THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Triple-Negative First-Line Study: Neoadjuvant trial of nab-paclitaxel and MPDL3280A, a pdl-1 inhibitor in patients with triple negative breast cancer. 2014-1043

Subtitle: Women's Moon Shot: anti-PDL-1 with Nab-Paclitaxel in TNBC

Study Chair: Clinton Yam

_____ _____
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.

STUDY SUMMARY

You are being asked to take part in this study because you have breast cancer that has not responded to chemotherapy, and your doctor thinks it is unlikely to respond to additional standard chemotherapy when given before surgery.

The goal of this clinical research study is to learn if receiving atezolizumab and abraxane (nab-paclitaxel) in combination before surgery and atezolizumab alone after surgery can help to control breast cancer. The safety of this study drug combination will also be studied.

This is an investigational study. Atezolizumab is not FDA approved or commercially available. It is currently being used for research purposes only. Nab-paclitaxel is FDA approved and commercially available for the treatment of metastatic (has spread) breast cancer. The study doctor can explain how the study drug combination is designed to work.

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

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

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

You may receive the study drugs for about 4 cycles before your surgery and about 4 cycles after your surgery (8 cycles total). 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 nab-paclitaxel and surgery.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard chemotherapy or surgery. You may also choose to receive nab-paclitaxel without taking part in this study. 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 help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 2 tablespoons) and urine will be collected for routine tests (including a check of your thyroid function and how well your blood clots).
- Blood (about 2 tablespoons) will be drawn for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.
- You will have an echocardiogram (ECHO) or a multi-gated acquisition (MUGA) scan to check your heart function.
- Leftover tumor tissue from a previous procedure, if available, will be collected for biomarker testing. If no leftover tissue is available, you will have a fresh tumor biopsy. The study doctor will discuss with you what type of biopsy you will have and its risks.
- You will have an ultrasound of your breast(s) to check the status of the disease. Additional imaging may be done as part of your routine care, if the doctor thinks it is needed.
- If the doctor thinks it is needed, blood (about 2 teaspoons) will be drawn to test for mononucleosis and hepatitis B and C.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test. To take part in this study, you cannot 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 treatment options will be discussed with you.

Up to 37 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

Each study cycle is 21 days. You will receive the study drugs in 2 sets of 4 cycles (4 cycles before surgery and 4 cycles after surgery).

On **Day 1 of Cycle 1,** you will receive atezolizumab by vein over about 60 minutes. On **Day 1** of each later cycle **before and after** surgery, if you tolerated the first infusion, you will receive future infusions of atezolizumab by vein over 30 minutes.

You will receive nab-paclitaxel by vein over about 30 minutes on **Days 1, 8, and 15 of Cycles 1-4 before** surgery.

If you have side effects, the study doctor may decide to lower your dose of study drugs or have you stop taking the drugs. You may be able to restart the study drug later at the same or a lower dose. The study doctor will discuss this with you.

You will no longer be able to take the study drug, if intolerable side effects occur, or if you are unable to follow study directions. You may be able to continue taking the study drugs if the disease gets worse if the doctor thinks it is in your best interest.

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

Study Visits

On **Day 1 of all cycles:**

- You will have a physical exam.
- Blood (about 2 tablespoons) will be drawn for routine tests.
- During Cycle 3, you will have an ultrasound of your breast(s) before surgery. Additional imaging may be done as part of your routine care, if the doctor thinks it is needed.
- During Cycle 3, blood (about 1 tablespoon each time) will be drawn before surgery and at the time of surgery.

On **Days 8 & 15** of **Cycles 1-4,** blood (about 2 tablespoons) will be drawn for routine testing.

Within 6 weeks after you have received 4 cycles of study drugs, you will have surgery as part of your standard of care and part of the tumor tissue that is removed during surgery will be collected for biomarker testing. You will be given a surgery consent form that describes the procedure and its risks.

On **Day 21 of Cycle 8**, blood (about 1 tablespoon) will be drawn for routine and biomarker testing.

Additional Research Testing

If there is any tumor tissue left over after study procedures, part of this tumor tissue will be sent to the sponsor (Genentech) for further biomarker and immune system testing. Before your samples are sent to the sponsor for banking, your name and any personal identifying information will be coded to protect your privacy. The sponsor will not have access to the codes that link the samples to your identity. MD Anderson will not have oversight of any leftover samples that will be banked by the sponsor for

additional research. The tissue samples sent to the sponsor for this additional research will be used up during this planned testing.

Follow-Up
Every 6 months for up to 3 years, you will either have a clinic visit or you will be called by a member of the study staff and asked how you are doing. If you are called, each call should last about 15-20 minutes.

Other Information
Atezolizumab and nab-paclitaxel may interact with other drugs you take in ways that are not currently known. You should always discuss the use of any drugs (including alcohol, over-the-counter, prescription, illegal, natural, or herbal health products) with your study doctor while you are in this study.

2. POSSIBLE RISKS

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

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

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 headaches) • 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)

Atezolizumab may cause low blood cell counts (red blood cells, 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 and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

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.

Nab-Paclitaxel Side Effects

Common (occurring in more than 20% of patients)

• abnormal EKG • swelling (arm/leg) • fatigue • nerve damage (possible numbness, pain, and/or loss of motor function) • hair loss (partial or total) • skin rash	• nausea • diarrhea • vomiting • dehydration • loss of appetite • low blood cell counts (red, white, platelets) • abnormal liver test (possible liver damage)	• abnormal liver or bone tests • nerve damage (loss of sensory function) • weakness • pain (muscle, joint) • infection • fever

Occasional (occurring in 3-20% of patients)

• swelling • low blood pressure (possible dizziness/fainting) • high blood pressure • chest pain • heart attack • sudden stopping of the heart • fast heartbeat • blood clots in a vein (possible pain, swelling, and/or redness) • headache • depression • low blood levels of potassium (possible weakness and/or muscle cramps) • constipation • abnormal taste	• mouth blisters/sores (possible difficulty swallowing) • intestinal blockage • abnormal liver tests (possible yellowing of the skin and/or eyes) • pain (arm/leg) • vision problems • eye disorder (possible vision loss) • swelling under the central part of the eye (vision loss) • abnormal kidney test (possible kidney damage) • lung inflammation (possible difficulty breathing) • difficulty breathing	• blood clots in the lung (possible failure to breathe) • blockage in the lung (possible pain, shortness of breath, and/or failure to breathe) • cough • nosebleed • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • flushing

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

• irregular/slow heartbeat • decreased blood supply to the heart • heart failure • severe heart problems • stroke and/or temporary stroke symptoms • nerve damage (affecting movement) • paralysis of nerves controlling the head and neck • decreased brain function due to liver damage • very severe blistering skin disease (with ulcers of the skin and digestive tract)	• very severe blistering skin disease (loss of large portion of skin) • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering) • severe sunburn-like rash at site of previous radiation (called radiation recall) • inflammation of the pancreas (possible abdominal pain) • hole in the intestines (possibly leaking contents into the abdomen)	• decreased blood flow to part of the bowel (possibly causing death of tissue) • paralysis of the intestines • liver damage and/or failure • blurred vision • eye inflammation • damage to an eye nerve • collapsed lung (possible difficulty breathing) • lung damage at the site of prior radiation • paralysis of the vocal cords

The following side effects were reported with a similar drug (paclitaxel) and may also be caused by nab-paclitaxel:

• decreased brain function due to liver damage • inflammation at the site of previous tissue death	• liver damage and/or failure • lung damage (possible difficulty breathing)	• tissue death at the injection site caused by drug leakage

Other Risks

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

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.

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. If you can become pregnant or father a child, you must use birth control during the study and for at least 6 months after your last dose of study drugs, if you are sexually active.

Birth Control Specifications: If you can become pregnant, you must use an acceptable method of birth control while you are on study, such as an intrauterine device (IUD) or barrier method (condom or diaphragm with spermicide).

Hormonal methods (such as birth control pills, injections, or implants) are not approved for use on this study.

If you can father a child, you must use a condom.

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 and for up to 90 days after the study, you must tell your doctor right away.

Males: If your partner becomes pregnant or suspects that she is pregnant during the study and for up to 90 days after the study, you must tell your doctor right away. The supporting company would like to collect information about the pregnancy. The supporting company'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 supporting company. 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.

Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, leftover tissue collected while on study will be stored in a research bank at MD Anderson for use in future research related to cancer.

Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Your samples will be given a code number. No identifying information will be directly linked to your samples. Only the researcher in charge of the bank will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed.

Optional Procedure #2: If you agree and if the disease appeared to get worse while you were receiving the study drugs, you will have a tumor biopsy for biomarker testing after you have stopped taking the study drugs and you and the study doctor have decided to start a new type of therapy.

Optional Procedure Risks:
MD Anderson and others can learn about cancer and other diseases from your **banked samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in families. 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.

If you withdraw your consent to the storage of leftover samples in the tissue bank, then they will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be destroyed.

However, if any of your de-identified samples were already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy them.

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.

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 leftover tumor tissue to be stored in a research bank at MD Anderson for use in future research related to cancer?

YES NO

Optional Procedure #2: If the disease appeared to get worse while you were taking the study drugs, do you agree to have a tumor biopsy for biomarker testing?

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

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

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

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

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

Additional Information

4. You may ask the study chair (Dr. Clinton Yam, at 713-792-2817) 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.

6. This study or your participation in it may be changed or stopped at any time by the study chair, Genentech, 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: Genentech.

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

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and Genentech 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 Genentech may be used in future research.

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 will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment.

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
   - Genentech, 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.

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 2014-1043.

_____ _____
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