INFORMED CONSENT FORM

Intermediate-Size Patient Population Expanded Access Protocol for Treatment of Coronavirus Disease 2019 (COVID-19) with Remdesivir (RDV; GS-5734™)

Principal Investigator (Treating Physician, Your Doctor):	_____
Telephone Number:	_____
Medical Treatment Facility:	_____
Telephone Number:	_____
Patient Name:	_____
Patient ID Number:	_____
Sponsor:	The Surgeon General, Department of the Army
Institutional Review Board (IRB):	Headquarters (HQ) US Army Medical Research and Development Command (USAMRDC) IRB

Summary	
Informed Consent	It is important that you understand this treatment, so you can make an informed decision. This process is called informed consent. Please ask questions about anything you do not understand. Feel free to talk with your family, friends, or others before you decide. After your questions have been answered, you will be asked if you want to receive the treatment. If you agree, you will sign this consent form. You will be given a copy of this form to keep.
Voluntary Participation	You do not have to receive this treatment. It is your choice. You can choose to stop treatment at any time.
Purpose	The purpose is to treat coronavirus (COVID-19) infection.
Duration	You will be in this study for about 29 days.
Procedures	While you are on the treatment protocol, you will receive up to 10 doses of study treatment and standard care from your doctor.

Summary	
Treatment	Intravenous infusion (IV, administered into a vein over a 30 to 60 minute period) of remdesivir, which is also called RDV and GS-5734.
Risks	The most common side effects include: increased liver function test results, increased bleeding time, constipation, nausea, vomiting, decreased appetite, and headache.
Benefits	You may not benefit from receiving this treatment. If remdesivir works, you may get better sooner and/or get a less severe disease.
Payment	You will not be paid for participating in this study.

1. INTRODUCTION

You have been diagnosed with moderate to severe Coronavirus Disease 2019 (COVID-19), so you may be able to receive an experimental treatment called remdesivir. There are currently no treatments approved by the US Food and Drug administration (FDA) for treating this infection. Remdesivir has been used in animals and human studies to treat this and similar viruses.

It is very important that you read and understand the following:

- You do not have to receive this treatment
- You may stop receiving treatment at any time
- There will be no penalty or loss of benefits if you refuse to participate
- The treatment you will receive is investigational, meaning it is not approved by the US Food and Drug Administration (FDA)
- Remdesivir is an experimental treatment for COVID-19 caused by severe acute respiratory syndrome-coronovirus-2 infection

This informed consent form explains the experimental treatment. After you read it, feel free to ask your doctor any questions. The doctor will go over the information in this form with you and answer any questions you have.

If you agree to receive the experimental treatment, you will be asked to sign and date this form. You will be given a signed and dated copy of this form to keep.

2. WHY IS THIS TREATMENT BEING OFFERED

You are being offered this treatment because you have moderate to severe COVID-19, and there are no FDA-approved treatments for this disease. Common symptoms and signs include fever, cough, shortness of breath, breathing difficulties, and other respiratory symptoms. In more severe cases, this infection can lead to pneumonia, severe acute respiratory syndrome, kidney failure, and death.

Remdesivir has not been proven safe or effective in treating COVID-19. Your doctor cannot promise that remdesivir will provide a benefit to you. In laboratory and animal experiments,

Remdesivir has shown activity against the virus that caused COVID-19 and other similar types of viruses.

3. WHAT ARE THE REQUIREMENTS

You must have a diagnosis of COVID-19, be a member of or affiliated with the Department of Defense (DoD), and be over the age of 18. You cannot be pregnant or breastfeeding. Your doctor will discuss any other requirements with you.

4. HOW LONG WILL YOU BE TREATED

You will get one treatment every day for up to 10 days while you are in the hospital, and then you will attend 7 follow-up visits over the next several weeks. Remdesivir will be given through a vein in your arm and takes 30 minutes to 1 hour for each dose. You will be watched closely for side effects during and after each dose. The maximum number of doses you will get is 10. After you are discharged from the hospital, you will not receive any more doses.

5. WHAT WILL BE DONE

You will also get standard medical care from your doctor. During the treatment protocol, the activities shown in the table below will occur.

Days	**Anticipated Activities**
Screening Day	Informed consent Demographic information and medical history collected Physical exam Blood and urine tests Confirmation of COVID-19 diagnosis Pregnancy test, if you are a female who can have children
Days 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10	Remdesivir treatment - The recommended remdesivir dosing duration is a total of 5 days and up to 10 days Physical exam Blood and urine tests
Days 11 and 29	If you are a female who can have children, a pregnancy test will be performed on Day 11 or on the day treatment ends (if before Day 11) and at the end of follow-up on Day 29
Days 11, 12, 13, 14, 15, 22, and 29	Physical exam Blood and urine tests

Your doctor may do more as part of your care.

You will remain at the medical facility during the entire treatment period. After treatment, you may be discharged, or you may need to stay at the medical facility longer.

Even after you finish your treatment and follow-up visits, if you think you are having any reactions to the treatment, you should report it to your doctor. If an emergency room visit is necessary, you should ask them to notify the doctor.

6. POSSIBLE RISKS OR DISCOMFORTS

Short-term medical care will be provided if there are side effects. It is important that you always tell your doctor if you have any problems.

6.1. Remdesivir

Remdesivir has been given to a small number of healthy, not sick, people in research studies in the United States to test drug safety. Remdesivir has also been given to Ebola survivors in West Africa and to people with Ebola virus disease. Some of these people had side effects. The most common side effects were:

- Increase in liver function test results that may cause treatment to be stopped
- Abnormal blood clotting test resulting in longer bleeding time
- Constipation
- Nausea
- Vomiting
- Decreased appetite
- Headache

Less common side effects were:

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

You will receive your test results and be notified of any abnormal results.

In animal studies, some animals who got remdesivir showed changes in lab tests of their kidneys. There did not seem to be a problem with how the kidneys worked. Their test results went back to normal after the drug was stopped. There have not been kidney problems seen in humans who have been given remdesivir. Your kidney function will be monitored during treatment and follow-up.

You could have an allergic reaction to the drug that could be life-threatening. Equipment is available to handle emergencies. Some things that happen during an allergic reaction to any type of medication are:

- Rash
- A hard time breathing

- Wheezing when you breathe
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

Since this is a new drug, there may be unknown side effects. You will be told of any new information that might cause you to change your mind about continuing to take part in this experimental treatment.

The treatment medication remdesivir may not work or may not work as well when given while also taking chloroquine or hydroxychloroquine medications.

6.2. Needles

You may feel a pinch when the needle goes through your skin, and a bruise may appear. You may have swelling and soreness in that area. These are common and should go away in a couple of days.

There is a small chance of an infection where you have the tube in your arm. An infection could be treated with antibiotics.

6.3. Pregnancy

The risk to pregnancy or to a child of nursing mother is not known.

For males and females, avoid sexual intercourse and pregnancy or causing pregnancy during treatment and for 1 month post-treatment period. Use 2 reliable forms of birth control, including one barrier method, such as a condom with spermicide.

For females, if you become pregnant before your treatment is complete, we will ask to follow you to term (pregnancy outcome).

7. BENEFITS

You may not benefit from receiving this treatment. If remdesivir works, you may get better sooner and/or get a less severe disease.

A description of this treatment protocol will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

8. ALTERNATIVES

At this time there are no FDA approved treatments for COVID-19. The standard treatment for the disease is treating the symptoms.

9. CONFIDENTIALITY

Documents created solely for the purpose of the remdesivir treatment protocol that are not required for medical care will be labeled or coded with only a patient identification number.

Confidentiality of your records will be protected to the extent possible but cannot be guaranteed. Complete confidentiality cannot be promised because reporting information to appropriate medical or command authorities may be required.

10. VOLUNTEER REGISTRY DATASHEET

It is the policy of the United States Army Medical Research and Development Command (USAMRDC) that data sheets be completed for all individuals receiving treatment with an investigational drug sponsored by the Surgeon General, Department of the Army (Form 60-R, Volunteer Registry Data Sheet). The data sheets will be entered into this Command's Volunteer Registry Data Base. Information entered into this confidential data base includes the patient's name, address, social security number, protocol title, and dates of participation. The intent of this data base is two-fold: first, to readily answer questions concerning an individual's receipt of treatment sponsored by USAMRDC; and second, to ensure that USAMRDC can exercise its obligation to ensure patients are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRDC for a minimum of 75 years and is kept confidential. The Volunteer Registry Data Base is separate from and not linked to the treatment protocol database.

11. HIPAA AUTHORIZATION

The Federal Health Insurance Portability and Accountability Act (HIPAA) establishes privacy standards to protect your health information. This law requires the doctor and staff to obtain your permission (by signing this form) before they obtain, use, or disclose (share) your protected health information (PHI) for this treatment.

By signing this form, you are authorizing the use and disclosure of your PHI by the doctor and other members of the medical facility staff, including results of physical examinations, blood tests, and other diagnostic and medical procedures, as well as medical history. Your PHI may also be viewed and used by other regulatory and medical representatives, including but not limited to representatives from The Surgeon General of the US Army (the sponsor of this treatment protocol); the Headquarters USAMRDC Institutional Review Board (reviews this treatment protocol to make sure that it is ethical); the Army Human Research Protections Office; state and federal government agencies (including, but not limited to, the FDA, the Department of Health and Human Services, the DoD, and USAMMDA). Protected health information of military service members may be used or disclosed for activities deemed necessary by appropriate military command authorities to ensure the proper execution of the military mission.

Health information that has been shared may be re-disclosed by the recipient of the information; these other organizations may then share your health information with others without your permission.

There is no expiration date for this authorization.

You will receive a copy of this form.

If you choose not to authorize these uses and disclosure of your PHI, you cannot receive remdesivir. However, your decision not to sign this consent will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

You may change your mind and cancel this Authorization at any time. Cancellation will not alter disclosure of PHI already collected; however, no further PHI about you will be collected or disclosed and you will not be allowed to continue this treatment.

To cancel this authorization, send your written request to:

US Army Medical Materiel Development Activity
Force Health Protection Division
1430 Veterans Drive
Fort Detrick, MD 21702-5009

12. ADDITIONAL COSTS

If you are a DoD beneficiary, there is no charge to you receiving this treatment. If you are not a DoD beneficiary, although no charge this treatment, there may be a charge for other costs of the hospital and medical care that may be billed to your insurance.

Transportation to and from DoD medical facilities will not be provided or reimbursed.

13. COMPENSATION FOR INJURY

If you are injured because of your treatment with remdesivir and you are a DoD healthcare beneficiary (for example, active duty in the military, dependent), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

If you are not a DoD healthcare beneficiary, you or your insurance may be billed for medical care you receive for your injury.

For DOD and non-DOD healthcare beneficiaries: No reimbursement is available if you incur medical expenses to treat protocol-related injuries due to participation in the protocol. No compensation is available for protocol-related injuries. You are not waiving any legal rights. If you believe you have sustained an injury, please contact your doctor.

14. SIGNIFICANT NEW FINDINGS

You will be notified of any new findings that could affect your decision to continue treatment.

15. APPROXIMATE NUMBER OF PATIENTS

Up to 200 patients may be included in this treatment protocol.

16. WITHDRAW

Taking remdesivir is voluntary. You can decide not to take it or to stop taking it at any time. You will still receive medical care and other benefits to which you are entitled.

Remdesivir treatment may be stopped, with or without your consent, if:

1. You don't comply with procedures as outlined in this informed consent.
2. Your safety or health may be negatively affected. Counseling will be provided about your health if you are asked to leave the protocol for a medical reason.
3. You are transferred to another medical facility, unless the receiving medical facility is an approved site for the treatment protocol.

If you will not be available in person for follow up visits, please make sure the doctor has your contact information and knows your assignment location, so we can contact you by phone and safety follow ups can be coordinated with the next treatment facility.

17. QUESTIONS AND ADDITIONAL INFORMATION

For further information: If you have a question about remdesivir treatment, and/or illness or injury related to participation in this protocol, contact the doctor:

Name: _____

Telephone: _____

Email: _____

Or the sponsor's representative:

US Army Medical Research and Development Command (USAMRDC)
1430 Veterans Drive, Fort Detrick, MD 21702 USA
Telephone 301-619-0317

If you have questions about your rights as a patient in this protocol, you may contact:

HQ USAMRDC IRB Office
Telephone: 301-619-6240/DSN 312-343-6240
Email: usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil

18. CONSENT

If there is any portion of this protocol or informed consent that you do not understand, ask the doctor before signing. If this signed form cannot be collected from you, we may use an electronic method of consent. If this signed form cannot be collected from you and there is no electronic method: An impartial witness and your doctor will sign a separate copy of this form for your file or a photograph of the consent form signed by you will be collected and added to your file. A copy of this form will be provided to you.

By signing this form, you are stating:

I have read the information provided above. I have been given an opportunity to ask questions, all of my questions have been answered to my satisfaction, and I agree to participate in the treatment protocol.

Printed Full Name of Patient

Signature of Patient Date

Note: If patient is unable to sign, a legally authorized representative may sign.

Printed Full Name of Legally Authorized Representative Date

Signature of Legally Authorized Representative and Relationship to Patient

My signature certifies that this consent was signed in my presence as a voluntary act:

Printed Name of Healthcare Professional Performing Informed Consent

Signature of Healthcare Professional Performing Informed Consent Date

My signature attests that this consent was signed in my presence as a voluntary act:

Printed Name of Impartial Witness

Signature of Impartial Witness Date

19. REQUIREMENT FOR TRANSLATION

If this consent form is translated from English to a foreign language, the translator must complete the following.

I certify that this is an accurate and true translation of the Informed Consent form.

Printed Name of the Translator

Signature of the Translator Date

Address of the Translator:

Telephone Number:

Fax Number:

20. IF OBTAINING INFORMED CONSENT IS INFEASIBLE

If obtaining informed consent is infeasible because the patient is unable to respond and make his or her wishes known about remdesivir treatment and no legally authorized representative is available, the doctor may make a clinical determination to treat with remdesivir provided that the doctor and an independent physician certify the following within 5 working days of treating the patient with remdesivir:

21 CFR 50.23 All Criteria (check (✓) Must Apply)	
☐	1. The patient is confronted by a life-threatening situation necessitating the use of remdesivir
☐	2. Informed consent cannot be obtained from the patient because of an inability to communicate with or obtain legally-effective consent from the patient
☐	3. Time is not sufficient to obtain consent from the patient's legally authorized representative
☐	4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient

Include documentation in the patient's files, and, when possible, ensure the patient or the patient's legally authorized representative is made aware that investigational remdesivir was administered.

Printed name, signature, and date of the treating physican who made the determination to administer remdesivir to the patient when informed consent could not be obtained:

Printed Name of the Treating Physician

Signature of Treating Physician Date

Printed name, signature, and date of a second physician, who reviewed and evaluated the decision to administer remdesivir to the patient but is not otherwise participating in this treatment protocol:

Printed Name of the Second Physician

Signature of Second Physician Date