

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

Study Title: A Phase I/II Study of the PD-1 Antibody
Nivolumab in combination with
Lenalidomide in relapsed/refractory Non-
Hodgkin's Lymphoma (NHL) and
Hodgkin's Disease (HD)

Principal Investigator: David Bond, MD

Sponsor: Ohio State University

Support Bristol-Myers Squibb Research and
Development

- **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 the study is to determine the safety and tolerability of the combination of lenalidomide (Revlimid®) and nivolumab (OPDIVO®) in patients with relapsed/refractory Non-Hodgkin's Lymphoma (NHL) and Hodgkin's Disease (HD).

Nivolumab and lenalidomide have been approved by the United States Food and Drug Administration (FDA) for treating patients with other kinds of cancer such as lung cancer, melanoma (a type of skin cancer), a specific subtype of lymphoma and a related cancer called multiple myeloma. However, use of these two drugs as a combination therapy in this study is not FDA approved and is considered investigational. An investigational drug is one that has not been approved by the FDA. We want to find out what effects, good and/or bad, these two drugs given together, have on you and your lymphoma.

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 and will be divided into two parts. Approximately 73 patients will be enrolled in this study.

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

The study will be conducted in two parts.

- The phase I portion of the study will be conducted:
 - To assess safety and tolerability,
 - To determine the recommended doses of the combination ,
- The phase II portion will be conducted to assess whether the drugs help slow the growth of cancer in patients with relapsed/refractory large B Cell Lymphoma.

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.

Phase I

Lenalidomide will be taken by mouth every day on days 1 through 21, followed by one week off of lenalidomide. This will make up one cycle, which is a total of 28 days. Lenalidomide should be taken at the same time once a day with or without food with 8 ounces (approximately 240 mL) of water. Swallow the capsules whole. Do not chew, crush, open or

dissolve capsule in water. If a dose is not taken at the regularly scheduled time, it can be taken as soon as possible **on the same day**. You will return to your normal dosing schedule the following day. If you miss a dose, it will not be made up. If you vomit, do not take another dose. Lenalidomide should be stored at room temperature.

Nivolumab will be administered as a 60 minute intravenous infusion (IV) every 2 weeks for first four (4) cycles. After that nivolumab will be administered on Day 1 of each cycle through 12 cycles.

Provided you do not experience significant toxicity, treatment will be continued as above unless unless your cancer becomes resistant to this drug combination.

Phase Ib expansion

Once the best dose is determined, a phase Ib dose expansion will occur to further determine feasibility, side effects, and effectiveness. The schedule for your visits will be the same as described for “Phase II” below.

Phase II

Phase II study will include patients

1. Patients with relapsed/refractory large B-cell lymphoma.
 - All patients will have laboratory assessment on day 1 of each cycle prior to treatment.
 - During cycle 1, a CBC will be checked during weeks one and three.
 - Response will be assessed by PET/CT scans (Positron emission tomography–computed tomography) and/or CT after cycles 2, 4 and 6 and then every 3 cycles until the end of the 1st year and/or completion of 12 cycles of treatment and then every 6 months until disease progression, medically indicated or at the discretion of the investigator.
 - A biopsy of your tumor may be performed before starting treatment (take a piece of tumor, refer to risk section) to collect tumor tissue for confirmation of your disease and for research purposes. If this is not possible, a stored tumor biopsy sample from your diagnosis may be used. A tumor biopsy may be performed after cycle 2 depending on your disease response. A tumor biopsy may also be performed if your lymphoma gets worse at the time that you stop treatment.
 - A bone marrow biopsy will be performed only in patients who have no evidence of lymphoma on their scans to confirm a complete response, meaning that there is no active lymphoma as it has all resolved with therapy. This will only be done in the patients
 - that had HD or DLBC in their bone marrow in the beginning of treatment
 - if the investigator has a suspicion that HD or DLBC might exist in patient’s bone marrow.

4. How long will I be in the study?

Some patients will be in the study for a short time and others may stay in the study for many months. If you do not stop the study due to symptoms, and if your disease does not get worse, you will be allowed to stay in the study for as long as you would like to continue to receive this treatment. Patients will be followed at least every 3 months for 2 years, then every 6 months for a maximum of 5 years from study entry.

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.

If you get sick due to the study medication, or if we are concerned about your lab work or symptoms at any time, you will stop the study. If your disease gets worse you will stop the study and have the opportunity to try a new treatment. Patients will be followed for 4 weeks after removal from study.

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

While on this study, you are at risk for the side effects outlined below. You should discuss these risks with your Study Doctor. In addition, if you think you may be allergic to anything or any medicines taken concurrently during the study, please inform your study doctor. The side effects will vary from person to person. Your study doctor will watch you carefully for side-effects; however, you should discuss the appearance of any side-effects with your study doctor. Unanticipated side effects may occur which have not been reported. Your study doctor will be paying particular attention to those side effects that may be more severe or occur in greater frequency as a result of the combination of the study treatment you will receive. Your study doctor may decide to discontinue treatment without your agreement if the treatment is too toxic or harmful.

Based on safety information from the patients already treated with **nivolumab** alone or in combination with other medicines, the most frequent risks and side effects may include, but are not limited to:

Likely

- Feeling tired (Fatigue)
- Weakness
- Skin problems: including rash, itchiness, redness, or dry skin
- Loose stools (Diarrhea)

- Loss of appetite
- Nausea (Feeling sick to your stomach)
- Vomiting (Throwing up)
- Joint pain or inflammation
- Fever and chills

Less Likely

- Decreased white blood cells which may affect your ability to fight infections.
- Shortness of breath
- Headache
- Cough
- Lung inflammation (see below for details)
- Bowel inflammation (diarrhea, blood or mucus in the stool, abdominal pain)
- Dry Mouth
- Allergic reaction during infusion of study drug
- Muscle pain
- Arm or leg pain
- Postnasal drip
- Abdominal pain
- Heartburn
- Sensation of lightheadedness or vertigo (spinning sensation) (Dizziness)
- Constipation
- Peripheral neuropathy

Less common side effects

- Back pain
- Swelling of the arms or legs
- Fluid collection in the abdomen
- Injection site reaction
- Constipation
- Trouble sleeping
- Night sweats
- Excessive sweating
- Hair loss
- Altered taste
- Irritability
- Kidney failure
- Muscle spasm
- Brain inflammation (meningitis or encephalitis)

- Hemophagocytic lymphohistiocytosis, a life-threatening immunodeficiency which causes fevers, enlarged spleen, low blood counts and liver abnormalities Loss of nerve function (Guillain-Barre syndrome)
- Nerve-associated muscle weakness (myasthenia gravis)
- Muscle inflammation and breakdown (polymyositis and rhabdomyolysis)
- A syndrome associated with muscle pain and stiffness in the neck, shoulders, and hips
- Fulminant type 1 diabetes mellitus, a severe form of type 1 diabetes that is characterized by extremely rapid disease onset. Flu-like symptoms (fever, upper respiratory symptoms, ect) or gastrointestinal symptoms (upper abdominal pain, nausea, and/or vomiting, ect) precede the disease onset.
- A severe life-threatening skin disorder, known as Stevens-Johnson Syndrome, which can lead to fever, rash, and skin lesions and can involve other mucous membranes including the mouth, eyes, and genital region.

Lung Inflammation: It is possible that nivolumab may cause inflammation of the tissues of the lung. This adverse effect has been reported infrequently in subjects treated with nivolumab. While many subjects with x-ray or CT abnormalities have not developed any symptoms, some patients have developed mild to severe symptoms and in rare cases, death has occurred as a result of their lung inflammation. Symptoms of lung inflammation may include difficulty breathing, pain or discomfort while breathing, chest pain, cough, shortness of breath, increased rate of breathing, fever, or fatigue. These symptoms may require treatment with steroids, which may increase your risk of infections.

Your study doctor and nurse will watch you closely for changes in your ability to breathe and for other signs or symptoms that might show you are developing this type of severe inflammation and will perform regular tests including physical exams, measurement of oxygen levels through non-invasive testing (i.e., pulse oximeter), blood tests, chest x-rays and/or CT scans.

At each visit, the study doctor will ask you about any unusual symptoms and other treatments you may have started. Should a serious side effect occur, the study medication will be stopped. You will be checked regularly for the improvement of the side effects. This may require extra visits and examinations including blood and urine tests as well as cardiac function tests. The study medication may be restarted at the same or a lower dose after the side effects improve or disappear, depending on the severity and the duration of the events.

You will be told if any new side effect is found as a result of this study or any other study using nivolumab that could affect your participation in this study. If you are concerned about your health between visits and because of the trial, then emergency telephone numbers are provided at the end of this document. You will be given any new information on nivolumab that may affect your willingness to start or continue in the study as it becomes available.

Risks to Reproduction, Unborn Babies and Nursing Infants

General Statement

You must not be pregnant or breastfeeding, and you should not become pregnant or breastfeed while you are taking the study treatments. Additionally, females should not breastfeed up to 5 months after the last dose of nivolumab. You must use an adequate method to avoid pregnancy for the duration of this study and for up to 5 months after the last dose after the last dose of study drug. Urine or serum pregnancy test to be done at screening and then anytime thereafter that pregnancy is suspected or possible. For women of childbearing potential, if on cycle 1 day 1 greater than 24 hours has elapsed since the last negative result, a serum pregnancy test must be repeated and be negative on C1D1 for patient to remain eligible. The use of nivolumab in pregnant women has not been formally investigated in clinical studies. Male subjects who are sexually active with a woman of child bearing potential should also use an adequate method of birth control to avoid pregnancy of their partner for up to 7 months after the last dose of study drug. You should immediately contact your study doctor if there is a change in your method to avoid pregnancy or if you start any prescription drug or other medication (including over-the-counter drugs and herbal supplements) not prescribed by the study doctor.

Unforeseeable Risks

There may be unknown risks to you, your unborn baby or nursing infant if you are or become pregnant during this study or are breastfeeding during this study.

Occurrence of Pregnancy or Suspected Pregnancy

If you become pregnant, suspect pregnancy or if you missed your period or it is late, or if you have a change in your usual menstrual cycle (e.g., heavier bleeding during your period or bleeding between periods), you should immediately contact your study doctor.

Discontinuation from the Study

Should you become pregnant during this study, you will immediately have the study medication permanently discontinued and be referred for obstetric care. You will continue to be followed for any side effects or potential benefits of the study treatment, provided it is safe for you and your unborn baby to do so. Your doctor will discuss this with you, as well as options for additional appropriate care for your cancer. The sponsor has not set aside any funds to pay for any aspects of obstetric, child or related care and does not plan to pay for them.

Information for Men with Partners of Childbearing Potential

Most study drugs do not pose a risk to a woman who becomes pregnant while her male partner is a study subject. However, you are asked to inform your study doctor if your partner becomes pregnant while you are enrolled in this clinical trial, and you and your partner will

be asked to provide information about the pregnancy outcome. The sponsor has not set aside any funds to pay for any aspects of obstetric, child or related care and does not plan to pay for them.

Risks and side effects related to Lenalidomide include:

The most common side effects reported are:

- Anemia which may require transfusion
- Constipation, diarrhea
- Tiredness
- Bruising, bleeding
- Low number of white blood cells (with or without fever);
- Decrease in cells that help your blood clot;
- Vision Blurred;
- Nausea;
- Vomiting;
- Feeling weak and unwell;
- Swelling;
- Fever;
- Chills;
- Pneumonia or other infections;
- Sore throat;
- Stuffy nose;
- Weight loss;
- Decreased appetite;
- High blood sugar;
- Chemical imbalance in blood;
- Pain including muscles, joints, and non-cardiac chest pain;
- Dizziness;
- Altered sense of taste,
- Headache;
- Eye lens cloudy;
- Abnormal sense of touch;
- Pain and decreased sensation in nerves;
- Shaking;
- Cough;
- Shortness of breath;
- Nosebleed;
- Blood clot in lower extremities, lungs, heart, brain, and other organs;
- Dry skin;

- Itching;
- Allergic reaction; 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
- Feeling sad,
- Not sleeping well.

Common:

- Abnormally low number of blood cells;
- Destruction of red blood cells;
- Heart attack; Abnormal heart beats; Heart stops working;
- Low oxygen to heart tissue;
- 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;
- Increase in liver protein that indicates inflammation in body;
- Loss of fluid;
- Diabetes;
- High uric acid in blood;
- Iron build up in body;
- Muscle weakness;
- Solid tumor cancers and blood cancers that causes decreased number of red blood cells, white blood cells, and platelets because they do not develop normally;
- Stroke;
- Tingling of skin;
- Fainting;
- Moody;
- Kidney failure;
- Breathing disorder;
- Excessive sweating;
- Night sweats;
- Skin redness;
- Swelling of skin filled with blood;
- Swelling of blood vessels; High or low blood pressure;
- Blood not getting to extremities;
- Clot in vein;

- Sudden increase in tumor size;
- Rapid death of cancer cells where the accumulating contents of dying cancer cells cause an imbalance in the chemistry of the body which can lead to kidney damage; also referred as Tumor lysis syndrome (TLS).
- A sensation of whirling and loss of balance

The following risks have been reported to be related to lenalidomide

- Swelling of lungs
- Over and underactive thyroid

Risks Associated with Pregnancy

Lenalidomide is related to thalidomide. Thalidomide is known to cause severe life-threatening human birth defects. Findings from a monkey study indicate that lenalidomide caused birth defects in the babies of female monkeys who received the drug during pregnancy. If lenalidomide is taken during pregnancy, it may cause birth defects or death to any unborn baby. Women must not become pregnant while taking lenalidomide. You have been informed that the risk of birth defects is unknown. If you are female, you agree not to become pregnant while taking lenalidomide.

For Women:

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 (not having menstrual cycles due to cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time during the preceding 24 consecutive months).

Birth defects and baby's death may occur with the use of lenalidomide, if you are pregnant or become pregnant while taking lenalidomide.

Lenalidomide cannot be taken if you are pregnant, breastfeeding a baby or able to get pregnant and not using 2 reliable methods of birth control. A highly effective method of birth control plus one additional effective method of birth control (contraception) at the SAME TIME must be used.

Highly effective methods:

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

- Diaphragm
- Cervical Cap

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) throughout lenalidomide therapy, including interruptions in therapy and 3) for at least 5 months after lenalidomide has been stopped. You must use these methods unless you are completely abstain from heterosexual sexual contact. If a hormone (birth control pill, injection, patch or implant) or IUD method is not medically possible, you may use another highly effective method or two barrier methods AT THE SAME TIME.

You must immediately stop taking lenalidomide and inform your study doctor, if you become pregnant while taking the drug, if you miss a menstrual period or have unusual menstrual bleeding, if you stop using 2 reliable forms of birth control, or if you think for any reason that you may be pregnant. You must talk to my doctor before changing any birth control methods.

Study patients who become pregnant will be monitored throughout the pregnancy including perinatal and neonatal outcome and, where applicable, offspring information must be reported on the Pregnancy Surveillance Form [provided upon request from BMS].

For Men:

Do not have unprotected sexual contact with a female who can become pregnant. Because lenalidomide is present in semen, you must completely abstain from sexual contact with females who are pregnant or able to become pregnant, or must use a latex condom every time engaging in any sexual contact with females who are pregnant or may become pregnant. This must be done for at least 7 months after completely finished taking lenalidomide.

Blood semen or sperm cannot be donated while taking lenalidomide and for 7 months after stopping lenalidomide.

Other Risks

Sometimes a new cancer arises after patients have undergone cancer therapy. Recently, in clinical trials of patients with another cancer, multiple myeloma, a higher number of new cancers has also been reported in patients treated with high doses of chemotherapy and/or bone marrow transplant followed by prolonged lenalidomide therapy, compared to those who received the high dose chemotherapy and/or transplant without the prolonged lenalidomide. It is not known if these new cancers were caused by lenalidomide or not.

We do not know at this time whether prolonged lenalidomide actually increases the risk of new cancers. The higher number of new cancers has not been seen in other patients receiving lenalidomide.

We will be carefully monitoring these new cancers in ongoing studies of lenalidomide and will inform you if there are any changes. We want you to be aware of this possibility and to continue to follow your doctor's recommendations for prevention and early detection of new cancers during and after your treatment

Risks associated with the combination of PD-1/PD-L1 agents and immunomodulatory agents

Trials evaluating the combination of a PD-1/PDL-1 antibody (pembrolizumab) in combination with a steroid called dexamethasone and either the immunomodulatory agent lenalidomide or the immunomodulatory agent pomalidomide were stopped early as the results showed an increased risk of death in patients when the 3 drug combinations were used together as compared to the combination of the immunomodulatory agents and steroid without the PD-1/PD-L1 inhibitors. The reason for this increase in death is not known. The trials were being done in patients with multiple myeloma, a different type of blood cancer than you have, but there is a potential risk that the combination of the PD-1 inhibitor nivolumab with the immunomodulatory agent lenalidomide could also increase the risk of death in patients with your type of lymphoma as compared to either agent alone or other therapies. We want you to be aware of this possibility.

Other Risks and inconveniences associated with the study procedures

Obtaining blood samples may cause some discomfort, pain, bruising, bleeding and or puncture into the vein and the formation of a blood clot. You may faint and or develop an infection with redness and irritation of the vein at the site where blood is drawn. The risk of a CT scan or a MRI is as follows:

- There is a slight risk of developing an allergic reaction to the contrast material. The reaction can be mild (itching, rash) or severe (difficulty breathing or sudden shock). Death resulting from an allergic reaction is rare. Most reactions can be controlled using medication. Be sure to tell your study doctor if you have allergies of any kind, such as hay fever, iodine allergy, eczema, hives, or food allergies.
- The contrast material used during CT scanning can cause water loss or damage to the kidneys that may lead to kidney failure. This is a concern if you are dehydrated or have poor kidney function. If you have a history of kidney problems, blood tests (creatinine, blood urea nitrogen) may be done before the CT scan to check that your kidneys are functioning properly.
- If contrast material is used, you may be at risk for kidney problems if you have diabetes, especially if you take metformin (Glucophage). You will need to stop taking metformin for a period of time before the test and resume taking it as directed by your study doctor or the radiologist.

- There is always a slight risk of damage from being exposed to any radiation, including the low levels of X-rays used for a CT scan. However, the risk of damage from the X-rays is usually very low compared with the potential benefits of the test.

You may also undergo a bone marrow biopsy as many as two times during the study where some cells from the inside of your bone will be removed with a needle. The risks associated with this include discomfort during the procedure and afterwards. This can be managed with medication. Additional risks involve bleeding from the site of the biopsy as well as infection. If you notice any increased pain, redness, swelling, or drainage at the site of the infection, please contact your physician immediately.

You may undergo a tumor biopsy as many as three times during the study. A biopsy is a procedure to remove a piece of your tumor either surgically or with a core needle biopsy. A core needle biopsy uses a hollow needle to withdraw small cylinders (or cores) of tissue from the tumor and the needle can be passed several times through the tissue being examined. Core needle biopsies are often done using computed tomography (CT) scan or ultrasound, which guides the surgeon to the right area. In a needle biopsy, you will feel a small sharp pinch at the site of the biopsy and local anesthesia (numbing medication) and/or medication for pain or to help you relax may be used to make the procedure less painful. It is possible that a biopsy procedure can cause bleeding, infection, pain, or other problems. In very rare cases, people might have an allergic reaction to the local anesthesia (numbing medication). The allergic reaction could include a skin rash or hives, flushing of the face, itching, wheezing, and tightness in the throat and could be life threatening in rare cases. If a pain medicine and/or medicine to help you relax is required, the risks of your particular medicine will be discussed with you before the biopsy procedure. You will be asked to sign a separate consent form for this procedure before having the biopsy performed and will discuss the biopsy and risks again with the provider performing the procedure at that time.

As part of this study, genetic testing will be performed on your tumor cells. This testing is looking at genetic changes (mutations) that occur only in your tumor cells and are not inherited (passed down) but may give us information on how treatment impacts tumor cells. This testing is being done for exploration and will not impact your or your family's care. Neither you nor your doctor will be given the results of any genetic research testing done on your samples. If you or your family are interested in learning more about inherited risk factors for cancer, ask your study doctor.

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

- Health insurance companies and group health plans may not request your genetic information from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions about your eligibility or premiums.

- Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this federal law. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under Ohio law, health insurance companies cannot ask about the results of a genetic test or use any information obtained from genetic testing to make decisions about providing coverage or benefits for health care services.

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

Most patients do not have a response to treatment on this type of study, but if you do respond to the therapy, you may feel better and may notice that your lymph nodes are smaller and/or your blood counts may improve. 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 nivolumab and it will be provided by Bristol-Myers Squibb Research. However, your insurance will be billed for the Lenalidomide you receive, and you may be responsible for the costs of the Lenalidomide 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 receive any payment for taking part in this study.

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

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 subject's 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; governmental agencies in other countries where the study drug may be considered for approval.
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- The drug supplier, Bristol-Myers Squibb Research and Development and its authorized agents; and
- Winship Cancer Institute of Emory University
- 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.

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 and study staff.

III. Who might get this information?

- The pharmaceutical funder of this research Bristol-Myers Squibb Research and Development “Pharmaceutical funder” means any persons or companies that are:
 - working for or with the pharmaceutical funder; or
 - owned by the pharmaceutical funder.
- 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 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.
- Winship Cancer Institute of Emory University

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?

**CONSENT &
AUTHORIZATION**
OSU 16167

IRB Protocol Number: 2016C0166
IRB Approval date: 18May2023
Version date: 11May2023

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

David Bond, MD
1140A Lincoln Tower
1800 Cannon Dr
Columbus, OH 43210
(614) 688-7942 (office hours)
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

David Bond, MD
1140A Lincoln Tower
1800 Cannon Dr
Columbus, OH 43210
(614) 688-7942 (office hours)
614-293-8000 (24 hours)

**CONSENT &
AUTHORIZATION**
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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 combined consent and HIPAA research authorization form.

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

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

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