THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Matched Paired Pharmacodynamics and Feasibility Study of Pembrolizumab in Combination with Chemotherapy in Frontline Ovarian Cancer 2014-0662

Subtitle: Neoadjuvant Pembrolizumab in Frontline Ovarian Cancer

Study Chair: Amir Jazaeri

_____ _____
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

The goal of this clinical research study is to learn about the safety of giving the combination of pembrolizumab, carboplatin, and paclitaxel to patients with high-grade epithelial non-mucinous ovarian, primary peritoneal, or Fallopian tube cancer. Researchers want to find out how the disease responds to therapy with pembrolizumab.

This is an investigational study. Pembrolizumab is FDA-approved and commercially available for the treatment of certain types of melanoma. Its use in patients with ovarian cancer is investigational. Carboplatin and paclitaxel are both FDA-approved and commercially available for the treatment of advanced ovarian cancer. The study doctor can explain how the study drug combination is designed to work.

The study drug(s) 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 will the receive study drug(s) for up to 23 cycles, or possibly more if the doctor thinks it is appropriate for you to have more than 3 Neoadjuvant Treatment cycles.

Pembrolizumab 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 carboplatin, paclitaxel, and surgery.

You may choose not to take part in this study. You may choose to receive the standard treatment for the disease. 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. You will have the following screening tests to help the doctor decide if you are eligible to take part in this study:

- You will have a physical exam, including an exam of your pelvis.
- Blood (about 3 tablespoons) and urine will be collected for routine tests and to check the level of fat in your blood, your blood sugar level, and to check your thyroid function. If you can become pregnant, part of this urine and/or blood sample will be used for a pregnancy test. To take part in this study, you must not be pregnant.
- You will have a computed tomography (CT) scan or magnetic resonance imaging (MRI) to check the status of the disease.
- You will have leftover tissue from a previous biopsy collected to confirm the diagnosis.

Tumor tissue will be used for research testing after being collected with one of the following methods:

- Tumor tissue will be collected from the laparoscopy surgery if you are scheduled to have or have already had this type of surgery.
- Tumor tissue will be collected from a diagnostic biopsy if the ovarian, primary peritoneal, or fallopian tube cancer has yet to be confirmed; OR
- You will have a tumor biopsy to collect tumor tissue if the ovarian, primary peritoneal, or fallopian tube cancer diagnosis has been confirmed but you are not planning to have a laparoscopy surgery before beginning treatment. The type of biopsy you will have will be explained to you.

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 30 participants will be enrolled in this study. All will take part at MD Anderson.

Treatment

If you are found to be eligible to take part in this study and agree, you will have standard chemotherapy, your scheduled surgery, and then chemotherapy in combination with pembrolizumab.

Neoadjuvant Treatment

You will receive standard chemotherapy treatment for three 21-day cycles, or possibly more cycles if the doctor thinks it is in your best interest:
On Day 1 of each cycle, you will receive carboplatin by vein over 1 hour.
On Days 1, 8, and 15 of each cycle, you will receive paclitaxel by vein over 1 hour.

Surgery

You will then have your scheduled surgery. Some of the tissue removed during the surgery will be used for immune system testing and to compare to tissue collected before chemotherapy.

Adjuvant Treatment and Maintenance

After you have recovered from surgery (about 3-6 weeks later), you will begin receiving chemotherapy again along with the drug pembrolizumab. You will receive the standard chemotherapy in the same way you received it during Cycles 1-3.
On Day 1 of each cycle, you will receive pembrolizumab by vein over 30 minutes during Cycles 4-26. Cycles 7-26 are called the Maintenance Phase.
You will receive carboplatin and paclitaxel during Cycles 4-6 only.

Study Visits

On **Day 1 of each cycle during Neoadjuvant Treatment**:

- You will have a physical exam. If the study doctor thinks it is needed, you will also have a pelvic exam.
- Blood (about 3 tablespoons) will be collected for routine tests. If you can become pregnant, urine will be collected and/or part of this blood sample will be used for a pregnancy test.
- In Cycle 1 only, blood (about 1 tablespoon) will be drawn for biomarker testing. The biomarker tests in this study may include genetic biomarkers. Biomarkers are found in the blood and tissue and may be related to your reaction to the study drug.

Study Visits during Neoadjuvant Therapy

On **Days 1, 8 and 15 of each cycle during Neoadjuvant Treatment**, blood (about 1-2 tablespoons) will be drawn for routine tests.

At your visit before the surgery:

- You will have a physical exam.
- Blood (about 3 tablespoons) will be drawn for routine and biomarker testing.
- You will have a CT scan or MRI to check the status of the disease.

You will sign a separate consent form for the surgery that explains the procedure and its risks. During the surgery, tumor tissue will be collected for biomarker and genetic testing. All samples will be stored at MD Anderson for an unlimited amount of time for testing related to this study.

On the day of surgery, blood (about 3 tablespoons) will be drawn for routine testing.

At your postoperative visit (visit after surgery):
- You will have a physical exam.
- Blood (about 3 tablespoons) will be drawn for routine testing.

Study Visits during Adjuvant Therapy
On **Day 1 of each cycle during Adjuvant Treatment:**
- You will have a physical exam.
- Blood (about 3 tablespoons) will be drawn for routine and biomarker testing.
- Urine will be collected for routine testing. If you can become pregnant, part of this urine and/or blood sample will be used for a pregnancy test.

On Days 8 and 15 of each cycle during Adjuvant Treatment, blood (about 1-2 tablespoons) will be drawn for routine tests.

Study Visits during Maintenance Therapy:
- You will have a physical exam.
- Blood (about 3 tablespoons) will be collected for routine tests and to check your thyroid function.
- Urine will be collected for routine testing.

Every 12 weeks, you will have a CT scan or MRI to check the status of the disease.

Length of Study
You will the receive study drug(s) for up to 23 cycles, or possibly more if the doctor thinks it is appropriate for you to have more than 3 Neoadjuvant Treatment cycles. You will no longer be able to take the study drugs if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

After you are no longer taking any study drugs, the study staff will continue to call you every 3 months to check the status of your health.

Post-Treatment Visits
After the last dose of study drug(s), the following tests and procedures will be performed:
- You will have a physical exam.
- You will have a CT or MRI to check the status of the disease.
- Blood (about 1-2 tablespoons) will be drawn for routine tests.

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

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 the drugs are stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs and procedures. You should talk to your doctor before taking all drugs, supplements, and vaccinations while on study.

Carboplatin, pembrolizumab, and paclitaxel may each 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.

Pembrolizumab Side Effects

Common (occurring in more than 20% of patients)

• 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)	• high blood sugar (possible diabetes) • high blood levels of fat (possible heart disease and/or stroke) • loss of appetite • nausea • constipation • diarrhea • abdominal pain • low blood cell count (white/red/platelets)	• abnormal liver test (possible liver damage) • pain • abnormal kidney test (possible kidney damage) • cough • difficulty breathing

Occasional (occurring in 3-20% of patients)

• swelling (face/arm/leg) • inflammation of the tissue around the heart (possible chest pain) • irregular heartbeat • headache • confusion • patches of skin color • underactive thyroid gland (possible weight gain, heart failure, and/or constipation) • 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 • blood in the urine • vomiting • abnormal liver tests (possible yellowing of the skin and/or eyes)	• 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)

Frequency Unknown

• heart failure • heart attack • build-up of fluid around the heart (possible heart failure)	• abnormal connections or passageways between organs or vessels • bleeding in the rectum and/or uterus	• blockage in the lung (possible pain and/or shortness of breath) • nosebleed • coughing up blood

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

• low blood pressure (possible dizziness/fainting) • heart inflammation • build-up of fluid in the tissue around the heart • blood vessel inflammation (possible bleeding and/or bruising) • seizure • immune system damage to the nervous system (causing muscle weakness, numbness, and/or paralysis) • 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)	• hormonal deficiency that affects the body's ability to control blood pressure and react to stress • pituitary gland inflammation (possible headaches) • inflammation of the thyroid gland (possible tenderness in the neck) • diabetes requiring insulin • severe high blood sugar due to uncontrolled diabetes • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • inflammation of the pancreas (possible abdominal pain) • anemia due to destruction of red blood cells • liver damage (hepatitis) • 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) • multi-organ disease causing lesions, most often in the lungs (sarcoidosis) • immune response (causing muscle weakness) • 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)

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. These side effects can affect more than one of your normal organs and tissues at the same time.

Carboplatin Side Effects

Common (occurring in more than 20% of patients)

• 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)	• vomiting • low blood counts (red/white/platelets) • pain	• abnormal liver tests (possible liver damage) • abnormal kidney test (possible kidney damage)

Occasional (occurring in 3-20% of patients)

• nerve damage (possible numbness, pain, and/or loss of motor function) • hair loss (partial or total)	• abdominal pain • nausea • constipation • diarrhea	• weakness • abnormal liver tests (possible yellowing of the skin and/or eyes) • allergic reaction • infection

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

• high blood pressure • low blood pressure (possible dizziness/fainting) • heart failure • stroke • dehydration • blood vessel blockage	• destruction of red blood cells (possible anemia, kidney damage, and/or failure) • reduced blood supply to the arms and legs • blindness • hearing loss	• difficulty breathing due to narrowing of the airways • tissue death at the injection site caused by drug leakage • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Carboplatin may rarely cause the cancer to spread.

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

• decreased bone marrow function

Paclitaxel Side Effects

Common (occurring in more than 20% of patients)

• abnormal EKG • swelling • flushing • hair loss (partial or total) • mouth blisters/sores (possible difficulty swallowing)	• nausea/vomiting • diarrhea • low blood cell counts (red/platelets/white) • abnormal liver tests (possible liver damage) • pain (muscle/joint)	• nerve damage (possible numbness, pain, and/or loss of motor function) • abnormal kidney test (possible kidney damage) • allergic reaction • infection

Occasional (occurring in 3-20% of patients)

• low blood pressure (possible dizziness/ fainting) • slow heartbeat	• skin rash • abdominal pain • abnormal liver tests (possible yellowing of the skin and/or eyes)	• weakness • injection site reaction (possible redness, swelling, skin discoloration)

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

• fast/irregular heartbeat • blood clots in a vein (possible pain, swelling, and/or redness) • heart failure • heart attack • decreased blood supply to the heart • high blood pressure • fainting • decreased brain function (possible paralysis and/or coma) • decreased brain function due to liver damage • seizure • severe sunburn-like rash at site of previous radiation (called radiation recall) • death of skin	• inflammation at the site of previous tissue death • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • inflammation of the pancreas (possible abdominal pain) • inflammation of the intestines • dehydration • paralysis of the intestines • intestinal blockage • hole in the intestines (possible leaking contents into the abdomen)	• difficulty walking • liver damage and/or failure • blind spot • hearing loss • decreased kidney function • blockage in the lung (possible pain and/or shortness of breath) • lung inflammation and/or damage (possible difficulty breathing) • blood clots in the lung (possible failure to breathe) • difficulty breathing • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

• worsening of existing scleroderma (severe hardened skin, which can cause difficult movement)	• decreased blood flow to part of the bowel (possibly causing death of tissue)	• tissue death at the injection site caused by drug leakage

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.

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.

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 or breastfeed a baby while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: You must use 2 of the following forms of birth control during this study and for 120 days after your last dose of study drugs:

- Birth control pills, injections, or implants
- Placement of an intrauterine device (IUD) or intrauterine system (IUS) (such as the coil)
- Barrier methods of birth control: condom or occlusive cap (such as a diaphragm or cervical/vault cap) with spermicide
- Male partner with sterilization/vasectomy

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.

Getting pregnant may 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 or Merck Pharmaceuticals 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. Amir Jazaeri, at 713-745-1613) 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 without your consent at any time by the study chair, Merck Pharmaceuticals, 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 Pharmaceuticals.

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

Future Research

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

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

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

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

Genetic Research

Samples collected from you as part of this study 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.

Conflict of Interest

Dr. Anil Sood (Collaborator) has received compensation from Merck as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Merck Pharmaceuticals, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - QualTek Molecular Laboratories
   - 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.

   QualTek Molecular Laboratories will also receive slides of tissue for research testing.

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 2014-0662.

_____ _____
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