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

Study Title: Randomized Double-Blind, Phase 2 Trial of Ibrutinib versus Standard Treatment for COVID-19 Illness Requiring Hospitalization with Safety Lead-In

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Sponsor: The Ohio State University

Drug & Funding Support: Janssen Scientific Affairs, LLC

- **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.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

There is not a standardized usual treatment approach for patients infected with COVID-19 and researchers are trying to develop a standard treatment approach for patients affected by the virus. Currently, the following is being done to ease symptoms and prevent the spread of

infection: isolation of infected patients; supportive care, including fluids, supplementary oxygen, and mechanical ventilator support; and research trials to test different drugs in treatment of COVID-19.

We are asking you to take part in this research study because you have COVID-19 infection, you are hospitalized and have or had a type of cancer or you have a pre-cancerous condition that lowers your immunity. The purpose of this study is to test if Ibrutinib administration in cancer patients or patients with pre-cancerous conditions can diminish respiratory failure or death in COVID-19 infected patients. To test this, we will randomize (like flipping a coin) patients to receive either Ibrutinib or placebo (sugar pill). Study treatment with either ibrutinib or placebo will take two weeks.

We want to make sure you know about a few key risks right now. Some of the most common side effects of Ibrutinib that the study doctors know about are:

- Occurrence or increase in frequency of loose or watery stools (Diarrhea)
- Muscle and bone pain (Musculoskeletal pain)
- Bleeding (Hemorrhage)
- Rash
- Fatigue
- Bruising
- Low platelet level (thrombocytopenia)
- Low white blood cell count (neutropenia)
- Low red blood cell count (anemia)

There may be some risks that the study doctors do not yet know about.

You may or may not benefit from participating in this study, however, the information provided may guide doctors in how to help future people with COVID-19.

You may choose not to participate in this study and receive the usual approaches for patients infected with COVID-19.

1. Why is this study being done?

We are doing this study because we want to test how well ibrutinib works in treating COVID-19 infection.

The study drug, called ibrutinib, is being looked at to see if it may help treat patients with COVID-19 infection and decrease the number of patients that get intubated, requiring mechanical ventilator or other machines that help breathing and die because of respiratory failure. Ibrutinib is a “kinase inhibitor”. “Kinases” are a type of enzymes (a protein that

speeds up chemical reactions in the body). "Kinases" are a part of many cell processes. The specific kinases inhibited or blocked by this study drug are believed to help decrease lung inflammation by shutting down what is called inflammatory cytokine release while not affecting your body's natural defense towards the virus and even might improve the natural defense against the virus and minimize the need to use ventilators. Ibrutinib is not currently approved by the Food and Drug Administration (FDA) for use in patients with COVID-19 infection. Ibrutinib is currently approved for certain types of cancer including; mantle cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma with 17p deletion, Waldenström's macroglobulinemia, marginal zone lymphoma and chronic graft versus host disease.

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

Up to 78 people will take part in this study.

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

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Tests & Procedures

- Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not all be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects. For this study a cycle is defined as 7 days. You will have 2 weekly lab draws (and other interventions) as described below. Physical exams, vital signs and EKG
    - Screening
    - Day 1 and Day 8
    - When stopping study treatment

- Blood counts (will check your levels to determine risk of infection and if needs for blood or platelet transfusions):
    - Screening
    - Day 1 and Day 8
    - When stopping study treatment
    - 1, 2, 3, 6, and 12 months from enrollment

- Blood testing (to check your electrolytes and your organ function of kidneys and liver)

  - Screening
  - Day 8
  - When stopping study treatment
  - 1, 2, 3, 6, and 12 months from enrollment

- Blood testing – coagulation (to check how quickly your blood clots)
  - Screening
  - Day 1 and Day 8
  - When stopping study treatment
  - 1 month from enrollment
- Blood testing – inflammatory markers (e.g., Ferritin, C-reactive protein (CRP), and troponin which help determine if you have any inflammation)
  - Screening
  - Daily while you are receiving treatment (Days 1-14)
  - When stopping study treatment
  - 1 month from enrollment
- Blood testing – immune response (so see how your body responds to the infection and treatment)
  - Screening
  - Day 8
  - When you stop study treatment
- Blood testing - Serum Immunoglobulins testing (to measure the level of certain antibodies which are proteins made by the immune system to fight bacteria, viruses, and toxins)
  - Screening
  - When stopping study treatment
  - 2, 3, 6, and 12 months after enrollment
- Other Blood tests done at screening:
  - Hepatitis B and C test (to check if you have active infection with hepatitis B or C virus)
  - Serum pregnancy test (if you are a woman and can become pregnant)
- Urine pregnancy test (if you are a woman and can become pregnant)
  - Screening

- COVID-19 Nasal Swab Test
  - Screening
  - When stopping study treatment
  - 1 month from enrollment (if this test is negative, you will not be tested again)
  - If 1 month test was positive, test at 2, 3, 6, and 12 months from enrollment (stopping when the test is negative)

- Other Blood samples for research only
  - Screening
  - Day 1 and Day 8

- When stopping study treatment
- 1 3, 6, and 12 months from enrollment

Note: if you are discharged from the hospital before completing study treatment, you may not have all labs drawn as described above

Treatment

This study will go through two phases. You will be in one of the following two groups.

Group 1 (12 participants)

If you are in this group, you'll receive all available usual treatment approaches for COVID-19 with the addition of the study drug, ibrutinib.

You will also receive the study drug, ibrutinib, in a capsule (pill) form once daily with water for 14 days (2 cycles).

Group 2 (about 60 participants)

If the information collected from the first 12 participants shows that the use of ibrutinib in patients with COVID-19 is safe, the study will move forward with the second phase.

If you are in this group, you will be randomly assigned (like flipping a coin) to receive either:

- the study drug, ibrutinib, plus standard treatment or,
- placebo (sugar pill) plus standard treatment

This study is double blinded which means that you, your study doctor, and the OSU study personnel will not know which group you will be assigned to. Regardless of your group assignment, you will receive treatment in the following manner:

- You will receive all available usual treatment approaches for COVID-19 with the addition of the study drug, ibrutinib or placebo. You will receive the study drug, ibrutinib or placebo, in a capsule (pill) form once daily with water for 14 days (2 cycles).

Follow-up

After you complete treatment the study doctor or study team will follow up with you by phone or by a video call after 1 month from enrollment, then after 2, 3, 6, and 12 months. You will also return to OSU Medical Center outpatient laboratory (when feasible and allowed per OSU Medical Center COVID-19 isolation requirements) to get your blood drawn and have a nasal swab done as part of this study at the same follow-up time points after you complete treatment while you are on this study. This blood tests will continue as long as you are in the

study, but if the COVID-19 nasal swab is negative at any point, we will stop testing you for that. If you come off study, follow up will be decided by your doctor.

4. How long will I be in the study?

Your treatment with study drug, ibrutinib or placebo, will last 14 days. You will then be followed for up to 12 months.

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.

Additionally, the study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest
- New information becomes available and the study is no longer in your best interest
- You do not follow the study rules
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor

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

General Risks

If you choose to take part in this study, there is a risk that the addition of study drug, ibrutinib, given with supportive care may not help your infection with COVID-19.

There is also a risk that you could have side effects from the blood draws, like soreness or bruising.

Side Effect Risks

If you are randomized to receive ibrutinib, there may be side effects that affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.

3. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

Ibrutinib Drug Risks

The side effects listed below have been reported by patients who have received ibrutinib in clinical trials and from post-marketing sources. Keep in mind that there might be other side effects doctors do not yet know about. You should tell the study doctor about any side effects that you develop. If important new side effects are found, the study doctor will discuss these with you.

The most common side effects occurring in at least 1 of every 5 (≥ 20%) patients have been:

- Occurrence or increase in frequency of loose or watery stools (Diarrhoea)
- Muscle and bone pain (Musculoskeletal pain)
- Low white blood cell count (cells that help fight infection) (Neutropenia)
- Rash
- Nausea
- Low platelet count (cells that help blood to clot) (Thrombocytopenia)
- Bleeding (Haemorrhage)
- Fever (Pyrexia)

Side effects that have been seen in at least 1 of every 10 (≥ 10%) patients include:

- Common cold (Upper respiratory tract infection)
- Swelling of the hands or feet (Oedema peripheral)
- Constipation
- Sores in mouth (Stomatitis)
- Vomiting
- Pneumonia
- Joint aches (Arthralgia)
- Headache
- Weakness, tingling, numbness, and pain from nerve damage, usually in the hands and

feet (Peripheral neuropathy)
- High Blood pressure (Hypertension)
- Skin infection
- Muscle spasms
- Dizziness
- Urinary tract infection

Side effects that have been seen in at least 1 of every 100 (≥ 1%) patients include:

- Sinus infection (Sinusitis)
- Increased level of uric acid in the blood (Hyperuricemia)
- Abnormal heart rhythm (Atrial fibrillation)
- Non-melanoma skin cancer
- Blurry vision (Vision blurred)
- Low white blood cell counts with fever (Febrile neutropenia)
- Severe infection throughout the body (Sepsis)
- Redness of the skin (Erythema)
- Increase in specific white blood cell count (Leukocytosis, Lymphocytosis)
- Breaking of the nails (Onychoclasis)
- Inflammation within the lungs that may lead to permanent damage (Interstitial lung disease)
- Increased level of "creatinine" in the blood (Blood creatinine increased)
- Heart failure (Cardiac failure)
- Indigestion (Dyspepsia)

Side effects that have been seen in less than 1 of every 100 (<1%) patients include:

- Unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells, which may lead to changes in kidney function, abnormal heartbeat, or seizures. (Tumor lysis syndrome)
- Itchy rash (Urticaria)
- Inflammation of the fatty tissue underneath the skin (Panniculitis)
- Swollen face, lip, mouth, tongue, or throat (Angioedema)
- High WBC count with abnormal clumping that can lead to bleeding (Leukostasis syndrome)
- Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome)
- Liver failure (Hepatic failure)
- Abnormal rapid and/or irregular heart rhythm that starts from the lower chambers (ventricles) of the heart (Ventricular tachyarrhythmias).
- Temporary or permanent decrease of brain or nerve function due to reduced blood flow to the brain (mini-stroke or stroke)
- Tender or painful bumps or ulcers on the skin, sometimes with a fever (Neutrophilic dermatosis)
- Bleeding in the eye (Eye hemorrhage)

Most of these 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.

You should tell your study doctor or medical team about any side effects you are having. 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.

Bleeding

You may experience bruising or nosebleeds during treatment with ibrutinib. Rarely, serious internal bleeding, such as bleeding in your stomach, intestine, or brain may occur, sometimes resulting in death. 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 other vitamin K antagonists 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 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 rapid and/or irregular heart rhythm (atrial fibrillation, atrial flutter, and/or ventricular tachyarrhythmia) and heart failure, including some fatal events, which could sometimes be sudden, have been reported in patients treated with ibrutinib, especially when they also have heart conditions, increased blood pressure or have diabetes, infections, or had abnormal heartbeat in the past. Tell your study doctor immediately if you have any symptoms of heart problems such as feeling as if your heartbeat is fast and irregular, lightheadedness, dizziness, shortness of breath, chest discomfort, swollen legs, or you faint.

Infections

You may experience viral, bacterial, or fungal infections during treatment with ibrutinib. Some of these infections have led to hospitalization and death. Contact your study doctor immediately if you have fever, chills, weakness, confusion, body aches, cold or flu symptoms, vomiting, jaundice, feel tired or feel short of breath - these could be signs of an infection. Your study doctor may start or continue medication to help prevent or treat an 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.

Lymphocytosis and leukostasis

You may experience an increase in the number of lymphocytes, which is a specific 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.
In rare cases, increased number of white blood cells in your bloodstream may change the 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.

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 to 3 weeks or longer after starting ibrutinib.

There have been rare reports of severe skin reactions (known as severe cutaneous adverse reaction or “SCAR”, 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 of the body (Stevens-Johnson syndrome). These skin rashes 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.

Non-Melanoma Skin Cancer and Other Cancers

Non-melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma of the skin) has been reported with more frequency and may be related to the use of ibrutinib. Other cancers have been reported such as solid tumors and blood cancers, the relationship to the use of ibrutinib is unknown. You should tell your study doctor if you develop a new cancer while in the study.

Tumor Lysis Syndrome (TLS)

Unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells have happened during treatment of cancer and sometimes even without treatment. This may lead to changes in kidney function, abnormal heartbeat, or seizures. Your study doctor may do blood tests to check for TLS.

Hypertension

Hypertension is also called high blood pressure and has been commonly reported in subjects treated with ibrutinib. Sometimes, people with high blood pressure may have headaches, dizziness, nervousness, sweating, difficulty in sleeping, facial flushing, or nosebleeds, but in some cases, there may be no symptoms and it may go undetected. After starting ibrutinib, your doctor may measure your blood pressure regularly. You should let your study doctor know if you have any of the symptoms of high blood pressure which may mean that you have developed hypertension or that your hypertension is getting worse. Your study doctor may adjust existing anti-hypertensive medications and/or initiate anti-hypertensive treatment as appropriate.

Stroke

Cases of stroke, with and without changes in heartbeat rhythm and/or hypertension have been reported with the use of ibrutinib. Some of these cases have led to death. Seek immediate medical attention if you notice or someone notices in you, any of the following: sudden numbness or weakness in the limbs (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sight loss, difficulty walking, loss of balance or lack of coordination, and/or sudden severe headache with no known cause. These may be signs and symptoms of a stroke.

Liver Failure

Rare cases of liver failure have been reported in patients treated with ibrutinib. Symptoms of liver failure include yellowing of the eyes and skin (jaundice), itching of the skin, dark colored urine, gray or clay-colored stools, confusion, nausea, loss of appetite, and fatigue or diarrhea. You should tell your study doctor immediately if you have any of these symptoms which may suggest liver disease. Your study doctor may be able to diagnose and provide you required medical care.

Interstitial lung disease

Interstitial lung disease is a group of lung disorders in which the tissues become inflamed and may become damaged. Interstitial lung disease is not associated with infections (e.g., bacteria, viruses, fungi) and has been reported in patients treated with ibrutinib. You should report to your physician if you have a cough, or any signs of new or worsening respiratory symptoms, such as shortness of breath or difficulty breathing.

Interference with other drugs/food

Some foods like grapefruit juice 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 also possible that taking the study drug with your regular medications or supplements, including fish oil, Vitamin E, or other vitamins, may change how your regular medications, or your regular supplements, work. It is very important that you avoid grapefruit juice and Seville oranges and tell the study doctor about all medications, supplements, or herbal medicine like St. John's wort that you are taking during the study. You should notify your study doctor immediately about any side effects to avoid possible harm.

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 planned surgical procedures. For emergency surgical procedures, ibrutinib should be discontinued (stopped) after the procedure until the surgical site is reasonably healed (not oozing fluid).

Please contact your study doctor as soon as possible and your study doctor will tell you when to stop ibrutinib and when to restart it following a surgical procedure.

In addition to the risks listed above, there could be unknown or unexpected side effects associated with the use of ibrutinib. You will be told in a timely manner, verbally and in writing, of any new information, findings, or changes to the way the research will be done that might influence your willingness to continue your participation in this study.

You may have all, some, or none of the listed side effects of ibrutinib. Your study doctors and nurses will check you closely for side effects. You may receive medicines or other treatments to prevent or reduce some of these effects. Please tell the study doctor or study staff right away

if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think they are related to the study drug.

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

Reproductive effects

The effects of ibrutinib on a developing baby are unknown; therefore, women who are pregnant or nursing are not allowed to be in this study. Nobody knows what these risks are right now. Some drugs cause women to have their babies prematurely (early) or to have babies with birth defects.

Women: If you are able to have children, you must use a highly effective method of birth control and a barrier method, or sexual abstinence (which is defined as refraining from all aspects of sexual activity), while taking study treatment, as well as for 1 month after you stop taking study treatment, to prevent pregnancy, unless your partner is sterilized. A "highly effective method of birth control" is defined as a method that has a low failure rate (i.e., less than 1% per year) when used consistently and correctly and includes implants, injectables, birth control pills with 2 hormones, some intrauterine devices (IUDs). If you are using hormonal contraceptives such as birth control pills or devices, a second barrier method of contraception (e.g., condoms) must be used.

Men: You must use a barrier method while on treatment with ibrutinib and for 3 months after the last dose of treatment to prevent pregnancy of your partner. You should not donate sperm while you are taking the study drug and for 3 months after you stop taking the study drug.

Note: Some birth control pills may not work when you are taking certain drugs. If you have any questions about this, please discuss this with the study doctor.

Be aware that you can still become pregnant even if you use a highly effective method of birth control.

Women: If you become pregnant while you are on study treatment or within 1 month of your last dose of ibrutinib you must notify the study staff. If you become pregnant on the study, you must immediately stop taking the study treatment. The Sponsor will continue to collect information about your pregnancy and the birth of your baby even after study treatment is stopped.

Men: If your partner becomes pregnant while you are on study treatment, or within 3 months of your last dose of ibrutinib, you must notify the study staff. The study staff will discuss this with you further.

Breast-feeding

It is not known whether ibrutinib or its metabolites are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from ibrutinib, breast-feeding should be discontinued during ibrutinib treatment.

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

You may or may not benefit from participating in this study. However, the information gathered from this study may help the study doctors learn how to help other people in the future.

There is no guarantee that the addition of ibrutinib to supportive care will benefit you but the study doctors are testing if ibrutinib will decrease the respiratory failure or death due to COVID-19. This treatment regimen may also cause some risks to you. However, the benefits could be an easing of symptoms and/or decreased risk of death.

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.
- You may choose to receive usual treatment approaches for your condition.
- You may choose to take part in a different research study, if one is available for you.
- You may choose to receive comfort care to help relieve your symptoms.

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

The Collaborator will provide the study drug, ibrutinib and the placebo, and it will not be billed to you and/or your insurance company while you are participating in this study. In addition, all procedures that are required only for this study, which are not part of your regular medical care, will not be billed to you and/or your insurance company.

You and/or your insurance company will need to pay for the costs of your regular medical care you get as part of the study, just as you would if you were getting the usual care for COVID-19. This includes:

- The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety and prevent and treat side effects.
- Your insurance co-pays, coinsurance, and deductibles.

Talk to your insurance company and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance company.

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

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not receive any payment.

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 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 research participants.

13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent. Your tissue samples called specimens will be collected. The samples

will then be sent to the clinical trials processing laboratory, and studies will be performed in the Experimental Hematology Laboratory at OSU unless otherwise noted. Samples not immediately used will be stored at OSU for future study to examine mechanism or response to this novel treatment. These samples will only be used for research associated with this trial.

14. 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 Collaborator (Janssen) supporting the study, their agents or study monitors; and
- 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.

15. 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 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:
  - The Collaborator, Janssen Scientific Affairs, LLC and their study drug co-development partner, Data and Safety Monitoring Committee (DSMC)
  - Pelotonia

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.

16. 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**:**

Jennifer Woyach, MD
455D Wiseman Hall
400 W 12th Ave
Columbus, OH 43210
614-685-5667

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

HIPAA Privacy Officer
Suite E2140
600 Ackerman Rd
Columbus, OH 43202
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 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, MD
455D Wiseman Hall
400 W 12th Ave
Columbus, OH 43210
614-685-5667

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