THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Phase I Study of Pomalidomide in relapsed or refractory Waldenstrom Macroglobulinemia
2009-0972

Subtitle: Pom for WM

Study Chair: Sheeba K. Thomas

Participant's Name _____ Medical Record Number _____

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. You may choose not to take part in this study.

1. DESCRIPTION OF STUDY

The goal of this clinical research study is to find the highest tolerable dose of pomalidomide that can be given to patients with relapsed or refractory WM. The safety of this drug will also be studied.

This is an investigational study. Pomalidomide is FDA approved and commercially available for the treatment of certain types of MM. Its use in this study is investigational.

While you are on this study, pomalidomide will be provided at no cost to you.
Up to 30 patients will take part in this study. All will be enrolled at MD Anderson.

In order to obtain pomalidomide free of charge from Celgene, your name, address, phone, date of birth and the fact that you are participating in this trial will be disclosed to Celgene and its agents or vendors that supply pomalidomide and administer the POMALYST REMS™ program. By signing this consent form you agree to this disclosure.

2. STUDY PROCEDURES

The Study Drug

Pomalidomide is designed to change the immune system, which may interfere with the development of blood vessels that help support tumor growth. This may reduce or stop the growth of cancer cells.

Screening Tests

Signing this consent form 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 complete medical history will be recorded.
- You will be asked about any drugs you may be taking.
- You will have a physical exam, including measurement of your height, weight, and vital signs (blood pressure, heart rate, temperature, and breathing rate).
- You will be asked how well you are able to perform the normal activities of daily living (performance status).
- You will have an electrocardiogram (ECG -- a test that measures the electrical activity of the heart).
- Blood (about 1 tablespoon) will be drawn for routine tests.
- Blood (about 1 teaspoon) will be drawn for tests to check for hepatitis.
- Blood (about 1 teaspoon) and urine will be collected to check the status of the disease. You will collect urine over a 24-hour period. You will be given a container to collect the urine in.
- You will have computed tomography (CT) scans and/or magnetic resonance imaging (MRI) scans of the chest, abdomen, and pelvis to check the status of the disease.
- If your study doctor thinks it is needed, you may have a CT or MRI scan of the brain to check the status of the disease.
- You will have an x-ray of your chest.
- If your study doctor thinks it is needed, you will have x-rays of your bones to check for any bone lesions you may have.
- Blood (about 1 tablespoon) or urine will be collected for a pregnancy test for women who are able to become pregnant. To take part in this study, the pregnancy test must be negative.
- You will have a bone marrow aspiration and biopsy. To collect a bone marrow aspirate/biopsy, an area of the hip bone is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.

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 options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be assigned to a dose level of pomalidomide based on when you join this study. Up to 4 dose levels

of pomalidomide will be tested. Three (3) participants will be enrolled at each dose level. The first group of participants will receive the lowest dose level. Each new group will receive a higher dose than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of pomalidomide is found.

Dosing Schedules/Study Drug Administration

You will be enrolled in one of two dosing schedules (Schedule A or Schedule B) based on how previous participants have reacted to the study drug.

- If you are in Schedule A, you will take pomalidomide by mouth 1 time each night for 28 days in a row. These 28 days make up 1 "study cycle".
- If you are in Schedule B, you will take pomalidomide by mouth 1 time each night for 21 days in a row, followed by a 7-day "rest period".

You should take the study drug at about the same time every night. You should take it with a glass of water on an empty stomach. Pomalidomide capsules should be swallowed whole, and should not be broken, chewed, or opened. Pomalidomide should be taken without food, at least 2 hours before or 2 hours after a meal.

If a dose of pomalidomide is missed, it should be taken as soon as possible on the same day. If it is missed for the entire day, it should not be made up. Rather, it should be taken at the next scheduled time point.

Patients who take more than the prescribed dose of pomalidomide should be instructed to seek emergency medical care if needed and contact study staff immediately. You should bring any unused pills/bottles with you to each study visit.

You will also take aspirin every day that you take pomalidomide to help lower the chance of side effects.

Study Drug Diary

You will be given a study drug diary at the beginning of each cycle. You should bring the completed diary with you to each study visit. You should write about any missed or vomited doses in your diary. If you miss a dose of pomalidomide, it should be taken as soon as possible on the same day. If you miss a dose for an entire day, do not try to make it up by taking 2 doses the next day. If you vomit a dose of study drug, do not take another dose on the same day or double the next dose.

Study Visits

On **Day 1 of each Cycle**:

- You will have a physical exam, including measurement of your vital signs and weight.
- You will be asked about side effects you are having and any drugs you may be taking.
- Your performance status will be recorded.

- Blood (about 1 tablespoon) will be drawn for routine tests.
- Blood (about 1 teaspoon) and urine will be collected to check the status of the disease. You will collect urine over a 24-hour period. You will be given a container to collect the urine in.
- Blood (about 1 tablespoon) or urine will be taken for pregnancy test for women who are able to have children.

On **Days 8 and 22 of Cycle 1**:
- Blood (about 1 tablespoon) or urine will be taken for pregnancy test for women who are able become pregnant.

On **Day 15 of Cycle 1**:
- Blood (about 1 tablespoon) will be drawn for routine tests.
- You will be asked about any side effects you may be having and any drugs you may be taking.
- Blood (about 1 tablespoon) or urine will be taken for pregnancy test for women who are able to become pregnant.

On **Day 1 of every odd cycle** (Cycles 3, 5, 7 and so on):
- If your study doctor thinks it is needed, you may have a CT or MRI scan of the brain to check the status of the disease.
- You will have an x-ray of your chest.
- If your study doctor thinks it is needed, you will have x-rays of your bones to check for any bone lesions you may have.

Starting with Cycle 3, you will have the following tests every 4 months for the first 2 years, then once a year as long as you are on the study, and when the study doctor thinks it is needed:
- You will have CT or MRI scans of the chest, abdomen, and pelvis to check the status of the disease.

If the disease completely responds to the drugs, you will have a bone marrow aspirate and biopsy to confirm complete response.

Length of Study
You will be able to take pomalidomide for as long as the doctor thinks it is in your best interest. You will be taken off study if the disease gets worse or you have intolerable side effects.

End-of-Treatment (discontinuation from study drug)
After you are taken off study, you will have an end-of-treatment visit. The following tests and procedures will be performed:
- You will have a physical exam, including measurement of your weight and vital signs.
- You will asked about any side effects you may be having and any drugs you may be taking.

- Your performance status will be recorded.
- You will have an ECG.
- Blood (about 1 tablespoon) will be drawn for routine tests.
- Blood (about 1 teaspoon) and urine will be collected to check the status of the disease. You will collect urine over a 24-hour period. You will be given a container to collect the urine in.
- You will have a CT and/or MRI scan of the chest, abdomen, and pelvis to check the status of the disease.
- If your study doctor thinks it is needed, you may have a CT or MRI scan of the brain to check the status of the disease.
- You will have an x-ray of your chest.
- You will have x-rays of your bones to check for any bone lesions you may have.

- Blood (about 1 tablespoon) or urine will be taken for pregnancy test for women who are able to become pregnant.

Safety assessment Visit

After you are taken off study, you will have a safety assessment visit 30 days after your last dose of the study drug. The following tests and procedures will be performed:

- You will have a physical exam, including measurement of your weight and vital signs.
- Your performance status will be recorded.
- Blood (about 1 tablespoon) will be drawn for routine tests.
- You will be asked about side effects you may be having.

Follow-up Phone Call

The study staff will call you every 6 months for 1 year to ask about any new treatments you may have started. The phone call should take about 5 minutes.

Additional Information

If you take more than the prescribed dose of pomalidomide you should seek emergency medical care if needed and contact the study staff right away.

Females who are able to become pregnant who might be caring for you should not touch the pomalidomide capsules or bottles unless they are wearing gloves.

In order to participate in this study you must register into and follow the requirements of the POMALYST REMS™ program of Celgene Corporation. This program provides education and counseling on the risks of fetal exposure, blood clots and reduced blood counts. You will be required to receive counseling, follow the pregnancy testing and birth control requirements of the program that are appropriate for you and take surveys regarding your compliance with the POMALYST REMS™ program.

3. 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.

Pomalidomide Side Effects

Common (occurring in more than 20% of patients)

● swelling (arm/leg) ● fatigue ● nerve damage (possible numbness, pain, and/or loss of motor function) ● dizziness ● fever ● skin rash	● abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) ● constipation	● nausea ● diarrhea ● loss of appetite ● low blood cell counts (red, white, platelet) ● weakness ● pain ● muscle spasms ● difficulty breathing

Pomalidomide may cause low blood cell counts (white blood cells, red blood cells, platelets).

- A low white blood cell count increases your risk of infection (such as viral or fungal 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.
- 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.

Occasional (occurring in 3-20% of patients)

● headache ● anxiety ● confusion	● high blood sugar (possible diabetes) ● dehydration	● kidney failure ● nosebleed ● cough

● chills ● difficulty sleeping ● itching/dry skin ● increased sweating	● weight loss/gain ● vomiting ● tremors	● severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Frequency Unknown, but between 1-10%

● heart attack/failure ● low blood pressure (possible dizziness/fainting) ● mental status change ● depression	● walking/balance problems (possible falling) ● abnormal liver tests (possible liver damage, yellowing of the skin and/or eyes)	● broken bone(s) ● collapse of bones in the spine ● bacteria in the blood ● multiorgan failure

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

● inability to urinate ● liver failure	● breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)	● allergic reaction

Pomalidomide may cause you to develop another type of cancer (such as acute myeloid leukemia, a type of blood cancer).

Pomalidomide may also cause blood-clotting events (such as deep vein thrombosis, blood clots in the lungs, heart attack, and stroke).

Please refer to the package insert for the known side effects of **aspirin**. Side effects related to bleeding may be more common when taking aspirin in combination with another blood-thinning drug.

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: Pomalidomide was found to cause birth defects in an experimental study in animals. Pomalidomide is related to thalidomide. Thalidomide is known to cause severe life-threatening human birth defects. Pomalidomide is therefore considered to have the potential to cause birth defects in humans. If pomalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Females must not become pregnant while taking pomalidomide. Because of this risk, all patients taking pomalidomide must read thefollowing statements that apply to them according to gender and menopausal status.

FOR FEMALES WHO ARE ABLE TO BECOME PREGNANT*
*(Sexually mature female who: 1) has not undergone a hysterectomy (the surgical removal of the uterus) or bilateral oophorectomy (the surgical removal of both ovaries) or 2) has not been naturally postmenopausal for at least 24 consecutive months)
Please read thoroughly and initial each space provided if you understand each statement
_____: I understand that birth defects may occur with the use of pomalidomide. I have been warned by my doctor that my unborn baby may have birth defects and can even die, if I am pregnant or become pregnant while I am taking pomalidomide.
_____: I understand that I must NOT take pomalidomide if I am pregnant, breast-feeding a baby or able to get pregnant and not using 2 reliable methods of birth control.
_____: If I am having sexual relations with a man, my uterus and/or both ovaries have not been removed, I have had at least one menstrual period in the past 24 months and/or my menses stopped due to treatment of my disease, I understand that I am able to become pregnant. I must use one highly effective method of birth control plus one additional effective method of birth control (contraception) at the SAME TIME.

Highly Effective Methods	Additional Effective Methods
Intrauterine device (IUD)	Latex condom
Hormonal (birth control pills, injections, implants)	Diaphragm
Tubal ligation	Cervical Cap
Partner's vasectomy	

_____: These birth control methods must be used during the following time periods related to this study: 1) for at least 28 days before starting pomalidomide therapy; 2) while participating in the study; during interruptions in therapy and 3) for at least 28 days after pomalidomide has been stopped. I must use these methods unless I completely abstain from heterosexual sexual contact. If a hormone (birth control pill, injection, patch or implant) or IUD method is not medically possible for me, I may use another highly effective method or two barrier methods AT THE SAME TIME.
_____: I know I must have a pregnancy test done by my doctor within 10 – 14 days and 24 hours prior to starting pomalidomide therapy, even if I have not had my

menses due to treatment of my disease or had as little as one menstrual period in the past 24 months. If I have regular or no menstrual cycles, I will then have pregnancy tests every week for the first 28 days, then every 28 days while I am taking pomalidomide, again when I have been taken off of pomalidomide therapy and then 28 days after I have stopped taking pomalidomide. If I have irregular menstrual cycles, I will have pregnancy tests every week for the first 28 days, then every 14 days while I am taking pomalidomide, again when I have been taken off of pomalidomide therapy, and then 14 days and 28 days after I have stopped taking pomalidomide.

_____: I know I must immediately stop taking pomalidomide and inform my doctor, if I become pregnant while taking the drug, if I miss my menstrual period or have unusual menstrual bleeding, if I stop using 2 reliable forms of birth control, or if I think for any reason that I may be pregnant. I must talk to my doctor before changing any birth control methods.

_____: I am not now pregnant, nor will I try to become pregnant for at least 28 days after I have completely finished taking pomalidomide.

_____: I understand that pomalidomide will be prescribed only for me. I must not share it with ANYONE, even someone that has similar symptoms to mine. It must be kept out of reach of children and should never be given to females who are pregnant or able to have children.

_____: I agree any unused drug supply will be returned to the research site at each visit.

_____: I know that I cannot donate blood while taking pomalidomide and for 28 days after stopping pomalidomide.

Study patients who become pregnant will be monitored throughout the pregnancy and will continue to be monitored for 30 days after delivery (premature delivery, aborted fetus, full-term pregnancy, or no longer pregnant).

FOR ALL MALES

Please read thoroughly and initial each space provided if you understand each statement:

_____: I understand that birth defects may occur with the use of pomalidomide. I have been warned by my doctor that an unborn baby may have birth defects and can even die, if a female is pregnant or becomes pregnant while taking pomalidomide.

_____: I have been told by my doctor that I must NEVER have unprotected sexual contact with a female who can become pregnant. Because it is not known whether pomalidomide is present in semen, my doctor has explained that I must completely abstain from sexual contact with females who are pregnant or able to become pregnant, or I must use a latex condom every time I engage in any sexual contact with females who are pregnant or may become pregnant. I must do this while I am taking pomalidomide and for 28 days after I stop taking pomalidomide, even if I have had a successful vasectomy.

_____: I know I must inform my doctor if I have unprotected sexual contact with a female who is pregnant or can become pregnant or if I think, for ANY REASON, that my sexual partner may be pregnant. Female partners of male patients taking

pomalidomide should be advised to call their own physician immediately if they get pregnant.
_____: I understand that pomalidomide will be prescribed only for me. I must not share it with ANYONE, even someone that has similar symptoms to mine. It must be kept out of reach of children and should never be given to females who are able to have children.
_____: I agree any unused drug supply will be returned to the research site at each visit.
_____: I know that I cannot donate blood, sperm or semen while taking pomalidomide and for 28 days after stopping pomalidomide.

FOR FEMALES THAT ARE NOT ABLE TO BECOME PREGNANT
Please read thoroughly and initial each space provided if you understand each statement.
_____: I understand that birth defects may occur with the use of pomalidomide. I have been warned by my doctor that an unborn baby may have birth defects and can even die, if a female is pregnant or becomes pregnant while taking pomalidomide.
_____: I certify that I am not now pregnant, nor am I of child bearing potential as I have been in a natural menopause for at least 24 months (been through the change in life without even 1 menstrual period for the past 24 months); or I had my uterus removed (hysterectomy) or had both my ovaries removed (bilateral oophorectomy).
_____: I understand that pomalidomide will be prescribed only for me. I must not share it with ANYONE, even someone that has similar symptoms to mine. It must be kept out of reach of children and should never be given to females who are pregnant or able to have children.
_____: I agree any unused drug supply will be returned to the research site at each visit.
_____: I know that I cannot donate blood while taking pomalidomide and for 28 days after stopping pomalidomide.

ALL PATIENTS
You will be counseled at least every 28 days about not sharing pomalidomide (and other study drugs), the potential risks of fetal exposure, abstaining from blood and other donations, the risk of changes in blood counts and blood clots, and you will be reminded not to break, chew or open pomalidomide capsules. You will be provided with the “pomalidomide Information Sheet for Patients Enrolled in Clinical Research Studies” with each new supply of pomalidomide as a reminder of these safety issues.

_____:I understand and agree to receive counseling and to comply with the pregnancy precaution requirements of the POMALYST REMS™ program.

Pregnant females or females that are able to become pregnant should not handle or administer pomalidomide unless they are wearing gloves.

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 will result in your removal from this study.

4. POTENTIAL BENEFITS

Taking pomalidomide may help to control WM. Future patients may benefit from what is learned. There may be no benefits for you in this study.

5. OTHER PROCEDURES OR TREATMENT OPTIONS

You may choose to receive standard therapies including rituximab, cladribine with rituximab, bortezomib based therapy, or thalidomide based therapies. 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.

6. 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 Celgene Coorporation for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 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.

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

7. You may ask the study chair (Dr. Sheeba K. Thomas, 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 713-792-2933 with any questions that have to do with this study or your rights as a study participant.

8. Your participation in this research study is strictly voluntary. 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.

9. This study or your participation in it may be changed or stopped at any time by the study chair, Celgene Coorporation, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

10. 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.

11. MD Anderson may benefit from your participation and/or what is learned in this study.

12. This study is sponsored and/or supported by: Celgene Coorporation.

13. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s). If you have any questions about this, you may call the IRB at 713-792-2933.

Conflict of Interest

Dr. Sheeba Thomas (Study Chair) has received compensation from Celgene (the study sponsor) as a Scientific/Advisory Committee Member. The amount received was within the limits of the conflict of interest policy.

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

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Celgene Coorporation, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

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

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

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

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

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

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.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____ _____
SIGNATURE OF PARTICIPANT DATE

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.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____ _____
SIGNATURE OF LAR DATE

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____
RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT
I was present during the explanation of the research to be performed under Protocol **2009-0972**.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____ _____
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.

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.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS _____ _____
SIGNATURE OF STUDY CHAIR DATE
OR PERSON AUTHORIZED TO OBTAIN 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.

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 below.)

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE