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 on Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults with Laboratory Confirmed COVID-19 Infections"**
Protocol Number:	**20-0006**
NIH IRB Number:	**20I0073**
Principal Investigator: (Study Doctor)	**Richard Davey, Jr, MD**
Study Site:	**National Institutes of Health, Clinical Center**
Telephone:	**[redacted] (24 Hours)**
Address:	**National Institutes of Health NIH Clinical Center 10 Center Drive Bethesda, MD 20814**

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.
- 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 no approved medications to treat COVID-19 because it is a new disease caused by a virus that was just identified in 2019 in China. Some people who become sick with COVID-19 have serious disease and must be hospitalized. A small percent of hospitalized patients die. This study will test a drug in adults that are hospitalized with COVID-19. The drug has been tested before in humans with other diseases. In this study, we would like to make sure that it is safe for use in humans with COVID-19 and see if it can improve patients' health when they are sick with COVID-19.

What drug is being studied?

We are studying a drug called remdesivir. This drug has been studied in animals and in people. 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 the arm.

To find out if remdesivir (the study drug) works, we need to compare it to getting something that does not have the drug in it, something called a placebo. The placebo looks like the study drug but does not have the drug in it. Using a placebo is common in research studies. The placebo is also given as an infusion. Some people in the study will get the placebo.

Will you get the study drug or placebo?
There are 2 study groups. If you join the study, you will be randomly put into one of two groups. This is decided by chance. Out of every 2 people on this study, 1 will get the study drug and 1 will get placebo. You will have a 50:50 chance of getting the study drug. You and the study staff will not know what group you are in or if you are getting the study drug or the placebo. When the study is over, we hope to learn if the study drug is safe and if it was successful in treating people with COVID-19.

What will happen on this study?
If you agree to join this study, we will first do some tests to make sure it is safe for you to join. This includes tests of your blood and a swab of the back of your throat (also known as an OP swab). Only hospitalized adults 18 years old and older who are not pregnant and test positive for COVID-19 can join this study.

If you qualify for this study and decide to join, you will get 1 infusion of study drug or placebo every day while you are a patient in the hospital. You will not get infusions after you are discharged from the hospital. The maximum number of infusions you will receive is 10. You will come back to the site for study visits on Days 15 and 29. We will take one blood sample and one OP swab sample from you on Days 1, 3, 5, 8, and 11 as long as you remain a patient in the hospital, and at the follow-up study visits on Days 15 and 29. We will use the blood and OP swab samples for research and safety tests. Your total amount of time on this study will be about 29 days. You will not be compensated for taking part in the study.

What are the main study risks?
The study drug has been given to a small number of healthy (not sick) people in research studies in the United States. It has also been given to Ebola survivors in West Africa and to people with Ebola in the Democratic Republic of Congo (DRC) in Africa. Some of these people had side effects. The most common side effects included abnormal liver function test results, abnormal blood clotting test results, constipation, nausea, vomiting, decreased appetite, and headache. The abnormal liver function tests lasted longer than a few days but came back to normal levels during the studies.

The needle used to draw blood or place the tube in your arm for the infusion of study drug can hurt. 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. There is a very small chance of an infection where you have the tube in your arm. An infection could be treated with antibiotics.

Some people may have some side effects after the infusion. Other people may have no side effects. 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. You will be monitored closely during the infusions, and short-term medical care will be provided if there are side effects from the infusions that can be treated.

Most side effects are temporary and should not last more than a few days. Since this is a new drug that we are still studying, it may cause other changes that could hurt or bother you that we do not know about. It is important that you always tell the study staff if you have any problems and always keep in touch with them.

Are there benefits to being in the study?
You may not benefit from being in this study. If the study drug works and you received the study drug on this study, you may benefit by getting better sooner or having less severe disease.

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. Also, you should not take any over-the-counter, nonprescription medicines or herbal products for the 14 days after you start receiving study drug. If you feel that you need medicines or herbal products, you should talk to a member of the study team first.

For Women, Risks Related to Pregnancy
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

If you are pregnant or nursing a child during the study, there may be risks to you, the embryo, fetus, or nursing child. If you can become pregnant, you must use an acceptable nonhormonal method of birth control, from screening until 30 days after your last dose of study drug. 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 vaccinations. 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.

For Males
Men who are not permanently sterile must agree to use condoms with female partners, and not to donate sperm, from the first study dose vaccination until 3 months after the last study dose.

If your partner becomes pregnant, she will be asked to sign a separate consent form to allow the study staff to collect information about the pregnancy and its outcome.

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.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of 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 to sign and date this consent form. When you sign your name 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. Up to 394 hospitalized adults with COVID-19 will be in this study.

We will ask you some questions about your health, including whether you have liver or kidney disease, allergies to medications, and if you received any medications from your doctor during this illness. We will also perform a physical exam, measure your weight, get an OP swab sample to test for the virus, and take some of your blood to determine if your liver and kidneys are working well. 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.

2. What does the study involve?

If you qualify for the study and decide to join, you will get 1 infusion every day while you are a patient in the hospital. The maximum number of infusions you will receive is 10. The infusion will be either study drug or placebo, depending on what group you are in. The infusion takes about 1 hour and will be done in the hospital. We will watch you closely for side effects during the infusion and for 1 hour after the infusion. After you are discharged from the hospital, you will not receive any more infusions.

We will take one blood sample and one OP swab sample from you on Days 1, 3, 5, 8, and 11 as long as you remain a patient in the hospital. You will come back to the site for study visits on Days 15 and 29. During these follow-up visits, we will ask how you are feeling and if you have been sick. We will take one blood sample and one OP swab sample at Days 15 and 29.

We will use the blood and OP swab samples for research and safety tests. OP swab samples will be tested for presence of the virus that causes COVID-19.

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.

As part of this study, we will get 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. This extra research will occur in the future and it will help us to understand how the study drug works 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.

Your total amount of time on this study will be about 29 days.

3. What could be the side effects from the infusions?

The study drug has been given to a small number of healthy (not sick) people in research studies in the United States to test for safety of the drug. It has also been given to Ebola survivors in West Africa and to people with acute Ebola virus disease in the DRC. Some of these people had side effects. The most common side effects included:

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

Less common side effects (seen in 1 person) included:

- Dizziness
- Itching
- Shaking of the leg and arm
- Indigestion

The abnormal liver function tests lasted longer than a few days but came back to normal levels during the studies. You will receive results from the tests during your participation. If you have any abnormal test results that may require more medical care, we will share these results with you.

None of the side effects in these studies 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.

The study drug and placebo both contain a compound that in animals caused changes in the kidneys but did not affect how well the kidneys worked. The animals' kidneys went back to normal after the drug was stopped. We have not seen any kidney problems in humans who have taken remdesivir. We will be following your kidney function during the study to check for kidney damage.

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

We will insert a new, clean needle into a vein in your arm to take blood and to put in the sterile tube that we use for the study infusions. 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. There is a very small chance of an infection where you have the tube in your arm. An infection could be treated with antibiotics.

Since this is a new drug that we are still studying, it 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.

If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the drug being studied that could increase the risk of harm to a fetus. You need to wait until after the study before you become pregnant. If you think or know you have become pregnant during the study, 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 your baby until the end of your pregnancy.

The study drug was given to some people who were sick with Ebola virus disease in a study in DRC. One of these people died from a heart attack after receiving the study drug. However, this person was very sick with Ebola, so we cannot say if the heart attack was caused by the study drug or the Ebola disease. None of the healthy people who have received the study drug in other studies have had heart problems.

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

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.

5. Are there benefits to being in the study?

You may not benefit from being in this study. If the study drug works and you received it on this study, you may benefit by getting better sooner and/or getting less severe disease. If we find that the study drug does work, it will continue to be tested in more study volunteers until it can be approved as a treatment for COVID-19. Your participation in this study is important to learn more about the study drug, including if it is safe and works in hospitalized patients 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.

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 continue to receive regular supportive hospital care for patients with coronavirus.

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.

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. 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 and these leftover samples we plan to store and use 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 (between 2 and 3 teaspoons when other blood is drawn) to store and use for secondary research. Secondary research may help us understand how remdesivir works, 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 the SARS-CoV-2 infection. If you do not want to give leftover and extra samples for secondary research, you can not be in this study.

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.

Your samples collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. These researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

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 if you have been discharged from the hospital. We may ask you to return to the clinic for a medical exam.

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

It will not cost you anything to be in this study. NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

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

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

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines. NIAID will cover some or all of your travel expenses related to participation in this study. This may include direct payments or reimbursements for expenses related to transportation, lodging, and meals. The amount and form of these payments are determined by the NIAID Central Travel Policy for Research Protocol Participants. We will give you a copy of this policy.

10. 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 coronanvirus 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 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. Confidentiality Protections Provided in this Study

Will my medical information be kept private?
We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- The Advarra Institutional Review Board.
- The study Sponsor, the NIAID, NIH, or their agent(s), including regulatory oversight bodies within it.
- Qualified representatives from Gilead Sciences, Inc, the pharmaceutical company who produces remdesivir.

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality
To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or 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 Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

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 below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

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 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.

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 National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

Gilead Sciences, Inc., the company that makes remdesivir, is providing remdesivir 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. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713.

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.

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

The NIH Clinical Center 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, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date