THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

**Informed Consent**

# INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

An open label, Phase II investigator initiated study of venetoclax and acalabrutinib in previously treated relapsed/refractory patients with mantle cell lymphoma (MCL)
2018-0935

Study Chair: Michael Wang

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

## STUDY SUMMARY

The goal of this clinical research study is to learn if the combination of acalabrutinib (also called ACP-196) and venetoclax can help to control relapsed (has come back) or refractory (has not responded to therapy) mantle cell lymphoma (MCL).

The safety of this combination will also be studied.

**This is an investigational study.** Acalabrutinib is FDA approved and commercially available for the treatment of MCL in patients who have received 1 prior therapy. Venetoclax is FDA approved and commercially available for the treatment of chronic lymphocytic leukemia (CLL). The combination of these drugs is considered investigational. The study doctor can explain how the study drugs are 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 the availability of other standard treatments, possible side effects, potential expenses, hospitalization, and prolonged stay out of town/time commitment.

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

You may continue taking the study drugs for as long as the study doctor thinks it is in your best interest.

Acalabrutinib will be provided with at no cost to you. You and/or your insurance provider will be responsible for the cost of venetoclax. If your insurance provider will not pay for venetoclax, you will be removed from study.

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

## 1. STUDY DETAILS

Up to 50 participants will be enrolled in this study. All will take part at MD Anderson.

**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.
- You will have a neurological exam (tests to check the functioning of your nerves, including tests of your balance and reflexes).
- You will have an EKG and either an echocardiogram (ECHO) or MUGA scan to check your heart function.
- Blood (about 4 teaspoons) will be drawn for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drugs. This testing also helps the study doctor measure how much of the tumor's genetic material (DNA) is in the blood.
- Blood (about 4 tablespoons) will be drawn for routine tests and to test for hepatitis.
- You will have a CT scan, PET-CT scan, and a chest x-ray to check the status of the disease.
- If your doctor thinks it is needed, you will have a gastrointestinal endoscopy to check if the disease has spread to the digestive system. A gastrointestinal endoscopy has 2 parts, an upper endoscopy and a colonoscopy. During the

upper endoscopy, you will be mildly sedated, and a thin, flexible, lighted tube will be inserted through your mouth into the esophagus, stomach, and first part of the small intestine. During the colonoscopy, a tube-like scope is passed from the anus to the end portion of the large bowel. These procedures will allow the doctor to look for abnormal areas in your digestive system.

- You will have a bone marrow biopsy and/or aspiration to check the status of the disease. To collect a bone marrow aspirate and biopsy, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.
- You will have a new lymph node biopsy or other tissue biopsy or bone marrow biopsy will be used to confirm your diagnosis. Your doctor will explain the biopsy procedure to you in more detail, including its risks.
- If you can become pregnant, blood (about ½ teaspoon) or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

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 Drug Administration**

Each cycle is 28 days.

You will take 1 **acalabrutinib** tablet in the morning and evening (2 tablets each day total) about 12 hours apart, with a cup (about 8 ounces) of water You will take acalabrutinib every day while you are on study either with or without food. Each dose should be swallowed whole. If you miss a dose, you can take it up to 3 hours after the time you would have taken it. If it is later than 3 hours, you should skip the dose and start taking the tablets at the same time as usual the next day.

Starting on Day 1 of Cycle 2, **venetoclax** will be added to acalabrutinib. You will take venetoclax by mouth every day. If you miss a dose, you can take it up to 8 hours after the time you would have taken it. If it is later than 8 hours, you should skip the dose and start taking the capsules at the same time as usual the next day.

The dose of venetoclax you receive will be increased each week during Cycle 2 until you reach your targeted dose. If the disease does not respond after Week 16, your dose may be increased again. This will be discussed with you.

If the doctor thinks you are at risk for developing a side effect called tumor lysis syndrome (TLS), you may be hospitalized overnight. This will be discussed with you.

You will be given a study drug diary to write down when you take each dose of study drug and if you miss or vomit any doses. At each clinic visit, you must bring any unused study drug and your study diary to the study staff.

**Study Visits**

**On Day 1 of every cycle for the first 6 months and then every odd-numbered cycle after that:**

- You will have a physical and neurological exam.
- Blood (about 2 tablespoons) will be drawn for routine tests and to check the status of the disease.
- Blood (about 4 teaspoons) will be drawn for biomarker testing.
- If your doctor thinks it is needed, you will have a bone marrow biopsy and/or aspiration to check the status of the disease.
- If the study doctor thinks it is needed, you will have a gastrointestinal endoscopy.
- If your doctor thinks it is needed, you will have a PET/CT scan and/or bone marrow biopsy/aspiration to check the status of the disease.
- If you can become pregnant, you will have a blood (about ½ teaspoon) or urine pregnancy test.

On **Days 8, 15, and 22 of Cycle 2**

- You will have a brief physical exam.
- You may have blood (about 4 teaspoons) will be drawn for routine testing.

**End-of-Treatment Visit**

Within 30 days after your last dose of study drugs:

- You will have a physical and neurological exam.
- Blood (about 2 tablespoons) will be drawn for routine tests and to check the status of the disease.
- Blood (about 4 teaspoons) will be drawn for biomarker testing.
- If your doctor thinks it is needed, you will have a PET/CT scan and/or bone marrow biopsy/aspiration to check the status of the disease.
- If your doctor thinks it is needed, you will have a gastrointestinal endoscopy.
- If you can become pregnant, you will have a blood (about ½ teaspoon) or urine pregnancy test.

**Long Term Follow-Up**

After your end-of-treatment visit and if the disease has not gotten worse, you will return for a clinic visit every 4 months for 2 years, every 6 months for the next 2 years, and then every year after that

- Blood (about 2 tablespoons) will be drawn for routine tests and to check the status of the disease.
- You will have a PET/CT scan to check the status of the disease.

If you stop taking the study drugs because the disease gets better after 12 cycles:

- Blood (about 4 teaspoons) will be drawn for biomarker testing every 6 months (about every 6 cycles).
- You will have a CT scan to check the status of the disease every 3 cycles for 2 years, every 6 months for another 2 years, and then every year after that.

**Other Information**

Do not take acalabrutinib with grapefruit, grapefruit juice, Seville (sour) oranges, Seville orange juice, and products containing juices of these fruits.

If you take herbal remedies or dietary supplements, please tell the study doctor because some brands of these supplements should not be taken at the same time you take acalabrutinib.

Do not take acalabrutinib 3 days before and after any major surgical procedure. If you need a surgical procedure while on study, discuss this with the doctor as soon as possible.

## 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.

Acalabrutinib and venetoclax 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.

### Acalabrutinib Side Effects

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| • headache<br>• fatigue<br>• skin rash | • diarrhea<br>• bruising | • nausea<br>• muscle pain |

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| • irregular heartbeat (possible fainting, chest pain, and/or difficulty breathing)<br>• A-fib | • vomiting<br>• constipation<br>• abdominal pain<br>• bleeding<br>• low blood cell count (red, white, platelets) | • abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes)<br>• severe infection<br>• nosebleed |

Acalabrutinib may cause you to develop another type of cancer.

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

| | |
|---|---|
| • reactivation of hepatitis B infection (liver damage) | • severe bleeding (possibly in the digestive system and/or brain) |

If you are taking blood thinners (such as Warfarin), this may increase your risk of bleeding.

Acalabrutinib may cause progressive multifocal leukoencephalopathy (PML). PML is brain damage that is likely to result in paralysis and/or coma, which may be permanent. PML can also lead to death.

**Based on side effects seen in similar drugs, Acalabrutinib also may cause** life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure).

**<u>Venetoclax Side Effects</u>**

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| • fatigue<br>• diarrhea | • nausea<br>• low blood counts (red, platelets, white) | • upper respiratory tract infection |

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| • swelling (arm/leg)<br>• fever<br>• headache<br>• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood | • vomiting<br>• constipation<br>• back pain<br>• high blood levels of uric acid (possible painful joints and/or kidney failure) | • pneumonia<br>• cough<br>• tumor lysis syndrome (TLS)--breakdown products of the cancer cells entering the blood stream (possible |

| | | |
|---|---|---|
| pressure, organ failure, heart problems, changes in mental status, and/or seizure) | | weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage) |

TLS is a problem that can occur when cancer cells break down rapidly and the body has to get rid of the broken up cell parts. Sometimes your body, especially the kidneys, cannot remove the cell parts quickly enough, so the level of some of these cell products in your blood, such as salts and acids, can rise. This can happen especially in participants with large tumors or a high number of cancerous white cells in the blood. TLS can lead to serious problems, such as effects on your kidneys and heart (including abnormal heart rhythms), seizures, or even death.

If you develop TLS, your urine may look dark, thick, or cloudy. You may have fever, chills, nausea/vomiting, diarrhea, confusion, shortness of breath, irregular heartbeat, fatigue, muscle pain, joint discomfort, and/or seizure. If you notice any of these, tell your doctor or nurse right away. Your study doctor will closely watch and treat you as needed to lower the risk of any serious changes in your blood or other complications of TLS. You may need to have extra blood tests or EKGs to check for signs of TLS.

You should wear ear plugs or other hearing protection when involved in a loud activity.

If you notice any rash, hives, itching, or other signs of an allergic reaction such as swelling, wheezing, or you are having a hard time breathing, tell your doctor right away.

At this time, there are no known serious side effects that **occur in fewer than 3% of patients**.

**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.

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

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**Colonoscopy/endoscopy** could cause bleeding if a biopsy is performed. It could also cause infection, side effects to the medication used to induce sleep, or a tear in the nose, stomach lining, or intestine.

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

**MUGA scans** may cause allergic reactions to the radioactive tracer, injection site soreness, and/or swelling. They may cause damage to cells or tissue from being exposed to the radiation used in the scan. These side effects may occur in less than 10% of patients.

**CT scans** send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

**X-rays** send a small amount of radiation though the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

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 and for 2 days after the last dose of acalabrutinib and 30 days after the last dose of venetoclax, if you are sexually active.

Birth Control Specifications: If you can become pregnant, you must use a highly effective method of birth control.

Note: Some birth control pills may not work when you are taking certain drugs. If you have any questions about this, please discuss this with the study doctor.

Males: Do not donate sperm while on study and for 2 days after your last dose of acalabrutinib and 30 days after your last dose of venetoclax. Venetoclax may affect your ability to father children. 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.

## 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 Astrazeneca 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. Michael Wang, at 713-792-2860) 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. It may be dangerous to suddenly stop study treatment, and the study doctor can discuss ways to safely withdraw. If you withdraw from this study, you can still choose to be treated at MD Anderson. The study staff may ask if they can continue collecting the results of routine care from your medical record.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Astrazeneca, 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.

   Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

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: Astrazeneca.

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.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

**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.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

**Conflict of Interest**
Outside relationships are disclosed to and approved by the Conflict of Interest Committee, which reviews these relationships for compliance with institutional policy. This review helps the IRB to assure that financial relationships do not have an impact on the conduct of this study. The following members of the study staff have disclosed compensation from the funding source(s) of this study:

- Michael Wang (PI)

**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
   - Astrazeneca, who is a sponsor or supporter of this study
   - any future sponsors/supporters of the study
   - Acerta Pharma, who is the company who makes acalabrutinib and may receive data about safety and side effects
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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

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

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

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer 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 2018-0935.

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

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

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

**PERSON OBTAINING CONSENT**

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

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

**TRANSLATOR**

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

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

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