The Ohio State University Consent to Participate in Research

Study Title:	**A Phase II Study of MOR00208 in Combination with Lenalidomide for Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia(CLL)/Small Lymphocytic Lymphoma (SLL)/Prolymphocytic Leukemia (PLL), Including those who have Relapsed on a BTK inhibitor, or Patients with Untreated CLL/SLL/PLL**
Principal Investigator:	**Jennifer Woyach, M.D.**
Sponsor:	The Ohio State University

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

This study is being done to determine whether the combination of lenalidomide and MOR00208 is safe and effective in patients with CLL or SLL or PLL (hereafter referred to as CLL). Lenalidomide is a standard treatment for CLL both as an initial therapy for older patients, and for patients who have received other therapies in the past. This study is combining lenalidomide with MOR00208, which is a drug that has not been approved by the FDA and is an experimental drug. This is a phase II study, which means that all patients will receive the same dose, and the primary purpose of the study is to look at how effective this combination is. At the same time, we will collect information to evaluate side effects of this combination.

Another purpose of the study is to study how these drugs affect CLL cancer cells and the immune system of CLL. This will be studied using special laboratory tests on blood samples taken during the course of treatment. These research blood draws are described below.

MOR00208 is a man-made antibody that targets CD19, which is a protein on the surface of B cells, including CLL cells and B cell lymphoma cells. This antibody then causes these cells to die. This drug is given intravenously. Lenalidomide is a drug that can activate the immune system and can also cause CLL cells and lymphoma cells to die. This drug is a pill that is taken daily.

2. How many people will take part in this study?

Up to 75 patients will participate in this study. Of these 75, 20 of these patients will have CLL that has not yet been treated, 20 patients will have CLL that has been previously treated, and 25 will have CLL that has previously been treated with ibrutinib.

3. What will happen if I take part in this study?

This is a clinical trial (a type of research study). It includes only patients who choose to take part. You may take your time to make your decision and discuss this with your family and friends. By agreeing to take part in this study, you are agreeing to comply with the study requirements.

If you are included in Cohort 1 or 2:
Since the combination of drugs on this study has not been used before, the first 6 patients with relapsed CLL and the first 6 patients with untreated CLL will be enrolled separately to evaluate side effects of the combination. Once the combination is determined to be safe, the rest of the patients will be enrolled. While we expect that the doses used in the first 6 patients will be safe, it is possible that this group may experience different side effects or receive a different dose from the patients enrolled later in the study.

A single course of the study drug or "cycle" is 28 days. If you tolerate the study drug (MOR00208) and your study doctor feels that your cancer is stable or responding to the study drug or that you are benefiting from the study drug, you may continue to receive treatment until your disease progresses or unacceptable drug-related toxicity occurs. You will visit the clinic on days: 1, 2, 8, 15, and 22 for the first month of treatment (Cycle 1), followed by monthly evaluations and treatments for the next eleven months (Cycles 2-12).

You will receive your dose of study drug (MOR00208) by IV infusion on days: 1, 2, 8, 15, and 22 for the first month of treatment (Cycle 1), followed by monthly on Day 1 of each cycle after this. You will take your first dose of lenalidomide on Cycle 1, Day 9 and take it orally daily for as long as your study doctor feels that your cancer is stable or responding to the drug or that you are benefiting from the drug, you may continue to receive treatment until your disease progresses or unacceptable drug-related toxicity occurs. You will receive enough lenalidomide to last you until your next clinic visit

(enough for a full cycle). You should make all attempts to follow the treatment schedule and take the drug at the assigned time. You should take the drug around the same time each day.

If you miss a dose of the lenalidomide, it can be taken up to 6 hours after the scheduled time. On the following day, you should return to taking the drug at the normally scheduled time. If more than six hours have passed since the regularly scheduled time you take the drug, you should just skip the dose and resume taking the drug at the next scheduled time. The missed dose will not be made up.

If you are included in Cohort 4:
Patients in Cohort 4 (previously on ibrutinib) will not receive lenalidomide, and will instead be treated with ibrutinib plus MOR00208. Since the combination of drugs on this study has not been used before, the first 6 patients with relapsed CLL and the first 6 patients with untreated CLL will be enrolled separately to evaluate side effects of the combination. Once the combination is determined to be safe, the rest of the patients will be enrolled. While we expect that the doses used in the first 6 patients will be safe, it is possible that this group may experience different side effects or receive a different dose from the patients enrolled later in the study.

A single course of the study drug or "cycle" is 28 days. If you tolerate the study drug (MOR00208) and your study doctor feels that your cancer is stable or responding to the study drug or that you are benefiting from the study drug, you may continue to receive treatment until your disease progresses or unacceptable drug-related toxicity occurs.
You will visit the clinic on days: 1, 2, 8, 15, and 22 for the first month of treatment. During the next 2 months (months 2 and 3), you will visit the clinic on days 1,8,15, and 22. Following this, you will have twice monthly evaluations and treatments for the next nine months (Cycles 4-12).

You will receive your dose of study drug (MOR00208) by IV infusion on days: 1, 2, 8, 15, and 22 during the first month of treatment, and days 1,8,15, and 22 during the next 2 months. This will be followed by twice monthly on Days 1 and 15 of each cycle after this. You will take ibrutinib through this entire study as you were previously, and will continue after MOR00208 is finished as long as your study doctor feels that your cancer is stable or responding to the drug or that you are benefiting from the drug. You should make all attempts to follow the treatment schedule and take the drug at the assigned time. You should take the drug around the same time each day.

If you miss a dose of the ibrutinib, it can be taken up to 6 hours after the scheduled time. On the following day, you should return to taking the drug at the normally scheduled time. If more than six hours have passed since the regularly scheduled time you take the drug, you should just skip the dose and resume taking the drug at the next scheduled time. The missed dose will not be made up.

If you decide you want to be in this study and you sign the consent form, you will be asked to have a medical evaluation done in order to determine if you qualify for the study. If you meet all of the requirements, you will be enrolled in the study. A description of tests and visits required for the medical evaluation are listed below:

Pre-treatment Evaluation:

To find out if you qualify for the study, you will undergo several tests and procedures, as well as a complete medical examination. These exams, tests and procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Medical History
- You will be asked for a complete list of medicines you are taking, including supplements and vitamins.
- Physical Examination (including vital signs, height and weight, measurement of lymph nodes, liver, spleen)
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, beta-2-microglobulin, direct Coombs, immunoglobulins, cytogenetics, and liver function tests).
- If you are a woman of child bearing potential you will be required to complete a serum pregnancy test with negative results within 10-14 days of treatment.)
- Women of childbearing potential and men must agree to use adequate contraception for at least 14 days prior to the study and for the duration of participation.
- A CT (computed tomography) scan or a PET/CT will be performed to measure the size of the cancer in your body. A CT scan is a computerized x-ray that gives your doctor clearer pictures of the inside of your body. CT scans are routine procedures used to help doctors diagnose and follow the size and location of your cancer.
- Bone Marrow Biopsy and Aspirate (this is a standard procedure, but an extra amount of bone marrow, about 2 teaspoons, will be collected for research).
- Research Buccal Swab (a swab will be taken of the inside of your mouth for DNA studies to compare leukemia DNA to your normal DNA)

During the Study:

If you qualify for the study, you will start treatment with the study drug as an outpatient on the schedule described above. While receiving treatments with the study drug your physician will continue to monitor your health and the status of your disease.

Cohorts 1 and 2:
Cycle 1-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.

- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes.
- Study drug MOR00208 will be given by IV infusion.

Cycle 1-Day2:

- Study drug MOR00208 will be given by IV infusion.

Cycle 1-Day8:

- Prior to treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes.
- Study drug MOR00208 will be given by IV infusion.

Cycle 1-Day9:

- Lenalidomide will be taken orally daily, through the end of cycle 12

Cycle 1-Days 15:

- Prior to treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes.
- Study drug MOR00208 will be given by IV infusion.

Cycle 1-Day22:

- Study drug MOR00208 will be given by IV infusion.

Cycle 2, 5, 8, and 11-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes.
- Study drug MOR00208 will be given by IV infusion.
- Lenalidomide monthly dose supply will be given.

Cycle 3, 4, 6, 9, 10, and 12-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Study drug MOR00208 will be given by IV infusion.
- Lenalidomide monthly dose supply will be given.

Cycle 7-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- A CT (computed tomography) scan will be performed to measure the size of the cancer in your body. A CT scan is a computerized x-ray that gives your doctor clearer pictures of the inside of your body. CT scans are routine procedures used to help doctors diagnose and follow the size and location of your cancer.
- A Bone Marrow Biopsy and Aspirate will be required if your doctor feels you are in complete remission. This is required to support the diagnosis as well as for research (an extra amount of bone marrow, about 2 teaspoons, will be collected for research)
- Study drug MOR00208 will be given by IV infusion.
- Lenalidomide monthly dose supply will be given.

Additional blood tests, x-rays, and procedures may be requested if your doctor feels they are medically necessary.

Cohort 4:

Cycles 1-3-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes.
- Study drug MOR00208 will be given by IV infusion.
- You will take ibrutinib starting Cycle 1 Day 1 and continuing throughout the study

Cycle 1-Day2:

- Study drug MOR00208 will be given by IV infusion.

Cycles 1-3-Day8:

- Prior to treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes during cycle 1 only.
- Study drug MOR00208 will be given by IV infusion.

Cycles 1-3-Day 15:

- Prior to treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.

- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes during cycle 1.
- Study drug MOR00208 will be given by IV infusion.

Cycles 1-3-Day22:

- Study drug MOR00208 will be given by IV infusion.

Cycles 5, 8, and 11-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Approximately 23 ml (5 teaspoons) of blood will be collected prior to taking the study drug for research purposes.
- Study drug MOR00208 will be given by IV infusion.

Cycle 4, 6, 9, 10, and 12-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Study drug MOR00208 will be given by IV infusion.

Cycle 7-Day1:

- Prior to the first treatment your physician will again assess you with a complete medical history, including how you are feeling and if there have been any changes in your health or medications since your last visit.
- A physical examination including height and weight and vital signs (blood pressure, pulse, respiratory rate and temperature) will be measured.
- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- A CT (computed tomography) scan will be performed to measure the size of the cancer in your body. A CT scan is a computerized x-ray that gives your doctor clearer

pictures of the inside of your body. CT scans are routine procedures used to help doctors diagnose and follow the size and location of your cancer.

- A Bone Marrow Biopsy and Aspirate will be required if your doctor feels you are in complete remission. This is required to support the diagnosis as well as for research (an extra amount of bone marrow, about 2 teaspoons, will be collected for research)
- Study drug MOR00208 will be given by IV infusion.

Cycles 4-12 Day 15:

- Routine Blood Tests (Complete Blood Count, test of blood chemistries – various substances in the blood, test of kidney function, and liver function tests) will be done prior to treatment.
- Study drug MOR00208 will be given by IV infusion.

Additional blood tests, x-rays, and procedures may be requested if your doctor feels they are medically necessary.

At the End of Treatment:

You may stop treatment with the study drug for several reasons: because your cancer is not responding to this treatment, because the treatment has caused too many side effects, or because you choose to stop treatment. No matter the reason for stopping treatment, you will continue to be followed. Within 28 days (4 weeks) of completing treatment, your doctor will repeat a medical history and perform a physical examination, including measurements of your lymph nodes, liver, and spleen. You will also have routine laboratory tests that are part of the regular care for patients with your cancer. CT scans will be repeated at this time, as well as Bone marrow biopsy and aspirate samples will be collected for patients who relapse or for patients who have a complete response at 12 months. Approximately 23 ml (5 teaspoons) of blood will be collected for research purposes. Additional blood tests, x-rays, and procedures may be requested if your doctor feels they are medically necessary.

4. How long will I be in the study?

You may continue to receive treatment with the study drug (MOR00208) for up to 12 cycles if you show no signs of worsening disease and do not suffer from dangerous side effects. If you are in Cohorts 1-2 you may continue to receive treatment with the Lenalidomide indefinitely if you show no signs of worsening disease and do not suffer from dangerous side effects. If you are in Cohort 4 you may continue to receive treatment with ibrutinib indefinitely if you show no signs of worsening disease and do not suffer from dangerous side effects. You will be seen and examined by your doctor monthly after cycle 1 to monitor how well your disease responded to this treatment, to make sure that any side effects have resolved, receive study drug, and to find out if you have developed any unexpected side effects.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. It is important to tell your doctor if you are thinking about stopping or decide to stop so any risks from the treatment can be evaluated and your doctor can inform you what follow-up care and testing could be most helpful for you. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

While you are taking part in this study, you are at risk for the following side effects. You should talk to the researcher and/or your medical doctor about these side effects. There also may be other side effects that are not known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and uncomfortable. Many side effects go away shortly after treatment is stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be a risk of death.

Sometimes a second primary cancer arises after patients have undergone cancer therapy, including therapy using chemotherapeutic agents used to treat multiple myeloma. Recently, in clinical trials of patients with newly diagnosed multiple myeloma, a higher number of second cancers has also been reported in patients treated with high doses of chemotherapy (induction therapy) and/or stem cell transplant followed by prolonged (maintenance) lenalidomide therapy compared to those who received induction therapy and/or transplant without maintenance lenalidomide.

We do not know at this time whether prolonged lenalidomide therapy in this clinical setting actually increases the risk of second primary cancers. No increase in second primary cancers has been observed in patients receiving lenalidomide therapy who have relapsed multiple myeloma or other types of cancer.

We will be carefully monitoring these events (second primary cancers) in on-going studies of lenalidomide therapy and will inform you if there are any changes. We want you to be aware of this possibility and to continue to follow standard medical advice for prevention and early detection of other cancers during and after your treatment. There is some concern that lenalidomide could cause second cancers, but the data is not clear. It is already known that standard chemotherapy has the risk of causing other bone marrow disorders as well.

You should talk to your study doctor promptly about any side effects that you have while taking part in the study.

MOR00208

MOR00208 is a monoclonal antibody which may affect the immune system and you may become more prone to infections. You may experience certain unwanted effects and symptoms as a result of treatment with MOR00208 and these side effects could be serious.

The known unwanted effects and symptoms include infusion-related reactions like:

- Chills
- Sweating
- Nausea and vomiting
- hypotension
- wheezing or difficulty breathing
- reduction in white blood cells and platelets
- unwanted effects of massively dying tumor cells
- hepatitis B reactivation
- skin reactions and infections.

In some rare cases the infusions of study medication may be temporarily interrupted due to infusion-related reactions; all study drug infusions will be performed under surveillance of authorized study team members.

Past experience has indicated that some adverse reactions not reported previously may occur when antibodies are taken.

Please inform your study doctor immediately about:

- any feeling of ill-health
- side effects
- discomfort
- elevated temperature
- changes in your body weight during the course of the study.

Your study doctor will then decide on treatment according to your individual need.

In addition to side effects, the administration of study drug requires the use of an intravenous catheter (cannula) which is usually placed in the forearm. While the drug is being administered, pain and/or bruising may be experienced at the insertion point. The risk of vein problems (phlebitis) or blood clots (thrombosis) cannot be eliminated. Damage to the nerves at the insertion point can be a rare side effect of having blood taken.

Lenalidomide (Cohorts 1-2)

The known side effects of lenalidomide are listed below:

Likely (>20% of patients):

- Lack of enough red blood cells (anemia) which may cause pale skin, dizziness, shortness of breath, and/or fatigue
- Constipation
- Diarrhea
- Fatigue or tiredness
- Decreased number of a type of white blood cell (neutrophil/granulocyte) which may cause you to be more at risk for infection
- Decreased number of a type of blood cell that helps to clot blood (platelet) which may lead to prolonged bleeding

Less Likely (≤20% of patients):

- Abnormally low level of thyroid gland hormone
- Nausea or the urge to vomit
- Vomiting
- Chills
- Swelling of the arms and/or legs
- Fever
- Infection
- Decreased number of a type of white blood cell (lymphocyte) which may cause you to be more at risk for infection
- Weight loss
- Decrease in the total number of white blood cells (leukocytes) which may cause you to be more at risk for infection
- Loss of appetite
- Joint pain
- Back pain
- Muscle cramps/spasms
- Muscle pain
- Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)
- Headache or head pain
- Difficulty sleeping or falling asleep
- Cough
- Shortness of breath
- Excess sweating
- Itching
- Skin rash with the presence of macules (flat discolored area) and papules (raised bump)
- A chronic, inflammatory skin condition with sores covering the skin
- Formation of a blood clot that plugs the blood vessel; which may block blood flow and oxygen supply to important organs such as the lung (breathing problems), brain (stroke), heart (heat attack) and intestines (abdominal pain and death of intestines) which can cause death

Rare but Serious (<3% of patients):

- Inflammation (swelling and redness) of the pancreas which may cause abdominal pain, nausea, and/or vomiting
- Serious, life-threatening allergic reaction requiring immediate medical treatment by your doctor. The reaction may include extremely low blood pressure, swelling of the throat, difficulty breathing, and loss of consciousness.
- Increased blood level of fat-digesting enzyme (lipase) which may indicate damage to the pancreas
- Group of signs and symptoms due to rapid breakdown of tumor that can occur after treatment of cancer has started that causes increased levels of blood potassium, uric acid, and phosphate, decreased levels of blood calcium, and kidney failure
- A blood disease (leukemia) caused by chemotherapy
- Decreased production of blood cells by the bone marrow which may cause you to be more at risk for infection
- Temporary growth in tumor or worsening of tumor related problems
- Development of a new cancer resulting from treatment of an earlier cancer
- Progressive necrosis (tissue death) of a part (the white matter) of the brain without inflammation (swelling and redness)
- Sudden decrease of kidney function which may cause swelling in the legs and feet, nausea and vomiting, decreased urination, and/or pain in the lower back
- Severe reaction of the skin and gut lining that may include pain or bleeding from rash and shedding or death of tissue
- Potentially life-threatening condition affecting less than 10% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer)
- Life-threatening condition affecting greater than 30% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer)
- Severe infection which may ultimately lead to death
- Choroidal effusion – a collection of fluid behind the eye that can lead to vision changes and possibly blindness
- Sudden death
- Heart failure
- Failure of multiple organs
- Mesenteric Infarction – death of the tissue of the intestines due to decreased blood flow

It is possible, though very unlikely, that your cancer may appear to get worse before it gets better (tumor flare) or it may not get better at all while on this therapy.

If you have ever received lenalidomide before, you are already registered in the Celgene REMS program (formerly known as RevAsssist) and there is no additional registration required for this clinical trial. If you have never received lenalidomide before, you will need to be registered in the Celgene REMS program. This program is a controlled prescription mechanism to dispense lenalidomide for any indication. The registration involves a separate consent process,

which outlines the reproductive risks related to this medication, and identifies you as a participant with this clinical trial. Information that will be required for consent includes your name, address, phone number, date of birth, and social security number. This information will be provided to Celgene Corporation and Biologics Incorporated to identify your registration in participating in this trial. The Celgene REMS program is the mandatory mechanism by the US Food and Drug Administration for dispensing lenalidomide.

Reproductive Risks:

Lenalidomide is related to thalidomide. Thalidomide is known to cause severe life-threatening human birth defects. Preliminary findings from a monkey study appear to indicate that lenalidomide caused birth defects in the offspring of female monkeys who received the drug during pregnancy. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Because of this risk, all patients taking lenalidomide must read the following statements that apply to them according to gender and menopausal status.

Patients should not donate blood during study treatment or for 28 days following discontinuation of lenalidomide.

You will be counseled at least every 28 days during lenalidomide treatment and again one last time when you stop taking lenalidomide about not sharing lenalidomide (or 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 lenalidomide capsules. You will be provided with the "Lenalidomide Information Sheet for Patients Enrolled in Clinical Research Studies" with each new supply of lenalidomide as a reminder of these safety issues.

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 lenalidomide. 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 lenalidomide.

_____: I understand that I must NOT take lenalidomide 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 lenalidomide therapy; 2) while participating in the study; during interruptions in therapy and 3) for at least 28 days after lenalidomide 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 lenalidomide 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 lenalidomide, again when I have been taken off of lenalidomide therapy and then 28 days after I have stopped taking lenalidomide. 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 lenalidomide, again when I have been taken off of lenalidomide therapy, and then 14 days and 28 days after I have stopped taking lenalidomide.

_____: I know I must immediately stop taking lenalidomide 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 lenalidomide.

_____: I understand that lenalidomide 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 to return any unused drug supply to the research site at each visit.

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

Patients who take lenalidomide and dexamethasone have a greater chance of having blood clots. Patients taking lenalidomide and oral contraceptives may have an increased change of having blood clots as both lenalidomide and oral contraceptives alone increase risk of clotting. Because of this, it is recommended patients not take birth control pills or hormone replacement therapy before discussing with the doctor and considering the risks and benefits of these choices.

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 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 lenalidomide. 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 lenalidomide.

_____: 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 lenalidomide 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 to return any unused drug supply to the research site at each visit.

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

FOR ALL MALES

When taking lenalidomide, the drug is present in semen of healthy men at very low levels for three days after stopping the drug. For patients who may not be able to get rid of the drug, such as people with kidney problems, lenalidomide may be present for more than three days. To be safe, all men should use condoms when engaging in sexual intercourse while taking lenalidomide, when temporarily stopping lenalidomide, and for 28 days after permanently stopping lenalidomide treatment if their partner is either pregnant or able to have children.

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

_____: I understand that birth defects may occur with the use of lenalidomide. 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 lenalidomide.

_____: 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 lenalidomide 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 lenalidomide and for 28 days after I stop taking lenalidomide, 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 lenalidomide should be advised to call their own physician immediately if they get pregnant.

_____: I understand that lenalidomide 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 to return any unused drug supply to the research site at each visit.

_____: I know that I cannot donate blood, sperm or semen while taking lenalidomide and for 28 days after stopping lenalidomide.

FOR ALL PATIENTS

You will be counseled at least every 28 days about not sharing lenalidomide (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 lenalidomide capsules. You will be provided with the "Lenalidomide Information Sheet for Patients Enrolled in Clinical Research Studies" with each new supply of lenalidomide as a reminder of these safety issues.

Ibrutinib (Cohort 4):

The side effects listed below have been reported by patients who have received ibrutinib in clinical trials.

Likely side effects (>20% of patients):

- Diarrhea
- Tiredness (Fatigue)
- Nausea
- Infection

Less likely side effects (10-20% of patients):

- Cough
- Swelling of the hands or feet (Peripheral edema)
- Rash
- Common cold (Upper respiratory infection)
- Fever
- Dizziness
- Constipation
- Joint aches (Arthralgia)
- Bruises (contusion)
- Headache
- Muscle aches (Myalgia)
- Shortness of breath (dyspnea)
- Vomiting
- Stomach pain (Abdominal pain)
- Muscles cramps (Muscle spasms)
- Decreased appetite
- Indigestion/heartburn (Dyspepsia)
- Low blood count (Anemia)
- Low platelets, cells that help blood to clot (Thrombocytopenia)

- Low white blood cells, cells that help fight infection (Neutropenia)

Most of these side effects have been mild to moderate in severity, however severe side effects have occurred. Some side effects have been severe enough to lead to hospitalization, disability and sometimes death. The severe side effects, seen in <10% of patients, include:

- Not having enough fluids (Dehydration) which can cause weakness
- Low white blood cells with fever (Febrile neutropenia)
- Abnormal heart rhythm (Atrial fibrillation) which can cause chest pain or shortness of breath
- Bleeding around the brain (Subdural hematoma) which can cause weakness or confusion
- Excess fluid in the lining of the lungs (Pleural effusion) which can cause shortness of breath or cough
- Acute kidney injury (Acute renal failure)
- Failure of the lungs to function properly (Respiratory failure) which can cause shortness of breath
- Increased level of uric acid in the blood (Hyperuricemia) which can cause kidney damage
- Decreased level of potassium in the blood (Hypokalemia) which can cause weakness or heart rhythm problems
- Increased level of calcium in the blood (Hypercalcemia) which can cause weakness, nausea/vomiting, confusion, and abdominal pain
- Fainting (Syncope)

Rare serious side effects (less than 1 in 100 patients) that you should know about are:

- Allergic reactions (Hypersensitivity) which can cause shortness of breath and low blood pressure
- Stroke with bleeding in the brain (Cerebrovascular accident with hemorrhage) which can cause confusion and weakness
- Colon inflammation with bleeding (Hemorrhagic colitis) which can cause weakness
- Release of tumor chemicals into blood (Tumor lysis syndrome) which can cause weakness, kidney damage, and heart rhythm problems

- Low levels of all types of blood cells -white blood cells, red blood cells and platelets (Pancytopenia) which can lead to weakness, shortness of breath, infections, or bleeding
- Enlarged spleen (Splenomegaly) which can cause abdominal pain
- Inflammatory state of the whole body (Systemic inflammatory response syndrome) which can cause fevers, low blood pressure, and weakness
- Pneumonitis which can cause shortness of breath and cough

You should tell your study doctor or medical team about any side affects you are having. Your doctor may be able to give you medications to help treat the side effects and prevent them from becoming worse. Your study doctor may also choose to stop ibrutinib for a short time or reduce its dose to allow you to recover from any side effects**.**

Most of the side effects listed above have been mild to moderate in severity; however severe side effects have occurred. Some side effects have been severe enough to lead to study drug discontinuation, dose modification or reduction, hospitalization, disability and sometimes death.

In addition to those listed above, study subjects taking Ibrutinib may also experience the following:

Lymphocytosis and leukostasis
You may experience an increase in the number of lymphocytes, a type of white blood cell, in your blood (lymphocytosis). This may occur in the first few weeks of treatment and you should not assume that this increase in white blood cells means that your disease is worsening. This increase may last for several weeks to months. Increased number of white blood cells in your bloodstream may alter blood flow resulting in bleeding or clotting (leukostasis). Isolated cases of these events have been reported in patients treated with ibrutinib. Your Study Doctor will monitor your blood counts and may administer additional therapy as needed. Talk to your Study Doctor about what your test results mean.

Bleeding effects
You may experience bruising or bleeding during treatment with ibrutinib. Rarely, serious internal bleeding may occur, such as bleeding in your stomach, in your intestine, or in or around your brain. If you take other medicines or supplements that increase your risk of bleeding, such as aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) or medicines used to prevent or treat blood clots or stroke, ibrutinib may increase this risk. Blood thinners such as warfarin or similar medications should not be taken together with ibrutinib. Supplements such as fish oil and vitamin E preparations should be avoided while taking ibrutinib. Call your Study Doctor immediately if you have signs or symptoms of severe bleeding in or around the brain such as sudden severe headaches, weakness in the arms or legs, difficulty speaking or understanding speech, or loss of balance. Also, call your Study Doctor if you have signs or symptoms of serious bleeding, such as blood in your stools or urine or bleeding that lasts for a long time or that you cannot control.

Effects on the heart
Abnormal heartbeats (atrial fibrillation and/or atrial flutter) have been reported in patients treated with ibrutinib. Atrial fibrillation/flutter is a common type of abnormal heartbeat. The heartbeat may be fast or irregular causing symptoms such as a pounding or racing heart, dizziness, weakness, feeling light-headed or shortness of breath. You should tell your Study Doctor immediately if you develop any of these symptoms while on the study drug.

Infections
You may experience viral, bacterial, or fungal infections. Some of these infections have been associated with hospitalization and death. Contact your Study Doctor if you have fever, chills or any other signs or symptoms of a possible infection.

A rare and usually fatal viral disease in the brain, Progressive Multifocal Leukoencephalopathy (PML), has been reported in patients treated with ibrutinib in combination with rituximab and in patients who were previously treated with rituximab. If you experience symptoms such as weakness, paralysis, vision loss and/or impaired speech, you should tell your Study Doctor immediately.

Decreased blood counts
Severe decreases in white blood cells, red blood cells, and platelets (neutropenia, anemia, and thrombocytopenia) were reported in subjects treated with ibrutinib. If you experience symptoms such as fever, weakness, or easy bruising and/or bleeding, you should tell your Study Doctor immediately.

Allergic reactions
Sometimes people have allergic reactions to drugs. Serious allergic reactions can be life-threatening. If you have an allergic reaction to ibrutinib, you might develop a rash, difficulty breathing, wheezing when you breathe, sudden low blood pressure with light-headedness, swelling around the mouth, throat or eyes, a racing heartbeat, and/or sweating.

Before starting the study drug, you must tell your Study Doctor about any drug allergies. You should tell the Study Doctor right away if you have any allergy symptoms listed above.

Rash
A maculopapular rash (flat, red areas on the skin with small bumps) has been commonly reported in patients treated with ibrutinib alone or in combination with other drugs. Most rashes are mild to moderate in severity and begin 2-3 weeks or longer after starting ibrutinib. There have been rare reports of severe rash (involving more than 50 % of the body) or rash with blisters and peeling skin, which may include open ulcers or sores in the mouth and other areas (Stevens-Johnson Syndrome). This could be life-threatening. You should notify your Study Doctor immediately if you develop a rash that spreads quickly, or if you notice peeling of your skin, with or without ulcers or sores in your mouth.

Other Cancers
Other cancers have been observed in patients who have been treated with ibrutinib. These include, skin cancer, solid tumors, and blood cancers. The causal relationship with ibrutinib is unknown. You should tell your Study Doctor if you develop a new cancer while in the study.

Interference with other drugs
Some juices or foods like grapefruit and Seville oranges, as well as some medications, may interfere with the way your body processes ibrutinib. This interference could cause the amount of ibrutinib in your body to be higher or lower than expected. It is very important that you tell the Study Doctor about all medications, supplements, or herbal medicine like St. John's wort that you are taking now and during the study.

Drug interruption for any surgical procedures
Ibrutinib may increase the risk of bleeding with any surgical procedure. Ibrutinib should be held at least 3 to 7 days before and after surgery depending upon the type of surgery and the risk of bleeding. Please contact your Study Doctor if you have any surgical procedures and your study doctor will tell you when to stop ibrutinib and when to restart it following a surgical procedure. For emergency surgical procedures, ibrutinib should be discontinued (stopped) after the procedure until the surgical site is reasonably healed (not oozing fluid). You should tell your Study Doctor or medical team about any side affects you may have during study participation. Your Study Doctor may be able to give you medications to help treat the side effects and prevent them from becoming worse. Your Study Doctor may also choose to stop ibrutinib for a short time or reduce its dose to allow you to recover from any side effects.

Additional Risks for all patients

Blood drawing risks:
There may be bruising, bleeding or inflammation at the sites where blood samples are taken. Care will be provided to avoid these complications.

Bone Marrow Biopsy risks:
A bone marrow biopsy and aspiration is a procedure in which an area of the hip is numbed with an anesthetic drug (similar to a shot of Novocain before dental work), and a needle inserted into the numbed area. A small sample of bone marrow and fluid is withdrawn through the needle.

Complications related to bone marrow aspirations and biopsies may include bleeding (inside or outside the body), pain, bruising, blood clots and infection. Care will be taken to avoid these complications.

Imaging (CT scans):

The known risks associated with CT scans include the rare occurrence of allergic reactions to the contrast dyes injected into a vein during the scan. Such allergic reactions can involve itching, rash, or in severe cases, difficulty in breathing and dangerous lowering of blood pressure. If you have known allergic reactions to imaging contrast agents, you should let your study doctor and radiologist know. Additionally, these scans are associated with exposure to vary small amounts of radiation.

Reproductive risks:
You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.
If you or your partner becomes pregnant while you are on the study, or within 30 days of your last dose of study drug, you must notify the study staff immediately. The study staff will discuss this with you immediately. If you become pregnant on the study, you must immediately stop taking the drug.

For more information about risks and side effects of these or any other tests and procedures, always ask your doctor or another member of your health care team.

7. What benefits can I expect from being in the study?

There is no guarantee that this treatment will benefit you. This treatment regimen may also be harmful to you. However, the benefits could be an easing of symptoms; decrease in the amount of cancer suggestive of improvement in your cancer, prolonged disease-free remission and/or survival or increased knowledge about this cancer treatment in patients with CLL/SLL/PLL. This could benefit patients in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate in this trial, other treatments you qualify for will be discussed with you. If you choose not to take part in any of those treatment options, you have the right to choose supportive care. Supportive care is when you decide not to treat your cancer, but instead decide to treat your symptoms in a manner that will keep you as comfortable as possible.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor (**MorphoSys AG)** supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

Under normal circumstances you would have physician appointments and undergo similar lab and scan procedures on the same schedule. It is known as standard of care, and therefore you and/or your insurance company will be billed for the physician visits, various blood tests, the study agents Lenalidomide or ibrutinib, CT scans, urinalysis, and serum HCG pregnancy test, bone marrow biopsy and aspirate and medication treatments given before and while being treated with the study drug. You will be responsible for co-pay/deductibles required by your insurance plan while on study.

If you have trouble paying for lenalidomide, you may be able to qualify for financial assistance from Celgene. To determine whether you are eligible for financial assistance, please contact Celgene's Patient Support services at 1-800-931-8691. Whether or not you qualify for assistance, the provision of lenalidomide to you does not imply that Celgene is the sponsor or has plans to compensate you for any injury.

The study agent, MOR00208, will be provided by **MorphoSys AG, Germany** the pharmaceutical company who manufactures the study drug, while you are participating in this study. This does not include the cost of preparing the drug and giving it to you, which will be billed to you/your insurance.

11. Will I be paid for taking part in this study?

You will not be paid to take part in the study.

12. What happens if I am injured because I took part in this study?

OHIO STATE UNIVERSITY LIABILITY

If you are injured as a result of your participation in this study, you may obtain immediate care at the Ohio State University Medical Center. The cost of this treatment will be charged to you or your insurance company. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study. The Ohio State University has no funding set aside for the payment of health care expenses for this study.

MorphoSys AG LIABILITY

MorphoSys AG agrees to pay the cost for any reasonable medical expenses incurred for the treatment of injury or illness that is directly related to failure of MorphoSys AG to provide Study Drug that meets the Study Drug specifications MorphoSys AG shall not be responsible for any costs covered by patient's insurance. MorphoSys AG shall not be responsible for the payment of medical expenses which are not directly related to failure of MorphoSys AG to provide Study Drug that meets the Study Drug specifications. MorphoSys AG shall not provide any other compensation for any research-related injuries.

By signing this consent form, you will not be waiving any of the legal rights which you otherwise would have as a subject in a research study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  HIV / AIDS
  Hepatitis infection
  Sexually transmitted diseases
  Other reportable infectious diseases
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires
  The diagnosis and treatment of a mental health condition
- Records about any study drug you received;
- Records about the study device; and

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact:
Jennifer Woyach, M.D.

410 W. 12th avenue, 455A Wiseman Hall
Columbus, Ohio 43210
Ph: 614-293-8165
24 hrs: 614-293-8000

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact:
Jennifer Woyach, M.D.
410 W. 12th avenue, 455A Wiseman Hall
Columbus, Ohio 43210
Ph: 614-293-8165
24 hrs: 614-293-8000

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time