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 Suberoylanilide Hydroxamic Acid (SAHA, Vorinostat) with Temsirolimus in Children with Newly Diagnosed or Progressive Diffuse Intrinsic Pontine Glioma (DIPG)
2014-0135

Subtitle: Phase I Study of SAHA with Temsirolimus in Children with DIPG

Study Chair: Wafik Zaky

_____ _____
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.

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

STUDY SUMMARY

You are being asked to take part in this clinical research study at The University of Texas MD Anderson Cancer Center ("MD Anderson"). This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you have diffuse intrinsic pontine glioma (DIPG) and you are 21 years of age or younger.

This is an investigational study. Vorinostat is FDA approved and commercially available for the treatment of cutaneous T-cell lymphoma (CTCL). Temsirolimus is FDA approved and commercially available for the treatment of kidney cancer. The use of these drugs in combination is investigational. The radiation therapy is delivered

using FDA-approved and commercially available methods.

The study doctor can explain how the study drug(s) are designed to work.

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

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may not want to take part in this study because standard treatment options may be available to you, taking part may require a prolonged stay out of town if you are not from the Houston area, and you may experience side effects, some of which may be severe or life-threatening.

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

If you are in Group 1, you will receive radiation therapy and chemotherapy for up to 7 weeks, followed by 4 weeks of rest, followed by up to 10 cycles of chemotherapy alone.

If you are in Group 2, you will receive up to 12 cycles of chemotherapy.

You and/or your insurance provider will be responsible for the costs of vorinostat and temsirolimus. If you receive radiation treatment, you and/or your insurance provider will also be responsible for this cost.

You may choose not to take part in this study. You may choose to receive radiation therapy 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 be performed to help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 1 teaspoon) and urine will be collected for routine tests.
- You will have magnetic resonance imaging (MRI) of the brain and spine to check the status of the disease.
- 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 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 treatment options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be in 1 of 2 study groups based on when you were diagnosed with DIPG:

- If you are newly diagnosed with DIPG, you will be in Group 1. You will receive radiation therapy and vorinostat, then the combination of vorinostat and temsirolimus.
- If you have been diagnosed with DIPG before and the disease has gotten worse since, you will be in Group 2. You will receive the combination of vorinostat and temsirolimus without receiving radiation therapy.

Up to 18 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

You will be assigned to a dose level of temsirolimus based on when you join this study. Up to 2 dose levels of temsirolimus will be tested. Up to 6 participants will be enrolled at each dose level. The first group of participants will receive the lowest dose level. The second group will receive a higher dose than the group before it, if no intolerable side effects were seen.

All participants will receive the same dose level of vorinostat, though the dose may be lowered if there are intolerable side effects.

Vorinostat should be taken with food. You should be careful not to open or break the capsules of vorinostat. If a capsule breaks, try to clean it up carefully without breathing in any of the powder. Wash the spill area at least 3 times with ethyl alcohol, and then rinse it 1 time with water. If the powder comes in contact with your skin, you should wash the affected area thoroughly with soap and water.

If you have trouble swallowing, you may receive vorinostat in liquid form. The dose amount will be based on your body surface area. The MD Anderson pharmacy will give you the drug in liquid form. You should store the liquid form of the drug at room temperature, away from excessive heat or humidity. The liquid form of the drug should be taken with food.

You should avoid spilling the powder from the capsules or the liquid form of the drug on your skin. If contact occurs, wash the area thoroughly with water.

Group 1

You will receive 30 treatments of radiation therapy over 6-7 weeks. You will sign a separate consent form for this treatment that will explain the procedure, as well as its risks and benefits. You will take capsules of vorinostat with food, every morning that you have a radiation treatment (Monday - Friday) at least 1-2 hours before radiation.

After you have finished radiation therapy, you will rest for 4 weeks in which you do not receive radiation therapy or study drug. After this, you will start receiving the

chemotherapy combination of vorinostat and temsirolimus in 28-day study cycles:

- You will take capsules of vorinostat with food 1 time every day on Days 1-8 of each cycle.
- You will receive temsirolimus by vein over about 30 minutes on Days 1 and 8 of each cycle.

Group 2
You will receive the chemotherapy combination of vorinostat and temsirolimus in 28-day study cycles:

- You will take capsules of vorinostat with food 1 time every day on Days 1-8 of each cycle.
- You will receive temsirolimus by vein over about 30 minutes on Days 1 and 8 of each cycle.

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

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

Study Visits for Group 1 during Radiation Therapy

Every week:

- You will have a physical exam.
- Blood (about 1 teaspoon) will be drawn for routine tests.

Study Visits for All Participants during Chemotherapy

Every week:

- You will have a physical exam.
- Blood (about 2-6 teaspoons) will be drawn for routine tests.

Every week during Cycle 1, then at the beginning of every cycle after that, urine will be collected for routine tests.

At the beginning of every odd-numbered cycle (1, 3, 5, and so on), you will have an MRI of the brain to check the status of the disease. If the doctor thinks it is needed, this will also include an MRI of the spine. If you are in Group 2, this will not need to be performed at Cycle 1 since your screening scans were recently performed.

End-of-Dosing Visit
After you have finished receiving chemotherapy, blood (about 1 teaspoon) will be drawn for routine tests.

Follow-Up
You will have follow-up visits 3, 6, 9, and 12 months after you finish receiving chemotherapy. The following tests and procedures will be performed.

- You will have a physical exam.
- You will have an MRI of the brain and spine to check the status of the disease.
- Blood (about 1 teaspoon) and urine will be collected for routine tests (Month 3 follow-up visit only).

2. POSSIBLE RISKS

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

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug/procedures.

Vorinostat and temsirolimus each may commonly 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.

Vorinostat Side Effects

Common (occurring in more than 20% of patients)

• fatigue • high blood sugar (possible diabetes) • diarrhea	• nausea • abnormal taste • loss of appetite • weight loss	• low platelet count • abnormal kidney test (possible kidney damage)

Occasional (occurring in 3-20% of patients)

• abnormal EKG • swelling (arm/leg) • chills • dizziness • headache • fever • hair loss (partial or total)	• itching • dehydration • dry mouth • constipation • vomiting • low red blood cell count	• muscle spasms • blockage in the lung (possible pain, shortness of breath, and/or failure to breathe) • cough • infection

Vorinostat may occasionally cause you to develop another type of cancer (such as squamous cell carcinoma (skin cancer).

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

• high blood pressure • chest pain • heart attack • blood clots in a vein (possible pain, swelling, and/or redness) • blood vessel inflammation (possible bleeding and/or bruising) • fatigue • stroke • immune system damage to the nervous system (causing numbness and/or paralysis) • fainting	• shedding and scaling of the skin (possible fatal loss of bodily fluids) • low blood levels of potassium (possible weakness and/or muscle cramps) • low blood levels of sodium (possible headache, confusion, seizures, and/or coma) • bleeding in the digestive system • gallbladder inflammation (possible abdominal pain) • inability to urinate	• low white blood cell count • kidney failure • loss of feeling or movement due to spinal cord damage • blockage in the tubes that drain urine from the kidneys • coughing up blood • blurry vision • deafness • bleeding in or from the tumor • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Vorinostat may rarely cause you to develop another type of cancer (such as lymphoma [cancer of the lymph nodes]).

<u>Temsirolimus Side Effects</u>

Common (occurring in more than 20% of patients)

• swelling (arm/leg) • pain • fever • skin rash • high blood sugar (possible diabetes) • low blood levels of potassium (possible weakness/muscle cramps)	• low blood levels of phosphate (possible bone damage) • high blood levels of fat (possible heart disease and/or stroke) • mouth blisters/sores (possible difficulty swallowing) • nausea • loss of appetite • diarrhea	• abdominal pain • low blood cell counts (red, white, platelets) • abnormal liver test (possible liver damage) • weakness • abnormal kidney test (possible kidney damage) • difficulty breathing • cough • infection

Occasional (occurring in 3-20% of patients)

• chest pain • headache • difficulty sleeping • itching	• nail changes • dry skin • constipation • abnormal taste	• vomiting • weight loss • pain (back/joint) • nosebleed • sore throat

Exact frequency unknown but occurring in between 1 and 10 of patients:

• high blood pressure • blood clots in the veins (possibly in a deep vein and/or lung) • chills • depression • acne	• holes in the intestines (possible leaking contents into the abdomen) • abnormal liver tests (possible yellowing of the skin and/or eyes)	• muscle pain • painful red eyes • runny nose • wound healing problems • infusion reaction (possible chills and/or hives)

The intravenous (IV) infusion of temsirolimus may commonly cause you to have an allergic reaction and/or infusion reaction. These reactions include severe allergic reaction, breathing interruptions, chest pain, difficulty breathing, flushing, low blood pressure, and/or loss of consciousness. Life-threatening reactions, including fatal reactions, have occurred.

Rare but serious (occurring in fewer than 1% of patients)

• build-up of fluid in the tissue around the heart • seizure • very severe blistering skin disease (with ulcers of the skin and digestive tract)	• breakdown of muscle tissue (possible kidney failure) • increased sensitivity to pain (possible burning, sweating, and/or swelling of the arms and legs) • kidney failure	• build-up of fluid around the lungs • lung inflammation (possible difficulty breathing) • fungal lung infection • pneumonia • drug leakage from injection site

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.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: If you can become pregnant or father a child, you must use appropriate methods of birth control while you are on study. Talk to the study staff about appropriate methods of birth control.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant may result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, additional blood (about 1 teaspoon each time) will be drawn at certain study visits for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. The timing of these blood draws will depend on which study group you are in:

- **Group 1**: Once before radiation therapy starts, once after you complete the final radiation therapy, once before you receive chemotherapy on Days 1 and 8 of Cycles 1 and 2 (6 time points).
- **Group 2**: Once before you receive chemotherapy on Days 1 and 8 of Cycles 1

and 2 (4 time points).

Optional Procedure #2: If you agree, you will have psychological tests at screening and at the end of chemotherapy. These will take about an hour to complete and will include a neurocognitive exam (tests to check your memory, thinking abilities, and concentration, for example).

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks

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

The **psychological tests** may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the tests, you are encouraged to contact your doctor or the study chair.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to allow extra blood to be drawn for biomarker testing?

YES NO

Optional Procedure #2: Do you agree to have psychological tests at screening and after you complete chemotherapy?

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 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. Wafik Zaky, at 713-792-6620) 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, 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.

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/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.

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. 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.

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
   - Any future sponsors and/or licensees of the study technology
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

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

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

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

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

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

CONSENT/AUTHORIZATION
(Adult Participants Only)

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 **2014-0135**.

_____ _____
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

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____Other parent is deceased, unknown, incompetent, or not reasonably available.

____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

X The IRB has determined that the signature of both parents is NOT required.
____

WITNESS TO PARENTAL/GUARDIAN PERMISSION

I was present during the explanation of the research to be performed under Protocol **2014-0135**. The child participant was also present. In my opinion, the parent(s)/guardian provided permission for the child to participate in the research.

_____ _____
SIGNATURE OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other: _____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

_____
PRINTED NAME OF MINOR

WITNESS TO ASSENT

I was present during the explanation of the research to be performed under Protocol **2014-0135**. The child participant was also present. In my opinion, the child assented to participate in the research. (Note: If obtaining assent, a witness signature is required.)

_____ _____
SIGNATURE OF WITNESS TO THE ASSENT (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE ASSENT

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