The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	A phase II study of brentuximab vedotin and lenalidomide in relapsed and refractory T-cell lymphomas
Principal Investigator:	**John Reneau, MD, PhD**
Sponsor:	The Ohio State University
Support	Celgene, Corporation

- **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?

The purpose of this study is to see the response of the combination of two cancer drugs lenalidomide (Revlimid®) and brentuximab vedotin (BV) in patients with relapsed or refractory cutaneous T-cell lymphomas (CTCL) / Peripheral T-cell lymphomas (PTCL) and follow-up for two years progression free survival.

Lenalidomide and and brentuximab vedotin are previously approved by the U.S. Food and Drug Administration (FDA) for treatment of cancer. Recently, the FDA approved brentuximab vedotin for the treatment of certain subtypes of CTCL. However, combination of these drugs has not

been approved by the US FDA for the treatment of patients with relapsed or refractory cutaneous T-cell lymphomas (CTCL) / Peripheral T-cell lymphomas (PTCL).

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

This study will be open to a group of patients with your type of disease. Approximately 46 patients will be enrolled in this study.

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

By agreeing to take part in this study, you are agreeing to comply with the study requirements.

Before you begin study treatment:

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or 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.

- You will need to supply a complete list of your current medications to the study doctor. This includes over-the-counter medications and herbal supplements. Some medications may interact adversely with BV and lenalidomide, and it is important that your study doctor and prescribing physician be aware of any potential risks so that they can prescribe alternative medications as necessary. If you do not already do so, please consider carrying a list of your medications at all times.

The testing indicated below includes standard (routine) tests that are part of regular cancer care:

- Medical History
- Physical Examination (vital signs, height and weight, full skin examination, contraceptive counseling)
- Routine Blood Tests
- Photographs of your skin (if the lymphoma involves your skin)
- If you are a woman of child bearing potential you will be required to complete a negative serum pregnancy test.
- Tumor Measurements, performed by PET or CT scans that are planned standard of care
    - CT (computed tomography) 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 PET (positron emission tomography) scan requires a small amount of radioactive material (tracer) to be given through a vein. PET scans are routine procedures used to help doctors diagnose and follow the size and location of your cancer.
    - A MRI (Magnetic resonance imaging) uses strong magnetic field rather than x-rays to provide clear and detailed pictures of internal organs and tissues.

MRI's are routine procedures used to help doctors diagnose and follow the size and location of your cancer.

- Bone Marrow Biopsy and Aspirate

Additional Tests:

- Blood tests for Hepatitis B and C, and HIV

It is possible that after your medical history and the results from the above tests and procedures are reviewed, you will not be able to continue in this study. If this occurs, your study doctor will go over the reasons with you.

During the study …

If your doctor decides that you meet all of the requirements to participate in this research study after the screening, and you agree to participate in this study, brentuximab vedotin will be given as an IV infusion over the course of 30 minutes on Day 1 of each cycle. Each cycle of treatment is 21 days long. You will also be asked to take lenalidomide by mouth daily for 21 days, with or without food at the same time each day. If you complete the first 16 cycles of treatment you will begin a 2-year lenalidomide maintenance regimen in which you will be asked to take lenalidomide by mouth daily for 28 days, with or without food at the same time each day.

You should swallow each dose of lenalidomide whole with water; you should not open, break, or chew the capsules. If you forget to take your dose and it is before 6:00PM, then take a dose. If it is after 6:00pm, then do not take a dose that day. Restart taking it the next day (do NOT take double your regular dose to make up for the missed dose).

You should record each dose of lenalidomide in the drug diary provided to you by a member of the study team.

In order to participate in this study, you must register into and follow the requirements of the Revlimid REMS^{TM} program of Celgene Corporation. The clinical research staff will assist you in completing this step through Celgene online portal. 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 every 28 days during treatment with lenalidomide, follow the pregnancy testing and birth control requirements of the program that are appropriate for you, and take telephone surveys regarding your compliance with the program. Please note that women of childbearing potential that might be caring for you should not touch the lenalidomide capsules or bottles unless they are wearing gloves.

You will also undergo regular monitoring of your lymphoma response to therapy including repeated skin examinations, and repeat CT scans or PET-CT scans which are all parts of the standard of care for managing your lymphoma. If the lymphoma involves your skin, you will also be asked to complete a short questionnaire to follow the symptom burden of your lymphoma and its impact on your quality of life.

Required Pregnancy Testing

Pregnancy testing will be performed in all women of childbearing potential, defined as a 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 (i.e., has had a menstrual period at any time in the preceding 24 consecutive months).

A pregnancy test must be performed 10 to 14 days prior to study entry and again no more than 24 hours before the first dose of lenalidomide. Women of childbearing potential with regular or no menstrual cycles must have a pregnancy test weekly during the first cycle of treatment and then on Day 1 of each cycle while on therapy (including breaks in therapy), at discontinuation of lenalidomide, and 28 days after the last dose of lenalidomide. Women of childbearing potential with irregular menstrual cycles must have a pregnancy test weekly during the first cycle of treatment and then every 14 days while on therapy (including breaks in therapy), at discontinuation of lenalidomide, and 28 days after the last dose of lenalidomide.

Procedures at the end of study:

Twenty-eight (28) to thirty-five (35) days after the last dose of either study drug, you will have the following tests and procedures:

- Physical exam
- Assessment of any disease-related skin lesions that you might have (if needed) along with repeat skin photographs.
- Blood tests to check your blood count, thyroid and organ function
- A pregnancy test if you are a woman of childbearing potential
- CT scan and PET scan (if needed)
- Bone marrow biopsy and aspirate (if needed)

Follow-up procedures:

After the last study visit, you will be followed to check on your health status and the status of your disease every 3 months for the first 2 years. This might involve an office visit, a phone call from a study coordinator or other study team member, or a review of your medical records.

Your tissue samples called specimens (such as blood and tumor) will also be used to study biomarkers to assess the influence of this novel combination in patients who don't respond or those that develop resistance to therapy with disease progression in order to predict which patients will benefit from this novel combination of therapy. Biomarkers are aimed to assess influence on immune suppression (by evaluating blood cells functions), gene (DNA) mutation and other cell functions.

4. How long will I be in the study?

If you agree to take part in this study, your involvement will last for up to 16 cycles (approximately 11 months). If your cancer does not get worse or if you get better, you may continue on a treatment extension with lenalidomide only for a total duration of 2 years. After the last study visit, you will be followed to check on your health status and the status of your disease every 3 months for the first 2 years.

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. 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?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. **Some risks described in this consent document, if severe, may cause death.**

Risks of Brentuximab Vedotin

The following side effects have been associated with brentuximab vedotin treatment in some patients:

Likely

- Abnormal nerve functions in arms or legs which may cause symptoms such as numbness, pain, tingling, or weakness."
- Low white blood cells which may put you at increased risk of serious infections
- Fever
- Tiredness
- Upper respiratory tract infection
- Nausea
- Diarrhea
- Vomiting

Less likely

- Alopecia (hair loss)
- Back pain
- Chills
- Constipation

- Cough
- Dizziness (vertigo)
- Itching
- Low platelets which may put you at increased risk for bleeding and bruising
- Low red blood cells which may make you more tired or short of breath
- Joint pain
- Muscle pain
- Rash
- Shortness of breath
- High blood sugar
- Stomach pain
- Weight loss

Infusion-Related Reactions

Some patients had an allergic reaction during or soon after brentuximab vedotin treatment. The allergic reactions included chills, nausea, cough, itching, and shortness of breath. You may have a life-threatening allergic reaction (trouble breathing, hives, itching, and swelling) that requires immediate medical attention and stopping treatment.

Peripheral Neuropathy

Some patients who were given brentuximab vedotin had problems with nerve function in their arms or legs (peripheral neuropathy). This can occur when damage is done to nerves that carry muscle movement information and feeling information such as touch, pain, and temperature. You may have a burning sensation, pain, weakness, or numbness and tingling (feeling of pins and needles) of your hands and/or feet. Some people had severe nerve function problems that caused difficulty walking.

Low Blood Cell Counts

Some patients had a drop in their white blood cells (neutropenia) that was related to treatment with brentuximab vedotin. This could increase your chance of infection. Very low white blood cells with fever (febrile neutropenia) can be life-threatening. Some patients had drops in their red blood cells (anemia) or their platelets (thrombocytopenia). Anemia can cause tiredness or shortness of breath. Thrombocytopenia can cause bleeding and bruising.

Infection Risk

Brentuximab vedotin may cause you to be less resistant to infections, including life-threatening infections. It is very important that you tell your study doctor if you get a fever, sore throat, or have trouble breathing and/or painful sores (ulcers) around the mouth and/or anus. If you can't reach your study doctor or other research team members,

you should go to the nearest emergency room. Be sure to mention your study doctor's name and that you are in a cancer treatment research study.

Other Important Side Effects

The following important or possibly life-threatening side effects have been reported less often in patients who were given brentuximab vedotin:

- Severe painful rash that spreads to most of your skin (Stevens-Johnson Syndrome//toxic epidermal necrolysis). This is a rare condition that could be life threatening. Get emergency medical care if you have any of the following: widespread skin pain, blisters, hives, tongue swelling, a red or purple skin rash that spreads, or unexplained shedding of your skin.
- Tumor lysis syndrome (TLS) is a condition that causes problems related to the breakdown of dying cancer cells. These problems, which can be life threatening, may include nausea, vomiting, edema (swelling), shortness of breath, abnormal heart rhythm, and kidney failure. If TLS occurs, it usually happens within a few days of the start of cancer treatment.
- Progressive multifocal leukoencephalopathy (PML) is a rare, serious brain infection caused by a virus. People with a weakened immune system can get PML. PML can result in death or severe disability. Tell your study doctor immediately if you have any of the following or if anyone close to you notices these: confusion or problems thinking, loss of balance or problems walking, problems speaking, decreased strength or weakness on one side of your body, blurred vision, or loss of vision.
- Acute pancreatitis is a condition in which inflammation of the pancreas causes pain in the upper abdomen. If severe, it could require hospitalization and may even be life-threatening. Seek emergency medical care if you develop sudden abdominal pain that may radiate to your back or get worse after you eat.
- Damage to the liver that can cause an increase in liver enzymes in the blood, and, if severe, be life-threatening.
- Damage to the lungs which may affect your ability to breathe and get enough oxygen into your bloodstream, and if severe, can be life-threatening.
- Gastrointestinal toxicity, which may result in conditions like ileus (paralysis or obstruction of the intestines), colitis (inflammation or infection of the intestines), and perforation of the intestines (hole in the intestines, which could possibly leak contents into the abdomen).

<u>Risks of Lenalidomide</u>

Lenalidomide has been studied in healthy volunteers and in patients with cancer of the blood and other organs of the body as well as in patients with other diseases. As with

any other experimental treatment there may be side effects or risks associated with lenalidomide, some of which are not yet known.

The following is a list of the side effects (presented by frequency as very common, common or uncommon) reported in completed and ongoing studies considered to be related to lenalidomide. In some cases, side effects can be serious, long-lasting, may never go away, or can cause death. Your study doctor will answer any questions you might have on these side effects and provide you with more information.

Very Common

- Low number of white blood cells (with or without fever), known as leukocytes or neutrophils (Leukopenia, Neutropenia, Febrile neutropenia)which increases your risk of infection
- Anemia (low red blood cells), which can cause fatigue
- Decrease in cells that help your blood clot (platelets), which increases your risk of bleeding
- Vision blurred
- Diarrhea
- Stomach pain
- Constipation
- Indigestion
- Nausea
- Vomiting
- Feeling weak and unwell
- Tired
- Swelling
- Fever
- Chills
- Pneumonia, upper respiratory tract, sinuses, urinary tract or other infections that are caused by a virus, fungus and/or bacteria
- Kidney failure
- Sore throat
- Stuffy nose
- Weight loss
- Decreased appetite
- High blood sugar
- Imbalance in blood for the following chemicals: decrease in potassium, decrease in calcium
- Pain including muscles and joints
- Dizziness (vertigo)
- Altered sense of taste
- Headache
- Eye lens cloudy
- Abnormal decrease in sense of touch

- Pain sensation in nerves
- Shaking
- Cough
- Shortness of breath
- Nosebleed
- Blood clot in lower extremities, lungs, heart, brain, and other organs
- Dry skin
- Itching
- Rash
- Feeling sad
- Not sleeping well

Common

- Low number of white blood cells (without fever) known as granulocytes or lymphocytes
- Abnormally low number of all blood cells
- Destruction of red blood cells
- Heart attack
- Abnormal rapid heartbeats
- Heart stops working well
- Low oxygen to heart tissue
- Infections that are caused by a virus such as cold sores/genital herpes, shingles, and flu
- Infections such as bacterial infection underneath the skin surface, bacterial infection in the skin, infections in the stomach and intestines, infections in the respiratory tract or blood
- Dry mouth
- Decreased action of intestine
- Bile flow from liver slowed or blocked
- Gout
- Fall
- Bruise
- Lowered level of consciousness with drowsiness, listlessness, and apathy
- Abnormal liver lab tests which could indicate liver damage
- Increase in liver protein that indicates inflammation in the body
- Loss of fluid
- Diabetes
- High uric acid in the blood
- Iron build up in body, decrease in phosphate, decrease in magnesium, decrease in sodium, increase in calcium
- Muscle weakness
- Cancer
- Stroke
- Decreased sensation in nerves

- Tingling of skin
- Fainting
- Vertigo
- Pain including non-heart related chest pain
- Moody
- Breathing disorder
- Excessive sweating
- Night sweats
- Skin redness
- Swelling of skin filled with blood
- Swelling of blood vessels
- High or low blood pressure
- Limited blood getting to extremities
- Clot in vein
- Sudden increase in tumor size
- With initiation of cancer therapy, cancer cell can break down and release large amounts of chemicals such as potassium, phosphate, uric acid into your blood circulation, which may then lead to kidney failure. Blood cancer that causes decreased number of red blood cells, white blood cells, and platelets because they do not develop normally

Uncommon

- Oversensitive to drug (drug intolerance)
- Reactivation of graft versus host disease (GVHD) if you have had allogeneic bone marrow or stem cell transplant in the past

Furthermore, the following risks have been reported after marketing of lenalidomide and are considered by Celgene to be related:

- Inflammation of the lungs (pneumonia)
- Over- and underactive thyroid
- Severe allergic conditions, including
  - swelling under skin
  - Severe skin reactions involving lining of the nose, mouth, stomach and intestines or rash leading to the separation of the top layer of skin (Stevens-Johnson syndrome and Toxic epidermal necrolysis)
  - A skin reaction [such as rash or skin peeling (exfoliative dermatitis)], elevated level of eosinophils (eosinophilia), fever, and/or swollen glands (lymphadenopathy) with other organ complications such as inflammation of the liver (hepatitis), inflammation of the kidney nephrons (nephritis), inflammation of the lungs (pneumonitis), inflammation of the heart (myocarditis), and/or inflammation of the sac surround the heart (pericarditis) [Drug reaction with eosinophilia and systemic symptoms (DRESS)]
  - Virus to become active again, in patients who carry the virus, resulting in a recurrence of the infection; viruses include hepatitis B or herpes zoster (also

known as shingles)
- With initiation of cancer therapy, cancer cell can break down and release large amounts of chemicals such as potassium, phosphate, uric acid into your blood circulation, which may then lead to kidney failure (Tumor lysis syndrome)

Second new cancers

In clinical studies of newly diagnosed multiple myeloma, more second new cancers, including acute leukemia (blood cancers) and lymph node cancers, were reported in patients who were treated with melphalan and lenalidomide or treated first with melphalan and stem cell transplantation and then taking lenalidomide versus patients treated with melphalan and/or stem cell transplantation then taking a placebo (a dummy capsule with no active medicine). When lenalidomide is given with dexamethasone a higher number of skin cancers and solid tumors have been reported. Patients should make their doctors aware of their medical history and any concerns they may have regarding their own increased risk of other cancers. Your doctor will be checking you for any possible new cancers that may develop during your treatment.

Other Risks

No studies on the effects on the ability to drive or use machines have been performed. Lenalidomide may have minor or moderate influence on the ability to drive and use machines. Fatigue, dizziness, drowsiness, vertigo, and blurred vision have been reported with the use of lenalidomide. Therefore, caution is recommended when driving or operating machines.

If any physician other than the study doctor prescribes medication for you for another condition, or you are taking any over-the-counter medications or vitamins, you must inform the study staff. This is important because the interaction of some medications may cause serious side effects. Lenalidomide has been shown to increase the level of digoxin in the blood in some patients; please tell your doctor if you are taking digoxin.

Risks of Blood Draw

Possible side effects from a blood draw include fainting, dizziness, pain, swelling, bruising, or bleeding where the needle is inserted. There is also a slight possibility of infection where the needle is inserted.

Risks of CT Scan

CT scans involve exposure to radiation. Although the amount of radiation exposure is higher than a typical x-ray, the risk of harmful effects from a single exam is very small. If you are scheduled for a CT with contrast, the dye that is injected into a vein for the scan is usually well tolerated. Some people feel dizzy, queasy, or get a headache when given the dye or notice a cold feeling near the injection site. There is a rare chance of

having an allergic reaction to the dye that very rarely can be serious or life threatening. You must tell your doctor if you have had bad reactions to dyes before. There is also a rare chance that a CT scan may cause a malfunction of worn or implanted medical devices. If you wear or have electronic medical devices such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff.

Risks of PET Scan

A PET scan uses a radioactive tracer to make 3D images of structures in your body. It is likely that you will experience discomfort from lying still on the enclosed scanning table. You may also experience claustrophobia. There is a slight risk of a possible allergic reaction to the injection of the radioactive tracer, which could include symptoms such as itching, a rash or hives, or difficulty breathing.

Risks of Radiation Exposure

This study will expose you to radiation from CT and PET/CT scans. These scans are necessary to monitor your response to study treatment. You will receive up to 3 CT and 3 PET/CT scans each year you are participating in this study. You would receive these scans at approximately the same intervals if you were receiving any other treatment for your disease that was not part of a research project. Because only the frequency of the scans is dictated by this research study and the exact scanning parameters are not dictated, we cannot give you an exact amount of radiation exposure you will receive. Please be assured that modern scanners are designed and operated to keep your radiation exposure as low as possible. While it is true that you will be exposed to more radiation than a person in the general population, these scans are necessary because of your disease.

Because certain research studies are subject to specific radiation exposure limits, it is important that you inform us if you have been in any other research studies in the last 12 months that involved exposure to radiation for research purposes (from x-rays, CT scans, PET scans or other nuclear medicine procedures). It is also important that you tell future investigators about your participation in this research study if you are asked to participate in another research study.

Risks of Biopsy

The doctor will inform you in detail about the risks associated with the biopsy. The level of risk will depend on where the tumor is located. In general, having a biopsy can cause pain, swelling, bleeding and/or infection at the site where the biopsy penetrates through the skin. There is also the possibility that having this procedure may shift some cells from the tumor into the surrounding tissues that come in contact with the biopsy needle. This means that the tumor may spread to that particular area. Depending on the area of the biopsy, a local anesthetic (to numb the area) may be injected into the skin, or a sedative medication may be given orally or intravenously. You will remain conscious

during this procedure. The risks of this anesthetic are minimal and include bleeding, bruising, infection, and allergic reaction. The risks associated with use of a sedative are similar, but also included drowsiness, slurred speech, staggering gait, poor judgment, and slowed reflexes.

Risks of Bone Marrow Biopsy

It is likely that you will experience discomfort or pain, redness, swelling and bruising at the site of the needle insertion. It is less likely that you will experience bleeding from site of the needle insertion. There is a rare chance (approximately less than 1/100) of developing a significant infection or bleeding from this procedure. An allergic reaction to the anesthetic may occur. A scar may form at the site of needle entry.

Special Considerations for Pregnancy/Childbearing

Lenalidomide is related to thalidomide. Thalidomide is known to cause severe life-threatening human birth defects. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Female patients must not become pregnant while taking lenalidomide.

You have been informed about the risk of birth defects. If you are female, you agree not to become pregnant while taking lenalidomide. For this reason, lenalidomide is provided to patients under a special distribution program called Revlimid REMS™.

Pregnancy Risk – Females

You will be required to use **TWO** reliable forms of birth control at the same time (one highly effective method and one additional effective method) or practice complete abstinence from heterosexual intercourse during the following time periods related to this study:

i. for at least 28 days before starting lenalidomide;
ii. while participating in this study, including during times when lenalidomide is temporarily stopped; and
iii. for at least 28 days after discontinuation from the study.

The following are the acceptable birth control methods:

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	

You must not breastfeed a baby while you are participating in this study and for at least 28 days after you have been discontinued from the study.

If you have any reason to suspect you are pregnant, you must IMMEDIATELY stop taking lenalidomide and tell your doctor.

Pregnancy Risk – Males

Lenalidomide is present at very low levels in human semen for three days after stopping treatment. For some men, such as men with kidney problems, lenalidomide may be present in semen for more than three days. To be safe, all male patients receiving lenalidomide must use a latex condom during any sexual contact with a pregnant female or with a female of childbearing potential while participating in this study, including during times when lenalidomide is temporarily stopped, and for at least 28 days after permanently stopping therapy, even if you have had a successful vasectomy. You must NEVER donate blood, sperm, or semen while you are participating in this study and for at least 28 days after you have stopped therapy.

All Patients

You must NEVER share lenalidomide (or other study drugs) with someone else. You must NEVER donate blood while you are participating in this study and for at least 28 days after you have stopped therapy. You must receive counseling and complete phone surveys as required by the Revlimid REMS® program.

Risks of Genetic Research

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Risks of Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure, and we think the risk of accidental disclosure is very small. Please see the section in this consent form titled *"Will my study-related information be kept confidential?"* for more information.

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

You are not expected to benefit. As a participant in this study, your condition could improve, stay the same, or worsen. However, this cannot be guaranteed. Future patients may benefit from what is learned.

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.

There is not a clear "best" therapy for your disease, but there are several options that may have benefit in your type of cancer. Be sure to ask your physician about other clinical trials at OSU and also around the country that you might qualify for. Other options include additional intravenous chemotherapy. These other options also can cause toxicity and may not result in improvement of your condition.

Many patients in your situation may also choose not to receive any additional chemotherapy or other treatment for your cancer. In those cases, we will continue to work with you to control your symptoms. However, if you choose not to pursue any additional treatment for your cancer, your cancer will likely continue to grow and will result in your death.

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

You will receive the study drug lenalidomide free of charge. Lenalidomide will be supplied by the Celgene Corporation. However, your insurance will be billed for the Brentuximab Vedotin (BV) you receive, and you may be responsible for the costs of the BV that your insurance company will not pay for.

You or your insurance company will be responsible for paying for procedures, tests and possibly medications that are part of standard care for patients with your type of cancer. You are responsible for any co-pays, co-insurance, and deductibles as required by your insurance company or charges your insurance company does not pay.

Participating in this research study may lead to additional costs to you. Your insurance company may not pay for costs associated with research studies like this one. Please feel free to contact your insurance company to review benefits provided by your insurance policy.

If you become sick as a result of this study, any medical care that you require will be billed to your insurance company and you may have to pay for any medical care, including hospitalization that your insurance company does not pay for.

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

You will not be paid for your participation in this study.

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

Ohio State University Liability: If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. 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.

13. 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 Celgene Corporation, the manufacturer of lenalidomide, and their representatives
- In order to obtain lenalidomide 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 lenalidomide and administer the REVLIMID REMS® program. By signing this consent form you agree to this disclosure.

- Your insurance company (if charges are billed to insurance).

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.

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;

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

Researchers, study staff and Celgene Corporation.

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;
- Others: Celgene Corporation that supports this research.

IV. Your information may 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.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact

John Reneau, MD, PhD
320 W 10th Avenue
Starling Loving
Columbus, Ohio 43210
Phone number: 614-293-3196; 614-293-8000 (24 hours)

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Manager:
The Ohio State University Medical Center
600 Ackerman Rd. Suite E2140
Columbus, OH 43202
Phone number: 614-293-4477

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**:**

John Reneau, MD, PhD
320 W 10th Avenue
Starling Loving
Columbus, Ohio 43210
Phone number: 614-293-3196; 614-293-8000 (24 hours)

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 consent to pictures or videos being recorded during my treatment, including appropriate portions of my body, for medical, research or educational purposes, as long as my identity is not shared.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization 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 fo subject (when applicable)** **AM/PM** **Date and time**
Relationship to the subject	

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 consen	**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