RESEARCH PARTICIPANT INFORMED CONSENT FORM FOR STUDY C

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 Platform Trial of Putative Therapeutics for the Treatment of COVID-19 in Hospitalized Adults" ACTIV5/BET**
Protocol Number:	**20-0013**
UAB IRB Protocol #:	**IRB-300007626**
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	[redacted]
Address:	[redacted]

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

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. One way to do this is by studying new drugs, to see if they could be used as medicines. In a study, the drugs are "experimental," which means they have not been proven to work. That is why studies are needed to find out if new drugs are safe and work in people.

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.
- This study is taking place at more than one site.
- This is a study that will test a series of different drugs, so drugs will be added or removed over time. However, the drugs that are currently being studied at this site are described in this consent.
- 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. However, please note that the United States Food and Drug Administration (FDA) requires that any information collected up to the point of your withdrawal cannot be removed from the study.
- The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:
    - If it appears to be medically harmful to you;
    - If you fail to follow directions for participating in the study;
    - If it is discovered that you do not meet study requirements;
    - If the study is cancelled; or
    - For administrative reasons.
- 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.
- As a part of this research, we will take blood from you to do genetic testing, which identifies your DNA. DNA is inherited material in your cells that tells us how your body works. We will do these tests to learn how your body responds to COVID-19.

What is this study about?

There are few approved medicines to treat COVID-19 illness. Some people who become sick with COVID-19 have serious disease and must be hospitalized, and a small number of people die. Research studies suggest that a recently approved drug called remdesivir (VEKLURY®) helps hospitalized people with COVID-19 recover faster than people who do not get remdesivir. We want to find out if other drugs given with remdesivir can improve recovery and are safe.

Over time, we will test a series of different drugs, so drugs will be added or removed over time. However, the drugs that are currently being studied at this site are described in this consent.

What drugs are being studied?

This study is designed to test remdesivir in combination with either 1 other study drug or placebo. A placebo is an inactive agent that looks exactly like the study drug but does not have

any active drug in it. Using a placebo is common in research studies. It will help us know whether the results of the study are actually caused by the study drug(s).

There may be more than 1 study drug that is available to be combined with remdesivir at a given time. The study drugs currently available to be combined with remdesivir at this site are described below (see Section 3).

What study drugs will you get?
Remdesivir is given to all people who enroll in this study. In addition to remdesivir, you will get 1 other study drug (see Section 3) or placebo. What you are assigned to receive in combination with remdesivir is decided by chance, like rolling dice. We will first check your health to see how many of the study drugs would be safe for you to use. Then, you will be assigned to receive one of the study drugs that you are eligible for or placebo. If 1 study drug is being tested at this site, you will have an equal chance of being assigned to the study drug or placebo. If more than 1 study drug is being tested at this site, you will have a higher chance of receiving a study drug than placebo. You can ask someone on the study team if you have any questions about what study drug or placebo you may get.

If you join this study, you will be randomly assigned to a study drug group. We will tell you which study drug group you have been assigned to, however, we cannot tell you if you will receive the actual study drug or placebo. The study doctors will not know this either, but they can find out in case of emergency. This is called a double-blind study, since neither you nor the study doctors know if you got the study drug or placebo.

What will happen during this study?
If you agree to join this study, we will first check your health to make sure it is safe for you to join. If you qualify for this study and decide to join, you will get remdesivir once daily for up to 10 days. It is given as an infusion into your bloodstream through an intravenous tube placed in a vein in your arm using a needle (IV line). You will also receive 1 other study drug or placebo, depending on your study drug assignment. More information about the study drugs and how they are given is provided below.

While you are in the hospital, we will collect information from your hospital records. We will take one or more blood sample(s) from you about 7 times, depending on how long you remain in the hospital. On 2 days, we may take blood before and at different times after study drug or placebo doses to check how much of the study drug is in your blood.

You will have up to 5 follow-up study visits after you leave the hospital. The exact number will depend on when you are discharged. At least 3 follow-up visits will be conducted over the phone. The others may be in-person visits at the study site or may be conducted over the phone. During follow-up visits, we will collect information about your health since your last visit. For in-person visits, we will also take one or more blood sample(s) and one swab.

We will use the blood collected on this study for research and safety tests.

Your total amount of time on this study will be about 2 months.

What are the main study risks?
The main risks of being in this study are related to the study drugs. The study drug remdesivir has been studied in healthy (not sick) people and in people with COVID-19 or other viral infections. Some of these people had side effects which were temporary and went away after a few days. Some people did not have side effects. The most common side effects included abnormal liver function test results, abnormal blood clotting test results, constipation, nausea, vomiting, decreased appetite, headache, and pain or infection around the IV line. The abnormal liver function tests lasted longer than a few days but came back to normal levels during the studies.

Risks of the other study drugs currently being tested at this site are given below (see Section 3).

Some people may have some side effects from the study drugs. Other people may have no side effects. Allergic reactions to these drugs, including hives, trouble breathing, or other allergic responses are very rare but are a possible effect of any drug. Allergic reactions may be severe or life-threatening. There may also be side effects and risks that we do not know about yet, even serious or life-threatening ones. We will watch you carefully for side effects during this study. We will provide short-term medical care if there are side effects from the study drugs that can be treated.

If you are pregnant or nursing a child during the study, there may be risks to you, the embryo, fetus, or nursing child from the study drugs. Therefore, you cannot join this study if you are pregnant or breastfeeding. If you are nursing a child, you must agree to discontinue breastfeeding while on this study.

If you can become pregnant, you must agree to remain abstinent (not having any sexual relations) or use birth control while taking part in this study and for 30 days after your last dose of the study drug or placebo. If you can get a partner pregnant, you must remain abstinent or use birth control during the study and for 90 days after your last dose of the study drug or placebo. Acceptable methods of birth control are condoms or diaphragms with spermicide, intrauterine devices (IUDs), or hormonal contraceptives (for example, an implant, injections, pills, a vaginal ring, or a skin patch). Please speak to the study doctor or study staff about acceptable methods of birth control.

Are there benefits to being in the study?
You may or may not benefit from being in this study. Results from studies suggest that your time in the hospital may be shorter by taking remdesivir. Everyone in this study receives remdesivir.

What are your other options?
You do not have to join this study if you do not want to. You can keep getting treated with standard care for COVID-19, which may include treatment with remdesivir.

There might be other clinical trials that you can join for experimental treatments for COVID-19. However, you cannot participate in this study and other clinical trials for experimental treatments for COVID-19 at the same time.

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.

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 agree to be in the study, we will ask you or your Legally Authorized Representative (LAR) 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. Approximately 200 hospitalized adults with COVID-19 will be asked to participate in each stage of this study.

To determine if you qualify for this study, we will ask you some questions about your health, including any chronic medical conditions and medications you take for them, allergies to medications, any COVID-19 symptoms you have had, and which medications you received from your regular doctor during this COVID-19 illness. We will perform a physical exam and measure your height and weight. We will review your hospital records for the result(s) of your SARS-CoV-2 test and any X-rays or CT scans you have had during this COVID-19 illness, and may also collect some of the other information listed above, such as COVID-19 symptoms, medications, etc. If you have had blood tests done within the past 48 hours to check how well your liver and kidneys are working, we will review the results of these tests in your hospital records; otherwise, we will collect a blood sample to do these tests. If you are a woman who is capable of getting pregnant, we will do a pregnancy (urine or blood) test. A member of the study team will explain these tests further. When we have the results, we will explain them to you.

2. What does the study involve?

If you qualify for the study and decide to join, you will get up to 10 days of remdesivir while you are in the hospital. You will also receive another study drug or placebo, depending on which one you were assigned to. You might also need to take an antibiotic starting before the first dose to 2 days after the last dose of study drug or placebo. More information about the study drugs, how they are given, and their risks is provided below in Section 3. After you are discharged from the hospital, you will take the study drug or placebo for 4 days, but you will not receive any more remdesivir. If you are readmitted to the hospital before Day 11, you may receive the rest of your remdesivir infusions, up to Day 10.

On the first day of study treatment, we will take your height and weight and check your vital signs. These include your temperature, blood pressure, heart rate, respiratory (breathing) rate, and blood oxygen level. Each day you are in the hospital, we will obtain some information about you from your inpatient hospital records, such as whether you are receiving oxygen or need

additional help breathing and what types of other medicines you are being given as part of your clinical care. This information will help us determine how sick you are and whether you are improving. We will take one or more blood sample(s) from you on Days 1, 3, 5, 8, and 11 as long as you remain in the hospital. On 2 days, we may take blood before and at different times after study drug or placebo doses to check how much of the study drug is in your blood.

You will have follow-up visits on Days 8, 15, 22, 29, and 60 if you have already been discharged from the hospital. The Day 15 and Day 29 visits will be in-person visits, if possible. If you have already been discharged from the hospital at these timepoints, we may ask you to come back to the site for these visits. However, if this is not possible due to quarantine restrictions or similar reasons, we will call you to collect information over the phone. All Day 8, 22, and 60 visits will be conducted over the phone (if you have already been discharged). For all follow-up visits (both in-person and by telephone), we will ask how you are feeling and if you have been sick. If you were already discharged, we will ask if you had any additional hospital stays or clinic visits or needed additional treatments or medicines since your discharge. On Days 29 and 60, we will ask you to answer a survey about your quality of life. If you have in-person visits on Days 15 and 29, we will also take one or more blood sample(s).

You may be given an optional memory aide that will help remind you when you took your study drug on the days after you are discharged.

The total amount of blood that we will collect from you for this study is about 34 tablespoons. If we take additional blood before and after doses of the study drug or placebo to check study drug levels, the total amount will be about 7 tablespoons more. We will use the blood samples collected on this study for research and safety tests.

As part of this study, we will collect some extra blood samples from you (included in the total amount given above) that we do not need for our current study goals. We will use your coded information, leftover samples, and extra blood samples collected during your participation on this study for secondary research. Secondary research is research that is not part of this study, and the research is not planned yet. This research will occur in the future and it will 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. More information about secondary research is provided below.

The last visit for this study is at Day 60. Your study participation will be complete after this visit. Your total amount of time on this study will be about 60 days.

3. What are the study drugs and their risks?

Remdesivir
Description: Remdesivir is an antiviral drug that blocks viruses like SARS-CoV-2 from replicating, or reproducing. The U.S. FDA recently approved remdesivir as a treatment for COVID-19, which means it can be given to COVID-19 patients as standard treatment.

Remdesivir is given as an infusion into your bloodstream through an intravenous tube placed in a vein in your arm using a needle (IV line). It is given once daily for up to 10 days. Each dose takes about 30 minutes to give, but could take up to 2 hours.

Risks: The most common side effects seen in people who received remdesivir in research studies included:

- Abnormal liver function test results
- Abnormal blood clotting test results
- Constipation
- Nausea
- Vomiting
- Headache
- Dizziness
- Pain or infection around the IV line

The abnormal liver function tests lasted longer than a few days but came back to normal levels during the studies. We have not seen any long-lasting kidney problems in humans who have taken remdesivir. We will be following your liver and kidney function during the study. If you have any abnormal test results that may require medical care, we will share these results with you.

In a 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
- Increased blood glucose

The occurrence of these adverse events were similar in the remdesivir and placebo groups.

None of the side effects in studies of remdesivir have been serious. Some people may have some side effects after the infusion. Other people may have no side effects. These side effects are temporary and should not last more than a few days.

We will monitor you closely for side effects while you are getting remdesivir. We will have medicine and equipment available to treat any side effects, including severe effects, if needed. If you have severe side effects that do not get better, we will not give you any more doses of remdesivir.

Danicopan

Description: Danicopan is a study drug that is under investigation as a potential treatment for COVID-19. It has been given to more than 266 people in completed studies, including healthy people and people with certain conditions that affect the liver, kidneys, or blood. Danicopan targets the immune system, part of the body that fights infections. We think that COVID-19 can

make people's immune systems overreact and attack their own bodies, which can damage their organs. Danicopan blocks part of the immune system that we think overreacts to COVID-19, so we think that this drug may be helpful as a treatment. Danicopan is not approved by the FDA to treat COVID-19, but they have given us permission to test it in this study.

Danicopan is given as a tablet that you swallow. It can also be given through a gastric or nasogastric tube if you have one. It is given 4 times a day until you are discharged from the hospital or up to 14 days. After that, you will take it 3 times a day for 2 days, and then 2 times a day for 2 days.

Risks: Other drugs that are similar to danicopan can lower the immune system's ability to fight some infections. They might also increase the risk for some serious, life-threatening infections such as infection with the bacteria meningococcus, which can cause complications like meningitis (swelling around the brain or spinal cord). It is possible that danicopan might also have these risks. It is also possible that this risk may continue even after you stop taking danicopan.

You must take an antibiotic during the study unless you are already taking one for another reason or you have been vaccinated against meningococcal infections in the past 3 years. The antibiotic will be given by mouth or IV once or twice a day starting before the first dose to 2 days after the last dose of study drug or placebo. Taking antibiotics can have some side effects, which are described below in Section 4.

Taking danicopan can cause abnormal results on liver function tests. These results have been seen in 3 people taking danicopan on other studies. Two of these people were healthy and one had a blood condition called PNH (paroxysmal nocturnal hemoglobinuria). None of these people showed signs of liver injury caused by danicopan, and the test results returned to normal shortly after stopping the study drug. We will check your liver function closely during the study, and we will stop giving you the study drug or placebo if needed.

Placebo
Description: The placebo for this study is an inactive tablet that is similar to danicopan, but does not have any active drug in it. It is given at the same schedule as danicopan: 4 times a day until you are discharged from the hospital or up to 14 days, then 3 times a day for 2 days, and then 2 times a day for 2 days.

Risks: There are no risks of taking the placebo.

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

General study drug risks
Since these are new drugs that we are still studying, they may cause other changes that could hurt or bother you that we do not know about. People can have allergic reactions to drugs, including hives, trouble breathing, or other allergic responses. This is very rare but is also a possible effect of any drug. Allergic reactions may be severe or life-threatening.

Short-term medical care will be provided if there are side effects from the study drugs 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.

Risks of Randomization
You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.
Blood draws and IV line placement
We will insert a new, clean needle into a vein in your arm to take blood samples and to insert the IV line. If you already have an IV line, the blood samples can be taken from that. You may feel a pinch when the needle goes through your skin. A bruise may appear where it was put in. You may also have swelling, and the area may be sore. These things are common and should go away in a couple of days. Drawing blood may cause brief discomfort and fainting. Fainting is usually for a short period and would be managed by having you lie down and elevate his/her legs. There is a very small chance of an infection where you have the tube in your arm. An infection could be treated with antibiotics.

Antibiotics
Taking antibiotics can cause side effects such as stomach pain or cramps, nausea, vomiting, and diarrhea. Most side effects are only mild or moderate and stop as soon as you quit taking them.

Confidentiality risks
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.

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research.
They include:

- The [redacted]). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- The Division of Microbiology and Infectious Diseases (DMID)
- The National Institute of Allergy and Infectious Diseases (NIAID)
- The National Institutes of Health (NIH)
- The Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

<u>Genetic Testing:</u>
As stated above, we will perform genetic testing on your blood sample. This genetic testing will focus on COVID-19 and provide information about how your body responds to the disease. Following genetic testing, and with your consent, your genetic testing information 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 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 may be stored and shared with other researchers, there may be a risk that information resulting from research genetic testing could be misused for discriminatory purposes.

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 that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. 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.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

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 <u>initial</u> your decision for us to use your information and samples for genetic research for this research study:

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

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

Risks to pregnancy and nursing children
If you are pregnant or nursing a child during the study, there may be risks to you, the embryo, fetus, or nursing child from the study drugs. If you are nursing a child, you must agree to discontinue breastfeeding while on this study. If you can get pregnant, you must agree to remain

abstinent or use birth control while taking part in this study and for 30 days after your last dose of the study drug or placebo. If you can get a partner pregnant, you must remain abstinent or use birth control during the study and for 90 days after your last dose of the study drug or placebo. A member of the study team will talk with you about acceptable forms of birth control. You should not participate in this study if you can become pregnant or get a partner pregnant. and cannot use one of these birth control methods. Be aware that women can still become pregnant even if using an acceptable birth control method.

If you think or know you have become pregnant or gotten a partner pregnant during the time specified above, please contact the research team member. You will not receive any more study drug. The team will ask your permission to follow-up with you about your health and the health of the baby until delivery.

5. Are there benefits to being in the study?

You may or may not benefit from being in this study. Your participation in this study can help to learn more about the study drugs if they are safe and work in hospitalized participants with COVID-19.

6. What instructions do you need to follow?

You should not drink any alcohol for 14 days after you start receiving the study drug on Day 1. If you feel that you need other medicines or herbal products, you should talk to a member of the study team first.

If you are nursing a child, you must agree to discontinue breastfeeding while on this study. If you can get pregnant or get a partner pregnant, you must agree to remain abstinent or use birth control as described above in section 4.

You may not volunteer for another study that gives participants a new study drug for COVID-19 for at least 29 days after you start receiving the study drug on Day 1. If you want to be in another study that follows people who have or have had COVID-19, you should talk to a member of the study team first, especially if the other study involves blood collection.

7. What other choices do you have?

Before you decide whether to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could look for other studies of experimental drugs for COVID-19. You can also continue to receive regular supportive hospital care for patients with COVID-19 instead of joining a research study. This could include treatment with remdesivir.

8. Will new findings be shared with you?

If we find out any new information that may affect your choice to participate in this study, we will contact you to explain what we have learned. This may be information we have learned

while doing this study or information we have learned from other scientists doing similar research in other places.

We are doing genetic testing (sequencing) for research purposes and not to look for inherited disease or defects; therefore, we will not return results from sequencing.

9. 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 SARS-CoV-2. 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. This information cannot be traced back to you. Your samples will not be sold. You will not be paid for any products that result from this research.

The only risk of allowing us to store your samples would be an accidental release of your identity.

Some of the blood collected for this study may not be needed to do the research tests. We plan to store and use these leftover 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 performed in the future. You will not be told about the future research. Also, we will collect extra blood samples (about 3 teaspoons when other blood is drawn) to store and use for secondary research. Secondary research may help us understand how remdesivir and the other study drugs work, study other infections or diseases, or develop other treatments. The types of research may include development of new laboratory tests to better understand responses to infection or for studies to better understand virus infections, including SARS-CoV-2 infection.

You may change your mind about secondary research 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.

Please <u>initial</u> your decision about permission for us to use your excess/leftover blood samples for future research:

_____ YES, you may collect and store my excess/leftover blood samples for an indefinite period of time and use them for future research.

_____ NO, you may not store my excess/leftover blood samples for an indefinite period of time and use them for future research. **I understand that by saying NO, I can still take part in this study.**

10. 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 (if you are still hospitalized) or call the study contact number you were given when you left the hospital (if you have been discharged). We may ask you to return to the study site for a medical exam and possible sampling.

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

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

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

You will not receive any monetary compensation for your participation in this study.

13. Who is watching over this study?

A Data and Safety Monitoring Board (DSMB) will be looking at the study information very closely. The DSMB is made up of doctors and other people who are not directly involved in the study and who have a good understanding of severe coronavirus infections 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 National Institutes of Health (NIH), local ethics and health authorities, and the U.S. FDA will also be watching over this study and have the authority to stop the study at any time.

14. 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 and the U.S. government including the NIH and their designees and the U.S. Food and Drug Administration, the Institutional Review Board (Advarra IRB), and the drug companies that make the study drugs (remdesivir by Gilead Sciences, Inc., and danicopan by Alexion Pharmaceuticals, Inc.). 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 U.S. 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.

15. 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 researchers may ask to see your health care records from your other health care providers. You will 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.

Your consent form will be placed in your medical record at [redacted]. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principle investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient) and are participating in a research study, results of research tests or procedures (i.e. laboratory tests, imaging studies, and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient) and are participating in a research study, a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

16. 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. This process is detailed in a Conflict of Interest (COI) Guide. You may ask your study team for a copy of the COI Guide or for more information. This study has investigators that are NIH employees and some that are not. All non-NIH investigators are required to follow the principles outlined in the COI Guide but they are not required to report their specific financial holdings to the NIH.

Gilead Sciences, Inc., the company that makes remdesivir, is providing remdesivir for this study to NIH without charge. Alexion Pharmaceuticals, Inc., the company that makes danicopan, is providing danicopan 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 study doctor 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 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
  6100 Merriweather Dr., Suite 600

Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00046406.

If you have questions about your rights as a research participant, or concerns, or complaints about the research, you may contact the [redacted] Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to tak to someone else.

D. 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.

[redacted] has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

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. 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.

Consent

Study staff have described this research study to me. I have read this consent form. All of my questions 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: _____/_____/_____ ; Time: _____
Signature of participant dd mm yy

_____
Printed name of participant

_____ Date: _____/_____/_____ ; Time: _____
Signature of investigator/designee dd mm yy

_____
Printed name of investigator/designee

FOR ADULTS NOT CAPABLE of GIVING CONSENT

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

_____
Printed name of LAR

_____
Relationship of LAR to Participant
(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: _____/_____/_____ ; Time: _____
Signature of witness dd mm yy

_____
Printed name of witness

[redacted]

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____

Research Protocol: A Multicenter Platform Trial of Putative Therapeutics for the Treatment of COVID-19 in Hospitalized Adults _____

[redacted] _

Principal Investigator: [redacted]

Sponsor: DMID, NIAID, NIH _____

What is the purpose of this form? You are being asked to sign this form so that [redacted] may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at [redacted] or elsewhere); other operating units of [redacted], as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____