blood (about 2-4 tablespoons) will be drawn for routine testing. This draw may be repeated any time the study doctor thinks it is needed. At the 6 and 12 month visit only, part of this sample will also be used for biomarker testing.
- You will have an MRI and/or CT scan that will include your chest, abdomen, and pelvis. These scans may be repeated at any time the study doctor thinks they are needed.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person and depends on the local therapy choice and location of the tumor(s). The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after the procedure, 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 procedure.

NBTXR3 Side Effects

This is an early study of NBTXR3, so the side effects are not well known. Based on early human studies, NBTXR3 may cause the following side effects:

• low blood pressure (possible dizziness/fainting) • dizziness • feeling hot • flushing • increased sweating • low blood levels of potassium (possible weakness and/or muscle cramps)	• abnormal blood tests (possible inflammation and/or clotting) • bleeding • numbness • interrupted breathing • pain at the tumor site • injection site infection, swelling, pain, and/or heat • wound healing problems	• life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) • drug leakage from the injection site

NBTXR3 may cause cytokine release syndrome. This involves a release of a large amount of proteins into the blood stream. This may cause changes in blood pressure and heartbeat, flu-like symptoms (nausea, fever, and chills), and/or affect your lung/liver/kidney function. It may also cause certain brain-related symptoms, such as dizziness, weakness, confusion, difficulty speaking, and/or decreased brain function (possible paralysis and/or coma).

Radiation Therapy Side Effects

It is not known how often the side effects of radiation therapy may occur.

• bleeding, irritation, and/or sores in the stomach, esophagus, and/or intestines • intestinal blockage • liver damage • inflammation of the stomach (possible indigestion and/or heartburn)	• inflammation of the intestines (possible cramping, diarrhea, and/or poor absorption of food) • kidney and/or liver and/or spinal cord damage that could lead to organ failure • hair loss at the treatment site	• urinary and/or bladder changes • trouble swallowing • nausea/vomiting • diarrhea • swelling (including the arms and chest) • skin changes (possible dryness, itching, peeling, and/or blistering) • sexual changes • inability to produce children • secondary cancers

Radiation therapy may cause low blood cell counts (platelets and white blood cells):

- 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.

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.

Prednisone Side Effects

It is not known how often the side effects of prednisone may occur:

• heart failure • high blood pressure • swelling • headache	• failure of hormone-producing organs • decreased ability to process carbohydrates	• stomach ulcer (with possible hole and bleeding) • esophagus sore

• increased pressure between the skull and brain (possible swelling of the eye nerve, vision changes, and/or headaches) • mental health disturbances (including euphoria [unusual feelings of happiness or well-being]) • difficulty sleeping • mood swings • personality changes • severe depression • seizure • fatigue and anxiety • dizziness • bruising • facial skin redness • tiny dots on the skin • thin fragile skin • hives • sweating • wound healing problems • Cushing's syndrome (possible weakness, diabetes, and/or bone weakness)	• high level of steroid in the body (possible mood changes and diabetes) • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • diabetes • abnormal blood acid/base balance (possible organ damage) • underactive thyroid gland (possible weight gain, heart failure, and/or constipation) • body-wide loss of proteins (possible weakness and/or swelling) • low blood levels of potassium (possible muscle cramps) • high blood levels of sodium (possible weakness and/or swelling) • abdominal swelling • inflammation of the pancreas (possible abdominal pain)	• abnormal liver or bone tests (possible liver damage) • pain or loss of function of the hips and/or shoulders due to bone death • loss of muscle • muscle weakness (possibly caused by muscle damage) • loss of bone strength (possible broken bones) • brittle/broken bones • tendon tear (particularly Achilles tendon) • collapse of bones in the spine • bulging eye • increased pressure in the eye (possible vision loss, pain, and/or blurry vision) • cataracts (clouding of the lens of the eye) • allergic reactions that are possibly life-threatening (such as difficulty breathing, low blood pressure, and/or organ failure)

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

Risks of Endoscopic Ultrasound (EUS)-guided injection

You will receive the study drug using EUS-guided injections. EUS-guided injections may rarely cause bleeding in the stomach or small intestine, the forming of a small tear or hole in the small intestines (possibly causing the contents to leak into your abdomen), inflammation of the pancreas (possible abdominal pain), or infection at the injection site. You will be given a general anesthetic during the procedure.

Risks of General Anesthesia

There could be side effects caused by general anesthesia. The common side effects of general anesthesia include nausea and vomiting, dry mouth, sore throat or hoarseness, chills, confusion, dizziness, muscle aches, itching and difficulty urinating. Serious, life threatening side effects such as **serious allergic reaction,** heart rhythm disturbances, strokes or accidents causing brain damage can occur. Death may occur but this is very rare, occurring in around 1 in every 100,000 cases.

Your study doctor will explain to you any risks associated with general anesthesia according to MD Anderson's practice. Depending on your circumstances, you will usually need to stay in hospital for a few hours or a day after the product injection.

Risks of forgoing standard of care resection

Toxicity from the investigational therapy may be severe and, in rare cases, could prevent the feasibility of the tumor operation. The common side effects of forgoing standard of care resection may include also a decline in your quality of life. Patients with your disease that have their tumor removed with surgery live longer than patients that do not have tumor removal.

Other Risks

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

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

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. When a CT scan of the abdominal area is taken, material may be inserted into the rectum to better define the bowel. You will usually drink liquid to help define various abdominal organs. This may cause nausea and/or vomiting. 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.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect

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

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

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

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 during the study and will continue to be stored securely after the study. Only authorized people who are working on this study will have access to study data.

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 entire study period (up to 3 months) if you are sexually active.

If you can become pregnant or father a child, you must use a medically accepted birth control methods, which include:

- birth control pills
- intrauterine device (IUD)
- double-barrier methods, such as a condom used in combination with a diaphragm

Males: Do not donate sperm while on this study. 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.

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. The sponsor will ask for information about the pregnancy.

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. Eugene Koay, at 713-563-2381) 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. If you withdraw from this study, you can still choose to be treated at MD Anderson. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Nanobiotix, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Reasons for stopped participation may include the disease getting worse, intolerable side effects, or not following study directions.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

   You may receive the results of the blood biomarker, imaging, and genetic tests done during 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: Nanobiotix.

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. This information, or data, may be used by researchers at MD Anderson and Nanobiotix, 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 Nanobiotix 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
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
   - Nanobiotix, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Individuals and third parties who work with Nanobiotix.
   - 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. However, your name and other identifying information will be kept confidential. Your information will be protected from disclosure to others to the extent required by law. The sponsor and MD Anderson cannot promise complete privacy.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

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

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

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

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

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

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____	_____	_____
NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)