Consent Revision Date: 05/20/2011

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Ofatumumab for Residual Disease and Maintenance Following Chemotherapy or Chemoimmunotherapy in Patients with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)
2010-0266

Study Chair: William G. Wierda

1.

Participant's Name	Medical Record Number

You are being asked to take part in this clinical research study at The University of Texas M. D. Anderson Cancer Center ("M. D. Anderson"). This consent 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 your doctors can still find chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) cells (called "residual disease") in your marrow, blood, or lymph nodes after treatment with chemotherapy or chemoimmunotherapy.

DESCRIPTION OF RESEARCH

2. PURPOSE OF STUDY

The goal of this clinical research study is to find out if ofatumumab can control CLL or SLL that is left after chemotherapy or chemoimmunotherapy. The safety of the drug will also be studied.

Optional Procedures: You are being asked to allow extra blood to be drawn and stored in a research blood bank at GlaxoSmithKline for DNA testing and use in future research related to cancer.

You are being asked to allow extra bone marrow to be drawn and stored in a research tissue bank at GlaxoSmithKline for DNA testing and use in future research related to cancer.

You are also being asked to allow additional blood to be drawn for pharmacokinetic (PK) and pharmacodynamic (PD) testing. PK testing measures the amount of study drug in the body at different time points and PD testing measures how the level of study drug in your body may affect the disease.

3. DESCRIPTION OF STUDY

The Study Drug
Ofatumumab is designed to bind to the surface of some white blood cells (B-cells) and to kill these cells. It can destroy cancer cells that come from B-cells, and can be used to treat cancers of B-cells such as B-CLL.

Screening Tests
Signing this consent does not mean that you will be able to take part in this study. You will have "screening tests" to help the doctor decide if you are eligible to take part in this study. The following tests and procedures will be performed:

- Your medical history will be recorded.

- You will have a complete physical exam, including measurement of your height, weight, and vital signs (blood pressure, heart rate, breathing rate, and temperature).
- Blood (about 2 tablespoons) will be drawn for routine and hepatitis testing. This blood test will include a pregnancy test for women who are able to have children. To take part in this study the pregnancy test must be negative.
- You will have a bone marrow biopsy/aspirate to check the status of the disease. To collect a bone marrow biopsy/aspirate, an area of the hip is numbed with anesthetic and a small amount of bone/bone marrow is withdrawn through a large needle.
- Blood (about 1 tablespoon) will be drawn for biomarker tests. Biomarkers are chemical "markers" in the blood/tissue that may be related to your reaction to the study drug.
- If your doctor thinks it is needed, you will have additional tests (such as blood draws or CT scans) to check the status of the disease. The doctor will tell you more about any additional tests that need to be performed.

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
If you are found to be eligible to take part in this study, you will receive ofatumumab up to 20 times during this study. You will receive 8 weekly infusions and then an infusion every 2 months for 2 years or until the disease gets worse. You will receive ofatumumab by vein over about 6 ½ hours the first time and over 4 hours for all the following infusions. The first infusion will be the smallest dose. The second and later infusions will be 3 times larger than the first.

Before you receive the study drug each time, you will receive Tylenol (acetaminophen) by mouth to reduce the risk of fever. You will receive Benadryl (diphenhydramine) by mouth or vein and prednisolone (a steroid) by vein over about 30 minutes to reduce the risk of an allergic reaction or an infusion reaction.

During the infusions, you will be monitored closely. You will be expected to stay in clinic for about 71/2 hours on the day of the first infusion and 5 hours for all other infusions.

You will be seen at MD Anderson for mandatory visits for enrollment, ofatumumab infusions, for response assessment after 8 weekly ofatumumab doses (Month 3), during maintenance every 6 months and for follow-up at least once a year. Your local doctor may perform other visits and laboratory studies.

If you decide to have your local doctor perform study visits and laboratory studies, a letter will be sent to your doctor, describing your participation in this study and asking for your doctor's agreement to help manage your care.

Study Visits
The following tests and procedures will be performed **every other week during Weeks 1- 8 (Weeks 1, 3, 5 and 7)**:

- You will have a complete physical exam including measurement of your vital signs.
- Your medical history will be recorded.
- Blood (about 2 teaspoons) will be drawn for routine tests.

Starting at **Month 3**, you will have the following tests and procedures **every 2 Months:**

- You will have a complete physical exam including measurement of your vital signs.
- Your medical history will be recorded.
- Blood (about 2 teaspoons) will be drawn for routine tests.

Starting at **Month 3**, you will also have the following tests and procedures **every 6 months**, in addition to the ones performed every 2 months:

- Blood (about an additional 1 teaspoon) will be drawn for other routine tests.
- You may have CT scans to check the status of the disease, if your doctor thinks that this test is needed (**at Month 3 only**).
- You will have a bone marrow aspirate/biopsy to check the status of the disease.

Additional Information
Depending on the results of your hepatitis tests performed at the screening visit, you may have additional hepatitis tests. The study staff will tell you if you will have these tests performed. If you do have the additional hepatitis tests, blood (about 2 teaspoons) will be drawn during Months 3-24. The blood will be drawn at the same time of the routine blood draws to prevent unnecessary needle sticks.

Length of Study
You may continue taking the study drug for up to 20 doses (up to 24 months). You will no longer be able to take the study drug if the disease gets worse or intolerable side effects occur.

Your participation on the study will be over once you have completed the follow-up visits, which will last until you begin receiving any other treatment.

Follow Up Visits
Every 3 Months

- You will have a complete physical exam including measurement of your vital signs.
- Your medical history will be recorded.

- Blood (about 2 teaspoons every 3 months, about 1 teaspoon every 6 months) will be drawn for routine tests.
- If your doctor thinks it is needed, blood (about 2 teaspoons) will be drawn for hepatitis testing.

Every 6 Months, you will have a bone marrow aspirate/biopsy to check the status of the disease.

This is an investigational study. Ofatumumab is FDA approved for CLL resistant to standard chemotherapy. Ofatumumab's use in patients with residual CLL or SLL is investigational.

Ofatumumab will be provided at no cost to you while you are on the study.

Up to 42 patients will take part in this study. All will be enrolled at M. D. Anderson.

Optional Procedures: If you agree, extra blood (about 1 teaspoon) and bone marrow will be collected at your screening visit for DNA testing. This blood and bone marrow will be stored in a research tissue bank at GlaxoSmithKline for use in future research related to cancer.

Before your blood and bone marrow are sent to GlaxoSmithKline for banking, your name and any personal identifying information will be coded to protect your privacy. GlaxoSmithKline will not have access to the codes that link the samples to your identity. M. D. Anderson will not have oversight of any leftover blood and bone marrow that will be banked by GlaxoSmithKline for additional research.

If you agree, you will have additional blood drawn for PK and PD testing (about 1 tablespoon each time) at the following time points:

- **At Weeks 1, 2, 4, 8 and then Months 5, 15, and 27**, before you receive ofatumumab and 2 more times after the end of the dose.
- **At Weeks 3, 5, and then Month 7** and **every odd numbered month after this (months 9,11, 13, and so on)** before you receive ofatumumab.
- **At 1, 3, and 6 months** after your last ofatumumab dose.

There will be no cost to you for taking part in the optional procedures.

You do not have to agree to take part in the optional procedures in order to receive treatment on this study.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

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 that the drug is known to cause. 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 after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even cause 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.

Ofatumumab Side Effects

Likely (occurring in more than 20% of patients)

• fever	• pneumonia	• infection

Ofatumumab may likely cause low white blood cell counts. This means that while you take the drug, there is more of a chance of getting an infection, including pneumonia.

Receiving ofatumumab may likely cause an infusion reaction, especially during the first 2 times you receive it. This could result in tightening of the airways, difficulty breathing, swelling of the voice box, build-up of fluid in the lungs, flushing, high or low blood pressure, fainting, decreased blood supply to the heart, back pain, abdominal pain, fever, skin rash, hives, and/or tissue swelling.

Common (occurring in 3-20% of patients)

• arm and/or leg swelling • high blood pressure • low blood pressure • fast heartbeat • fatigue • chills • difficulty sleeping • headache • skin rash	• hives • increased sweating • diarrhea • nausea • back pain • muscle spasm • cough • inflammation of the airways	• sinus infection and/or inflammation • head cold • severe blood infection • herpes infection causing painful skin rash (shingles)

Ofatumumab may commonly cause low red blood cell counts. You may become anemic, fatigued, and/or short of breath. You may need a blood transfusion.

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

• brain damage • chest pain due to heart trouble • shivering • inflammation of the abdominal wall • bacteria in the blood	• destruction of red blood cells • low oxygen level in the blood • liver inflammation (possible liver failure) • throat tightness	• swelling of the voice box • infectious lung disease • organ failure caused by blood infection • severe infection due to low white blood cell counts

Ofatumumab may rarely cause destruction of red blood cells in addition to low platelet counts. You may have problems with bleeding and/or bruising. You may need a blood transfusion if a problem with bleeding occurs.

Your immune response to receiving a vaccine could be impaired after you are given ofatumumab due to a decrease in B-cells. Your study doctor will review your immunization (vaccination) history with you before you are given study drug. In addition, while you are taking part in this study, tell your study doctor before you receive any new vaccines.

In people who have ever been infected with hepatitis B virus, there is a risk that the virus can flare up during treatment with drugs that affect your immune system, such as ofatumumab. This could lead to liver failure. The risk of hepatitis B virus flaring up may continue for several months after you stop taking the drug. If you become jaundiced (yellowing of the skin and eyes) or develop viral hepatitis while taking ofatumumab or after stopping treatment, you should tell your study doctor right away. Your study doctor will discuss this risk with you and explain what testing is recommended to check for hepatitis.

Diphenhydramine Side Effects

It is not well known how often the side effects of diphenhydramine may occur.

• chest tightness • irregular heartbeat • extra heartbeats • fast heartbeat • low blood pressure • chills • confusion • strong involuntary muscle movements • disturbed coordination • dizziness • euphoria (unusual feelings of great happiness or well-being) • fatigue • headache • difficulty sleeping • irritability • nervousness	• restlessness • abnormal feeling of relaxation • sleepiness • skin sensitivity to light • skin rash • hives • menstrual problems (early menstruation) • loss of appetite • constipation • diarrhea • dry mucous membranes • abdominal pain • nausea • vomiting • throat tightness • dry mouth • difficulty urinating • inability to urinate	• frequent urination • destruction of red blood cells • nerve inflammation • tickling/tingling sensation • muscle twitching • blurred vision • double vision • inflammation of part of the ear that controls balance • ringing in the ears • nasal stuffiness • increased thickness of secretions in the lung • wheezing • sweating • severe allergic reaction

Diphenhydramine may cause low blood cell counts (white blood cells and platelets). This means that while you take the drug, there is more of a chance of getting an infection, including pneumonia. You may have problems with bleeding and/or bruising. You may need a blood transfusion if a problem with bleeding occurs.

Prednisolone Side Effects

It is not well known how often the side effects of prednisolone may occur.

• enlarged heart • heart failure • swelling (including face) • high blood pressure • strong involuntary muscle movements • headache • difficulty sleeping • weakness	• thin, fragile skin • hives • lower carbohydrate tolerance • Cushing's syndrome (an abnormal body condition that leads to obesity) • stunted growth	• inflammation of the pancreas (possible abdominal pain) • sores in the stomach or small intestine • sores in the esophagus • weight gain • abnormal liver tests (possible liver damage)

• nervousness • increased pressure in the skull • depression • euphoria (unusual feelings of great happiness or well-being) • difficulty sleeping • mood swings • personality changes • anxiety • tiredness • dizziness • bruising • facial skin redness • increased hair growth • spots under the skin • inability to respond to TB skin test	• high blood sugar (possible diabetes) • high blood levels of sodium (possible weakness and/or swelling) • low blood levels of potassium (possible weakness) • menstrual irregularities • low nitrogen levels in the body • stoppage of cortisol production in the body • abdominal swelling/discomfort • increased appetite • nausea	• joint pain • bone tissue death in joints of arms/legs • decreased muscle mass • muscle weakness • decreased bone density (possible fractures) • tendon rupture • cataracts (clouding of the lens of the eye) • eye bulging • eyelid swelling • increased pressure in the eye (possible vision loss) • eye irritation • nosebleeds • increased sweating • slow wound healing • infection

An overdose of **acetaminophen** may cause damage to the liver.

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 count), which may create a need for blood transfusions.

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

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

4a. Because taking part in this study can result in risks to an unborn or breastfeeding baby, 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: Patients of childbearing potential (females who have not been post menopausal for at least 12 consecutive months or who have not undergone previous surgical sterilization or males who have not been surgically sterilized) must be willing to practice birth control during the study.
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 will result in your removal from this study.

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

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

Researchers can learn about cancer and other diseases from your **banked blood and bone marrow**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record by researchers under the supervision of the study chair. Sometimes your samples may be used for genetic research about diseases that are passed on in families. Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests will not be put in your health records. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

5. POTENTIAL BENEFITS

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

Optional Procedures: There are no benefits for taking part in the optional procedures. Future patients may benefit from what is learned.

6. ALTERNATE PROCEDURES OR TREATMENTS

You may choose not to take part in this study. You may choose other investigational therapy, if available. You may choose not to have treatment at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

Optional Procedures: Treatment with the study drug may be given without taking part in the optional procedures.

I understand that the following statements about this study are true:

7. M. D. Anderson may benefit financially from my participation and/or from what is learned in this study.

8. This study is supported by: GlaxoSmithKline.

9. The M. D. Anderson Conflict of Interest policy states that no M. D. Anderson employee may serve as the study chair or co-chair on a research study if he/she has received payments from the study sponsor that are valued at $10,000 or greater in the past 12 months and/or has any stock investments with the study sponsor. M. D. Anderson's Institutional Review Board (IRB - a committee that reviews research studies) reviews the research-related financial interests of researchers at least once a year.

   Researcher Name(s) and Type(s) of Interest(s)
   Dr. William G. Wierda (Study Chair) has received compensation from GlaxoSmithKline as a Speaker and Scientific Advisor. The financial interests are within the limits of the conflict of interest policy.
   Dr. Hagop Kantarjian (Department Chair) has received compensation from GlaxoSmithKline as a Speaker. The financial interests are within the limits of the conflict of interest policy.

10. In a medical emergency, it is possible that I may be cared for by a doctor and/or administrator who have some form of an equity, stock option, or other interest in the sponsor or supporter of this study. If I want to receive updated information about the financial interests of any doctor or other M. D. Anderson employee who has cared for me, I may call the IRB at 713-792-2933. If I ask, I will be given access to information that will let me know if any University of Texas System or M. D. Anderson administrators have a conflict of interest, and I will be given the names of all doctors, administrators, and/or other M. D. Anderson employees who have a financial interest in GlaxoSmithKline.

11. I may ask the study chair any questions I have about this study, including questions about the costs. I may contact the study chair, Dr. William G. Wierda, at 713-745-0428. I may also contact the Chair of M. D. Anderson's IRB at 713-792-2933 with any questions that have to do with this study or my rights as a study participant.

12. My participation in this research study is strictly voluntary. I may refuse to take part in this study without any penalty or loss of benefits to which I am otherwise entitled. I may also withdraw from participation in this study at any time without any penalty or loss of benefits. I should first discuss leaving the study with my doctor. If I withdraw from this study, I may still be treated at M. D. Anderson.

13. I understand that the study may be changed or stopped at any time by the study chair, GlaxoSmithKline, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP) (a regulatory agency that oversees research in humans), or the IRB of M. D. Anderson.

14. I will be informed of any new findings that might affect my willingness to continue taking part in the study.

15. M. D. Anderson will take appropriate steps to keep my personal health information private. However, there is no guarantee of absolute privacy. Federal agencies (such as the FDA and the OHRP), GlaxoSmithKline, Representatives of GlaxoSmithKline, and the IRB of M. D. Anderson might review my record to collect data or to check that the research is being done safely and correctly. In some situations, the FDA could be required to reveal the names of participants.

16. If I suffer injury as a direct result of taking part in this study, M. D. Anderson will provide medical care. However, this medical care will be billed to my insurance provider or me in the ordinary manner. I understand that I will not be reimbursed for expenses or compensated financially by M. D. Anderson or GlaxoSmithKline for this injury. I may also contact the Chair of M. D. Anderson's IRB at 713-792-2933 with questions about study-related injuries.

17. Certain tests, procedures, and/or medications that I may receive as part of this study may be without cost to me because they are for research purposes only. However, my insurance provider or I may be financially responsible for the cost of supportive care and treatment of any complications resulting from the research tests, procedures, and/or medications, including hospitalization, nausea, vomiting, low blood cell counts, and dehydration. Standard medical care that I receive under this research study will be billed to my insurance provider and/or me in the ordinary manner. I should learn before taking part in this study which parts of the research-related care will be provided without charge, which costs my insurance provider will pay for, and which costs will be my responsibility. I may ask to speak with a financial counselor about the costs of this study.

18. I understand that there are no plans to compensate me for any patents or discoveries that may result from my participation in this research. I will receive no compensation for taking part in this study.

19. If the study chair allows and I choose, part of my care may be provided outside of M. D. Anderson by my home doctor(s). If I choose, then the care that is provided by my home doctor(s) will become a part of my study participation. Before I return home,

my home doctor(s) will be told about the study, my participation in the study, and the guidelines that they will need to follow while I am on the study. My home doctor(s) will receive relevant documents and parts of my medical/research records so that they can provide proper care for me and comply with clinical research requirements. My home doctor(s) will also be responsible for providing the M. D. Anderson research team with any documents and records about my care. This is necessary for compliance with study requirements. If my home doctor(s) is/are unable or unwilling to provide the care or the documentation required, I may need to return to M. D. Anderson for all study-related treatments and tests. My participation in the study may also need to be reconsidered.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, the research team at M. D. Anderson will be collecting information about you. This information may include your medical history, study schedule, and the results of any of your tests, therapies, and/or procedures. The purpose of collecting and sharing this information is to learn about how the study procedures may affect the disease and any study-related side effects. Your doctor and the research team may share your study information with the parties named in Section E below.

B. If you refuse to provide your authorization to disclose your protected health information, you will not be able to participate in this research study.

C. Your protected health information will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point.

D. All identifying information such as your name and address will be kept private. This information may be kept at M. D. Anderson forever. You will be assigned a code number so that your name will not be used. The research team at M. D. Anderson will be able to link the code number to your name. In some instances, in order to ensure the scientific value of the study, the parties named in Section E below will be able to view your study record but will not be permitted to copy any identifying information contained in your record.

E. Your information may be shared with the following parties:

- GlaxoSmithKline
- Representatives of GlaxoSmithKline
- The FDA
- The OHRP
- The IRB of M. D. Anderson
- Officials of M. D. Anderson
- Clinical study monitors who verify the accuracy of the information
- Individuals with medical backgrounds who determine the effect that the study procedures may have on the disease
- Individuals who put all the study information together in report form

F. You have the right to see and reproduce your records related to the research study, and ask for corrections, for as long as this information is held by the study chair and/or M. D. Anderson. However, in some studies, in order to ensure the scientific value of the study, participants are not able to view or reproduce their study records until the research has been completed with all participants in the study. If possible for this study, your doctor will be able to discuss your clinical test results with you.

G. There is no expiration date for the use of your protected health information. You may withdraw your authorization to share your protected health information at any time in writing. Instructions on how to do this can be found in the M. D. Anderson Notice of Privacy Practices (NPP). You may contact the IRB Staff at 713-792-2933 with questions about how to find the NPP. If you withdraw your authorization, you will be removed from the study and the study chair and staff will no longer use or disclose your protected health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related protected health information to preserve the scientific value of the study. The parties listed in Section E above may use any study data that were collected before you canceled your authorization.

H. Information about this research study may be submitted to ClinicalTrials.gov, a publicly available online database managed by the U. S. National Institutes of Health. None of your identifying information will be submitted to ClinicalTrials.gov. If information from this study is submitted, none of it will be able to be directly linked to you.

CONSENT/PERMISSION/AUTHORIZATION
FOR TREATMENT AND OPTIONAL PROCEDURES

(Mark choice(s) with an "X")

I elect to ____ or not to ____ allow extra blood to be drawn and stored in a research blood bank at GlaxoSmithKline for DNA testing and use in future research related to cancer as an optional procedure.
Participant's Initials _____

I elect to ____ or not to ____ allow extra bone marrow to be drawn and stored in a research tissue bank at GlaxoSmithKline for DNA testing and use in future research related to cancer as an optional procedure.
Participant's Initials _____

I elect to ____ or not to ____ allow extra blood to be drawn for PK and PD testing for use in future research related to cancer as an optional procedure.
Participant's Initials _____

Having read and understood the above and having had the chance to ask questions about this study, think about the study, and talk 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 have been given a signed copy of this consent document.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

_____ _____
SIGNATURE OF PARTICIPANT DATE

I was present during the explanation of the research to be performed under Protocol **2010-0266**.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

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

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

_____ _____
SIGNATURE OF PERSON RESPONSIBLE & RELATIONSHIP DATE

I have discussed this clinical 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.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

_____ _____
SIGNATURE OF STUDY CHAIR OR PERSON OBTAINING CONSENT DATE

Translator

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

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

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.)