RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Sponsor / Study Title:	**Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) / "A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults"**
Protocol Number:	**20-0006**
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KEY INFORMATION

This consent form describes a clinical research study and is designed to help you decide if you would like to be a part of the study. A clinical research study helps doctors test new ways to treat a disease. In this study, we will be studying U.S. Food and Drug Administration (FDA)-approved (licensed) drugs that are usually used to treat other diseases to see if these drugs are safe and work in people hospitalized with COVID-19, an illness caused by the new coronavirus, SARS CoV-2. The use of these study drugs is "investigational" or "experimental", because the combination of these study drugs have not been approved by the FDA to treat COVID-19. This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. More information that may help you decide can be found in other sections of the document.

What you should know about this study:

- You are being asked to join this clinical research study because you are currently hospitalized with an illness known as COVID-19 caused by the new coronavirus, SARS CoV-2.
- Read this consent form carefully or have someone you trust read it to you. Take as much time as you need to understand the study.
- Ask the study team to explain any words or information that you do not understand.
- You are a volunteer and you do not have to join this study. Your other option is to continue receiving any other care you have already been receiving.
- If you join the study, you can change your mind later. You can decide not to take part, or you can quit at any time. There will be no penalty or loss of benefits if you decide not to join or to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

What is this study about?

There are now a few FDA-licensed medications to treat COVID-19, one is an antiviral drug called remdesivir (Veklury®). Data from an earlier related study (ACTT-1) found that hospitalized participants with COVID-19 who got remdesivir recovered faster than participants who did not get remdesivir. This study will also test two other licensed, anti-inflammatory drugs. One of these drugs, Baricitinib, has been issued an Emergency Use Authorization by the FDA for use in combination with remdesivir for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Each study drug will be given with remdesivir (Veklury®) to learn which combination study treatment is better and safer for treating adult participants hospitalized with COVID-19.

What drugs are being studied?

Remdesivir (Veklury®) is given to all people who enroll in this study. It is given as an infusion, which means that it is given through a plastic tube attached to a needle that is put into a vein in your arm.

Half of participants will get a licensed drug called baricitinib, plus remdesivir (Veklury®). Baricitinib is used to treat rheumatoid arthritis. Data from an earlier related study (ACTT-2) found that hospitalized participants with COVID-19 who got baricitinib plus remdesivir got better faster than participants who got remdesivir alone. Baricitinib is given as 1 to 2 tablets that you swallow.

Half of participants will get a licensed drug called dexamethasone, plus remdesivir (Veklury®). Dexamethasone is a steroid used to treat diseases that cause inflammation of the lungs, skin, eye, joints, and nervous system. Data from a study found that hospitalized participants with COVID-19 who got dexamethasone had a lower death rate than those who did not get dexamethasone. It is given as an intravenous (IV, into the vein) infusion over 3 to 5 minutes.

All participants will also get either a placebo tablet that looks like baricitinib or a placebo infusion that looks like dexamethasone (plus remdesivir). Placebo tablets or placebo infusions are not active drugs and are often used in research studies. The placebo tablet is made of inactive ingredients, like sugar (lactose monohydrate). The placebo infusion is a salt solution.

Will you get the study drug or placebo?
If you join this study, you will be randomly put into one of two study groups. This is decided by chance (like tossing a dice) and you will have an equal chance of being in either study group. Out of every two participants, one will get baricitinib and placebo infusion plus remdesivir, and one will get placebo tablets and dexamethasone plus remdesivir. You and the study staff will not know what group you are in or what study drug you are getting until the end of the study. However, your study doctor can find out which group you are in if there is an emergency.

What will happen on this study?
If you agree to be screened for this study, we will first do some tests, including blood draws, to make sure it is safe for you to join the study. Only hospitalized adults 18 years old and older who are not pregnant and who test positive for COVID-19 can join this study. If you are breastfeeding you may only join the study if you agree to discard the breastmilk from the time the first dose of study drug is given until 2 weeks after last study drug is given. You may not be able to join this study if you have abnormal kidney tests or very low levels of white blood cells, or if you have received a biologic therapy (including B-cell or T-cell targeted therapies) for the treatment of COVID-19 in the last 2 weeks. You may not also be able to join this study if you are taking high dose corticosteroids such as prednisone, take a medicine for gout called probenecid, have recently received live vaccines, or if you have influenza, deep vein thrombosis, tuberculosis, or another serious infection.

If you qualify for this study and decide to join, you will be placed into one of two study groups. One group will get baricitinib and placebo infusion and one group will get placebo tablets and dexamethasone. All participants will also get one remdesivir infusion every day for up to 10 days.

We will take blood and swab samples from you on Days 1, 3, 5, 8, 11, 15 and 29 for as long as you remain in the hospital. We will use the samples for research and safety tests. If you are discharged from the hospital before Day 15, you will come back to the site for study visits on Day 15 and 29 to have blood and swab samples collected. At these outpatient visits, we will ask if you were readmitted to a hospital and also ask about your health and recovery. If you are unable to come back for study visits, we will call you. We will also call you on Day 22 and Day 60 to ask you about your health, hospital readmissions and recovery. Your total amount of time on this study will be about 60 days.

What are the main study risks?
Remdesivir has recently been licensed for treatment of COVID-19. The most common side effects of remdesivir include:

- Abnormal liver function test results
- Abnormal blood clotting test results
- Constipation
- Nausea
- Vomiting
- Decreased appetite
- Headache

The study drug baricitinib is FDA approved for the treatment of rheumatoid arthritis. The side effects of baricitinib in this group of patients are well known. Baricitinib blocks the effects of proteins in the body called Janus kinases. Blocking these proteins can affect the immune system and this can increase the risk of infection and cancer. Side effects of baricitinib include:

- Increased upper respiratory tract infections
- Urinary tract infections
- Inflammation of the nasal passages, throat and or lungs
- Flu symptoms
- Stomach pain which may cause diarrhea, nausea and or vomiting
- Cold sores and shingles (herpes zoster virus or herpes simplex)
- Increases in blood tests related to the liver
- Higher number of platelets (part of the blood that helps in clotting)
- Upset stomach
- Rash
- Headache

Allergic Reactions can occur during or after receiving remdesivir. Tell your study doctor if you experience any of the following symptoms of an allergic reaction:

- Changes in heart rate
- Fever
- Shortness of breath
- Swelling of the lips or mouth
- Rash
- Sweating
- Shivering

Dexamethasone is a steroid approved to treat inflammation.

The side effects of dexamethasone are also well known. The most common side effects include:

- Increased blood glucose (sugar) levels
- Infections
- Upset stomach
- Stomach irritation (peptic ulcer)
- Vomiting
- Dizziness
- Inability to fall asleep (insomnia)
- Restlessness
- Depression
- Anxiety
- Easy bruising

Other Risks Associated with Study Participation
We will insert a new, clean needle into a vein in your arm to take blood samples. We will also insert a needle into your vein which will be attached to IV tubing so that we can give you remdesivir and dexamethasone infusions, or IV placebo. You may feel pain when the needle goes through your skin. You may have a bruise, soreness or swelling where the needle entered skin, but these should go away in a couple of days. There is a very small chance of an infection where you have the tube in your arm. An infection could be treated with antibiotics.

People can rarely have allergic reactions to a drug, including hives, rash, trouble breathing, low blood pressure, dizziness and fainting, swelling around the mouth, throat or eyes, a fast pulse, or sweating. Allergic reactions may be severe or life-threatening. Short-term medical care will be provided if there are side effects from study drugs that can be treated. It is important that you always tell the study staff if you have any problems.

We will be careful to keep your study information confidential, but there is a small risk that someone not involved in the study could get this information.

Are there benefits to being in the study?
Results from previous studies suggest that the study drugs work in participants hospitalized with COVID-19 but we do not know if you will benefit from being in this study. If one of the two combination study treatments work and you received that study treatment on this study, you may benefit by getting better sooner or having less severe disease. Information learned from the study may help other people in the future.

What instructions do you need to follow?
Female participants of childbearing potential must use effective contraception through Day 29. You need to wait until after the study before you become pregnant.

You should not volunteer for another study that gives participants a new study drug for COVID-19 for at least 30 days after you start receiving the study drug on Day 1. If you want to be in another study that includes people who have or have had COVID-19, you should talk to a member of the study team first especially if the other study will collect blood from you.

The rest of this document will describe more about the research study. This information should be considered before you make your choice. Members of the study team will talk with you about the information described in this document.

For Women, Risks Related to Pregnancy
If you are pregnant or nursing a child during the study, there may be risks to you, the embryo, fetus, or nursing child. Because of the potential risks, if you are a woman, you cannot be enrolled in this study if you are:

- Pregnant
- Planning to become pregnant during the study
- Nursing a child, unless you agree to discard breast milk from the time you start receiving the study drug until 2 weeks after you receive the last dose of study drug

If you can become pregnant, you must use an acceptable nonhormonal method of birth control, from screening until Day 29 of the study. Please speak to the study doctor or staff about acceptable methods of birth control. You should not participate in this study if you can become pregnant but cannot use one of these birth control methods. Some methods of birth control will not work when you are taking certain drugs. Be aware that women can still become pregnant even if using an acceptable birth control method.

If you become pregnant while you are in this study, you should report this immediately to the study staff and you will not receive any further study drugs. With your permission, the study doctor or study staff will ask about your health, collect information from you through the outcome of your pregnancy, and collect scheduled blood samples. The study doctor may share this information with the study sponsor and with the Advarra Institutional Review Board (IRB), a group of people who review research studies to protect the rights and welfare of research participants.

1. What will happen if you want to join this study?

If you think you may want to join this study, we will describe the study and answer any questions you may have. You can also talk to your friends and family about the study.

If you decide that you would like to be in the study, we will perform tests to see if you are eligible to participate (study screening). We will ask you to sign and date this consent form. When you sign your name or put your mark on the consent form and date it, it means that you agree to be in the study. You can change your mind at any time and leave the study. If you decide not to join the study or to leave the study later, you will not lose any regular health care services you already are getting.

You will also be asked if you consent to genetic testing. Participation in genetic testing is up to you and is completely voluntary. You can choose not to be part of that part of genetic testing at the end of this consent form.

After you sign and date the consent form, we will decide if you are eligible for the study. To do this, we will ask you questions about your health, including whether you have kidney disease and allergies to medications, and which medications you received from your treating doctor during this COVID-19 illness. We will take some of your blood to determine if your kidneys are working well and if you have a low white blood cell count. We may get some of this information from your inpatient hospital records. If you are a woman who is capable of getting pregnant, we will do a pregnancy test. A member of the study team will explain these tests further. When we have the results, we will explain them to you and provide counseling.

If you meet all requirements to be in the study, you will be enrolled in the study. About 1,500 eligible hospitalized adults with COVID-19 will be enrolled in this study.

2. What does the study involve?

If you are eligible for this study and decide to join, you will be enrolled and randomly placed into either study group 1 or study group 2 and receive the following study drugs:

Study Group 1	Study Group 2
• Baricitinib 1 or 2 tablets daily for 14 days • Placebo IV infusion daily for 10 days • Remdesivir IV infusion daily for 5 to 10 days	• Placebo 1 or 2 tablets daily for 14 days • Dexamethasone IV infusion daily for 10 days • Remdesivir IV infusion for 5 to 10 days

The number of tablets you receive each day will depend upon your kidney function. The remdesivir IV infusion takes about 1 hour and the dexamethasone IV infusion about 3 to 5 minutes. We will watch you closely for side effects while study drugs are being given. After you are discharged from the hospital, you will not receive any more infusions or tablets.

After study enrollment, the study doctor or your treating doctor will do a physical examination. We will collect your height and weight and information about you from your inpatient hospital records, such as medicines you are being given and whether you are receiving oxygen or need additional help breathing. This information will help us determine how sick you are and whether you are improving during the study.

Sample Collection

Blood and swab samples will be collected from you on Days 1, 3, 5, 8, 11, 15 and 29, as long as you remain a patient in the hospital. The swabs may be taken from the back of your throat (also known as an OP swab) or the back of your nose (also known as an NP swab). If either of these methods cannot be performed, we may swab the inside lower portion of your nose (nasal swab). If you are discharged before Day 15, you will come back to the site for study visits on Days 15 and 29. During these follow-up visits, you will be asked if you were readmitted to a hospital and about your health and recovery, and blood and a swab sample will be collected for research and safety tests. Swab samples will be tested for presence of the virus that causes COVID-19.

We will also call you on Day 22 and Day 60 to ask you about your health and recovery and if you were readmitted to a hospital or have seen a doctor for any reason. If you are an inpatient in the study hospital at Day 22 or Day 60 we will do the visit in-person. No samples will be collected. We may also collect health information from your hospital records on Day 29 and 60.

Secondary Research

As part of this study, we will collect extra blood samples from you. We will use your coded information, leftover samples, and extra blood samples for secondary research. Secondary research is research that is not part of this study, and the research is not planned yet. Secondary research will be done in the future to help us to understand how the study drugs work and to develop new treatments and lab tests. This secondary research will not include genetic testing. When you give consent, you will be taking part in the study and allowing for your samples to be used for secondary research.

Genetic Component of the Research

This study will also include optional genetic research testing. If you agree to genetic research testing, we will evaluate how your body responds to COVID-19 by identifying RNA. RNA is genetic material in your cells that tells us how your body works. The genetic research testing is for research purposes only and it will not be able to tell you about relatives, paternity, or country of origin. The genetic research testing done in this study will not tell you about diseases that you may get in the future. We will not give you the results from the genetic research testing. Genetic research samples will be collected on Days 1, 3, 8 and 29 for a total blood volume of approximately 2 – 3 teaspoons.

The Sponsor will generally not provide this information to others without your consent. Your study site also has to follow privacy laws to protect your information. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

3. What could be the side effects from the study drugs?

In earlier studies in healthy normal volunteers, the most common adverse events for remdesivir were abnormal liver function and blood clotting test results, constipation, nausea and vomiting, headache, dizziness, and infusion site pain or infection. In previous study with participants hospitalized with COVID-19, the most common adverse events included decreased renal function, decreased hemoglobin (anemia), decreased lymphocyte count, respiratory failure, fever, and increased blood glucose. The occurrence of these adverse events were similar in the remdesivir and placebo groups.

The abnormal liver function tests may last longer than a few days but come back to normal levels. Remdesivir contains a compound that caused changes in the kidneys of animals but did not affect how well the kidneys worked and went back to normal after the drug was stopped. We have not seen any long-lasting kidney problems in humans who have taken remdesivir. We will be following your kidney function during the study. If you have any abnormal test results that may require more medical care, we will share these results with you.

Baricitinib is a licensed drug that has a known safety profile for patients with rheumatoid arthritis who have taken the drug for long periods of time. The following table summarizes the risks and discomforts associated with baricitinib according to the package insert:

Very Common (10% or greater [affects more than 1 in 10 people])	**Common** (1- less than 10% [affects less than 1 in 10 people]))	**Uncommon** (0.1 to less than 1% [affects less than 1 in 100 people])
• higher amounts of cholesterol in the blood • upper respiratory tract infections	• small increases in blood tests related to the liver • higher number of blood platelets (parts of the blood that aid in clotting) • infections such as cold sores and shingles • upset stomach • rash • headache	• changes in blood tests related to muscles • acne • lower number of white blood cells, including special types of white blood cells (blood cells that fight infections) • higher amounts of fat in the blood • blood clots in blood vessels • hives • swelling of the face • weight increase

Baricitinib was studied in hospitalized participants with COVID-19 and the most common side effects were high blood glucose levels, anemia, decreased white blood cells (lymphocytes), and acute kidney injury. However, these events also occurred at a similar frequency in participants who got baricitnib and remdesivir, and in participants who got remdesivir alone.

Blood Clots in the Blood Vessels

Some people who received baricitinib developed blood clots in the blood vessels of their legs. In addition, COVID-19 may increase the risk of developing blood clots in various places in the body. These clots may then dislodge and travel to the lungs. Baricitinib should be used with caution in people who are at high risk for blood clots in their blood vessels.

Tell your study doctor if you have had blood clots in the veins of your legs or lungs in the past or with your current illness, or take a medicine for clots. The study drug will be stopped if signs or symptoms of blood clots develop. Your study doctor may advise that you take medications to reduce the risk of blood clots while you are hospitalized.

Dexamethasone is a steroid with a known safety profile. For this study, the most likely side effects will be:

- Increased blood glucose levels
- Infections
- Upset stomach
- Stomach irritation (peptic ulcer)
- Vomiting, dizziness
- Inability to fall asleep (insomnia)

- Restlessness
- Depression
- Anxiety
- Easy bruising

It is less likely that you will have side effects that happen with long term use of dexamethasone including:

- Muscle weakness
- Muscle inflammation (steroid myopathy)
- Bone loss (osteoporosis)
- Impaired wound healing
- Thin fragile skin
- Skin bleeding and easy bruising
- Reddened skin
- Seizures
- Elevation of blood pressure
- Salt and water retention
- Increased loss of potassium

4. What are the other risks or discomforts of the study?

This is a summary of the other risks or discomforts of being in the study:

- Pain during blood draws or placement of the tube in your arm for the IV infusions.
- Bruising, swelling and soreness at blood collection and IV infusion needle sites.
- Infection risk at blood collection and IV infusion needle sites.
- Temporary minor irritation at the nasal or oral swab site.
- Coughing, sneezing or gagging when swabs are taken.
- Allergic reactions (for example, hives, trouble breathing) to study drugs that may be severe or life-threatening.
- Private information accidently seen by someone not involved in the study.
- Risk to fetus or unborn child if you become pregnant during study.
- Other unknown risk may occur since dexamethasone has not been studied in combination with remdesivir, and dexamethasone and baricitinib are not licensed to treat COVID-19.

You will be monitored for safety until study day 29 and short-term medical care will be provided if there are side effects that can be treated. It is important that you always tell the study staff if you have any problems and always keep in touch with them.

5. Are there benefits to being in the study?

You may not benefit from being in this study. If the study drugs you received in this study work, you may benefit by getting better sooner and/or getting less severe disease. Your participation in this study is important to learn more about the study drugs if they are safe and work in hospitalized participants with COVID-19. It will help in the development of treatments for COVID-19 and may in the future help people all over the world.

6. What will happen to your samples and personal information?

We will store your samples and data (information) until we are able to test all samples for the virus that causes COVID-19. Your stored samples and data will be marked with a code and not with your name. Only researchers linked to this study can get the codes.

Your study information will be placed in a secure electronic system. It will not include your name so this information cannot be traced back to you. The only risk of allowing us to store your samples and/or information would be an accidental release of your identity.

Your samples will not be sold. Your samples collected during this study may be used for commercial profit (even if identifiers are removed). You will not be paid for any products that result from this research.

Some (about 5 teaspoons) of the blood collected at Day 1, 3, 5, 8, 11, 15 and 29 will be used for secondary research. We plan to store and use these samples along with your information (identified only by ID codes) for secondary research. Secondary research is research that is not part of this study but will be done in the future to help us understand how the study drugs work, study other infections or diseases, or develop new laboratory tests. You will not be told about the future research. Secondary research DOES NOT include genetic testing.

If you consent for blood collection for genetic research testing, you will have approximately 2 - 3 teaspoons of blood collected during the study. A summary of the genetic results from all participants in this study will be placed in a public, unrestricted open access database that anyone can freely use. No individual genetic research testing information or results will be placed in an open access database. The risk of anyone identifying you with this information is very unlikely and state and federal laws provide some protections against genetic discrimination.

You may change your mind about secondary research and/or genetic research testing and withdraw consent for the storage and use of your coded samples or information at any time. You will need to contact the study doctor using the contact information listed on page 1 of this form. We will do our best to follow your wishes but cannot promise that we will always be able to destroy your samples or data. For example, if your samples were already used, we would not be able to destroy them.

7. What do you need to do for follow-up on this study?

If you feel sick at any time during the study, it is important that you quickly tell the study team at the hospital or call the study contact number you were given when you if you have been discharged from the hospital. We may ask you to return to the clinic for a medical exam and possible sampling.

8. Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

9. Will you be paid if you join this study?

You will be paid up to $100 for your participation in this study, broken down as follows:

- $25 for completion of today's visit,
- $25 for the completion of the day 15 in-person follow-up visit,
- $25 for the phone visit on day 22, and
- $25 for the in-person follow-up visit on day 29.

Payment will be provided in the form of a gift card, which you will receive at the end of each in-person visit.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

10. Who is watching over this study?

A Data and Safety Monitoring Board (DSMB) will be looking at the study information very closely including safety data. The DSMB is made up of doctors and other people who are not directly involved in the study and who are experts on COVID-19 and research studies. The DSMB may recommend changing the study or stopping the study earlier than planned if they think it is not safe to continue. The NIH, local ethics and health authorities, and the U.S. Food and Drug Administration (FDA) will also be watching over this study and have the authority to stop the study at any time.

11. How will your privacy be protected?

We will keep your study information private. All files with information that could identify you will be kept in locked cabinets or secure password protected computers. People responsible for making sure that the research is done properly may look at your study records. This might include people involved in this study from this hospital, the NIH, the FDA, and the drug companies that make the study drugs (remdesivir is made by Gilead Sciences, Inc., and baricitinib is made by Eli Lilly and Company). All of these people will also keep your identity private. By signing and dating this consent form, you agree that results from this study, but not your identity, may be shared with local medical providers, makers of the study drugs or government health organizations to help them better understand COVID-19. When results of an NIH research study are reported in medical journals or at scientific meetings, the participants who take part in the study are not named or identified.

To help us protect your privacy, we have a Certificate of Confidentiality (Certificate) from the NIH. Study staff cannot provide to any person not connected with the research your name, or any materials that contain identifiable, sensitive information about you, unless permitted or required by a legal exception, such as state laws that require reporting of some contagious diseases. The most important protection provided by the Certificate is that the study staff cannot be forced to provide any of your identifiable, sensitive information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, such as if there is a court subpoena, without your permission. The study team will use the Certificate to resist any demands for information that would identify you.

Your information protected by the Certificate may still be disclosed or used when the information:

1. Is disclosed to people connected with the research, for example, information may be used for program evaluation internally by the NIH; or
2. Is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal US Food and Drug Administration (FDA);
3. Is necessary for your medical treatment and you have consented to this disclosure;
4. Is for other research;
5. Is disclosed with your consent (for example, an insurer or medical care provider gets your written consent for us to disclose the research information).

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing and dating below you consent to those disclosures.

12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the study team may ask to see your health care records from your other health care providers. This is done so we can track your improvement during the study. For example, need for oxygen, physical examination findings, and readmissions. You may be asked to give us a list of other health care providers that you use.

To do this research, we will need to collect, use, and share your private health information. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record. You will be asked to sign and date a separate document to authorize the collection, use, and disclosure of your personal health information.

We are doing genetic testing for research purposes only and will not diagnose or look for inherited disease or defects. The genetic test results will not give information on paternity or your country/region of origin. We will not give you the results from the genetic research testing.

13. What other things should you know about this research study?

A. ClinicalTrials.gov

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

B. Conflict of Interest

The policy of the NIH is to evaluate investigators at least yearly for any conflicts of interest. Research participants may review the system for assessing conflicts of interest by checking the web site link: http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf. Copies of the standards may also be requested by research participants. No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. This study has investigators that are NIH employees and some that are not. All non-NIH investigators are required to follow the principles of the Protocol Review Guide but are not required to report their financial holdings to the NIH.

Gilead Sciences, Inc., the company that makes remdesivir, and Eli Lilly and Company, the company that makes baricitinib, are providing these study drugs for this study to NIH without charge. No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. However, there are some research partners not associated with the NIH working on this study who may receive payments or benefits, limited by the rules of their workplace.

C. Whom to Contact About This Study?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00042130.

What should you do if you are injured or ill as a result of being in this study?

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

The study site will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures, such as the remdesivir, baricitinib, and dexamethasone used in this study. Because this study is covered by the Prep Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government. Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427. If you are eligible for this program, you must file a claim within one year of the administration or use of the covered countermeasure.

Study staff have described this research study to me. I have read this consent form. All the questions that I have been answered by the study staff to my satisfaction. I voluntarily consent to participate in this research study. My consent includes allowing storage of samples and/or use of my study information and samples for an indefinite period of time for secondary research. By signing and dating this consent form, I have not given up any of my legal rights. I will get a signed and dated copy of this consent form for my records.

If you agree to be in this study, please sign and date below.

_____ Date: _____/_____/_____
Signature of participant dd mm yy

_____
Printed name of participant

_____ Date: ____/_____/_____
Signature of investigator/designee dd mm yy

_____
Printed name of investigator/designee

FOR ADULTS NOT CAPABLE of GIVING CONSENT

_____ Date: _____/_____/_____
Signature or fingerprint of Legally Authorized Representative (LAR) dd mm yy

_____
Printed name of LAR

_____ Date: _____/_____/_____
Relationship of LAR to Participant dd mm yy
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

Complete if participant is illiterate:

Witness to Consent Interview

On the date given next to my signature, I witnessed the consent interview for the research study named above in this document. I attest that the information in this consent form was explained to the participant, and the participant indicated that his/her questions and concerns were adequately addressed.

_____ Date: _____/_____/_____
Signature of witness dd mm yy

_____
Printed name of witness

Genetic Research Testing

As stated above, we will perform genetic research testing on your blood sample. This genetic research testing will give us information about how your body responds to infection with the virus that causes COVID-19. With your consent, your genetic testing information and samples may be shared. A summary of the genetic results from all participants in this study can be placed in a public, unrestricted open access database that anyone can freely use. No individual genetic research testing information or results will be placed in an open access database. The risk of anyone identifying you with this information is very unlikely.

Since your genetic data and health information and samples may be stored and shared with other researchers, there may be a risk that information resulting from research genetic research testing could be misused for discriminatory purposes. However, state and federal laws provide some protections against genetic discrimination. If you have any questions, please ask your Principal Investigator. Researchers who will have access to genetic information about you will take measures to maintain the confidentiality of your information.

Please initial your decision for us to use and/or share your information and samples for genetic research for this research study:

_____ YES, you may use and/or share my information and samples for **genetic** research.

_____ NO, you may not use and/or share my information and samples for **genetic** research.