This consent form is written from the point of view of the patient. If a legally authorized representative will be providing consent, the words "you" and "your" should be read as ("the patient").

**What is casirivimab-imdevimab?**
Casirivimab-imdevimab is an investigational treatment used to treat certain people outside of the hospital with Coronavirus Disease 2019 (COVID-19). There is no U.S. Food and Drug Administration (FDA) approved treatment available for patients who are outside of the hospital with COVID-19, and casirivimab-imdevimab likewise has not been approved by the FDA. However, the FDA has made casirivimab-imdevimab available under an emergency access mechanism called an Emergency Use Authorization (EUA), and your doctor believes that the benefit to you of receiving casirivimab-imdevimab may be greater than the risk to you from the treatment because you are in a high-risk group of developing severe COVID-19.

Casirivimab-imdevimab is an investigational medication because it is still being studied. It is an antibody that binds to SARS-CoV-2, the virus that causes COVID-19, and it may help your immune system get rid of the virus. There are limited information and data about the safety and effectiveness of using casirivimab-imdevimab to treat patients with COVID-19. Casirivimab-imdevimab was shown in a clinical trial to shorten the time needed to clear, or get rid of SARS-CoV-2. It was also shown to decrease the time to recovery in people who were at high risk of developing severe COVID-19 and to decrease the chances of needing to be admitted to the hospital or go to the emergency department.

This document explains casirivimab-imdevimab treatment for COVID-19. Your doctor will go over this document with you. Your doctor will be available to answer all questions you have about the information in this document. You also will be given a "Fact Sheet for Patients and Parents/Caregivers: Emergency Use Authorization of Casirivimab-imdevimab for Coronavirus Disease 2019 (COVID-19)". We are asking you to read and sign this form so that we can be sure you understand the indications for casirivimab-imdevimab, its potential benefits, probability of success, likelihood of achieving the desired outcome, recuperative process, potential risks, potential complications, and potential side effects. We also want to be sure that you understand the potential alternatives, including the alternative of refusing casirivimab-imdevimab, along with the potential risks, complications and side effects of the alternatives. Please ask questions about anything on this form that you do not understand.

Signing and dating this document also is your acknowledgement that you received the "Fact Sheet for Patients and Parents/Caregivers: Emergency Use Authorization of Casirivimab-imdevimab for Coronavirus Disease 2019 (COVID-19)". You will be given a copy of both forms to keep. It is your choice to be treated or not to be treated with casirivimab-imdevimab. Should you decide not to receive it, or to stop it at any time, it will not affect the other medical care you may receive.

**What is an Emergency Use Authorization (EUA)?**
The FDA has made casirivimab-imdevimab available under an EUA because the federal government has determined that circumstances exist to justify the emergency use during the COVID-19 pandemic. Casirivimab-imdevimab has not undergone the same type of review as an FDA-approved or cleared product. The FDA has determined that there are no adequate, approved, or available alternatives to casirivimab-imdevimab. It also has made another antibody available by EUA called bamlanivimab, but there are not any significant differences between these two EUA options. The FDA made its decision based on the totality of scientific evidence available showing that it is reasonable to believe that casirivimab-imdevimab meets certain criteria for safety, performance, and labeling, and that it may be effective.
How long will treatment with casirivimab-imdevimab last?
This treatment involves giving a single dose of casirivimab-imdevimab through an intravenous catheter, or IV. The infusion lasts at least 1 hour, and you will be monitored for at least 1 hour after the infusion is complete. You will not receive any additional doses of casirivimab-imdevimab after this one dose.

What does treatment with casirivimab-imdevimab involve?
Casirivimab-imdevimab is administered intravenously (through a vein) one time. The medication is given over at least a 1-hour period. Blood may be collected for safety and treatment purposes. Casirivimab-imdevimab can be stopped at any time by your doctor based on the assessment of the safety in your individual case.

Can I receive casirivimab-imdevimab if I am pregnant?
Pregnant women can receive casirivimab-imdevimab. However, pregnant women were not included in casirivimab-imdevimab trials so the potential effects of casirivimab-imdevimab on pregnancy and/or an unborn child currently are not known. There is limited experience giving casirivimab-imdevimab to pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving casirivimab-imdevimab may be greater than the risk from the treatment, or it may not be. If you are pregnant and choose to get the treatment, it is recommended that you:

- Advise your obstetrics provider that you have received the medication as well your child’s pediatrician and ensure that your care and that of your child is monitored by a physician
- Talk to your doctor about whether you should breast-feed after completing casirivimab-imdevimab, and the risks that might be involved
- Tell your doctor all of the information you know about your health and medications you are taking prior to starting casirivimab-imdevimab
- Tell your doctor about any side effects that you may be experiencing when receiving casirivimab-imdevimab

Will casirivimab-imdevimab work any differently if I am 65 years old or older?
There are no data to suggest that casirivimab-imdevimab will work differently in people over the age of 65. However, it is unknown whether the body will clear or metabolize casirivimab-imdevimab differently in people aged 65 years and older compared to younger patients.

What are the possible risks, complications, and side effects?
Casirivimab-imdevimab is an investigational drug that is not approved by the FDA, but is being made available through an EUA. There may be risks involved with taking casirivimab-imdevimab, both known and unknown. Based on available information, most of these side effects are reversible when casirivimab-imdevimab is stopped. There were very few side effects observed in people who received casirivimab-imdevimab. In fact, there was no difference in serious side effects when casirivimab-imdevimab was compared to placebo. The specific risks, complications and side effects associated with this medication include but may not be limited to the following:

LESS LIKELY—Side effect(s) occurring in < 1% of patients or frequency not defined:

*Gastrointestinal:* Nausea, vomiting, diarrhea

*Skin:* Itching

*Neurologic:* Dizziness

*Miscellaneous:* Fever, chills, muscle aches

*Miscellaneous:* Infection, soreness, swelling, or bleeding at injection site
RARE BUT SERIOUS—Side effect(s) occurring in <1% but potentially serious:

Allergy: Allergic reactions are possible and serious allergic reactions that can be life-threatening may occur. Some symptoms of an allergic reaction include but are not limited to:

- Rash
- Difficulty breathing
- Wheezing when you breathe
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eyes

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS

There may also be unknown side effects that could harm you during your treatment or after you have completed the treatment. We cannot predict what these side effects may be, which is why it is so important for you to report any side effects that you experience to your doctor. There is always the possibility that you will have a reaction that, even if treated properly, could be life threatening.

PREGNANCY AND BREASTFEEDING

We do not know if casirivimab-imdevimab is harmful to an unborn baby or a nursing infant because pregnant women were not included in the studies evaluating the safety and effectiveness of casirivimab-imdevimab. If you are currently pregnant and if you consent to receive casirivimab-imdevimab for the treatment of COVID-19, you should get medical supervision during your pregnancy and for the baby after the baby is born. You should also discuss with your doctor whether you should breastfeed after completing casirivimab-imdevimab.

What should I do about the COVID-19 vaccine if I receive casirivimab-imdevimab?

It is unknown whether casirivimab-imdevimab may reduce the immune response to a COVID-19 vaccine, making it less effective. Interim guidance from the Centers for Disease Control and Prevention (CDC) states that the first dose of the vaccine should be postponed for at least 90 days following casirivimab-imdevimab to avoid potential interference with the immune response to the vaccine. If you have already received the first dose of the vaccine, then CDC recommends postponing the second dose for at least 90 days following casirivimab-imdevimab if possible. However, you should discuss timing of the vaccine with your doctors, as these recommendations are subject to change.

What are the possible benefits of casirivimab-imdevimab?

A study evaluating casirivimab-imdevimab found that patients who were at high risk of developing severe COVID-19 recovered faster with casirivimab-imdevimab compared to patients who received the placebo, or “inactive” treatment, in the study. Therefore, casirivimab-imdevimab may make you feel better faster if you receive it. In addition, patients who received casirivimab-imdevimab were less likely to need to be admitted to the hospital or go to the emergency department.

What happens if new information becomes available about this treatment?

During the course of your treatment, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about taking this drug. We will notify you as soon as possible if such information becomes available.

What are your other treatment options?

At this time, there are no medications that have been approved by the FDA for treatment of patients outside of the hospital with COVID-19. Like casirivimab-imdevimab, there may be other medications which have not yet been approved that the FDA has made available for emergency use to treat patients outside of the hospital.
hospital with COVID-19, including bamlanivimab, another antibody that has received EUA approval for COVID-19. There are no data to suggest that there is a significant difference between casirivimab-imdevimab and bamlanivimab. Receiving casirivimab-imdevimab instead of bamlanivimab is based on which option is most available. You should not receive both casirivimab-imdevimab and bamlanivimab because there is no evidence on the safety and effectiveness of using both of these treatments together. There also may be some other experimental treatments that your doctors may discuss with you as well.

If you do become sicker and require admission to a hospital, you may be eligible for other approved treatments for treatment of hospitalized patients with COVID-19.

**What happens if you no longer want to take part in treatment?**
Your decision to receive casirivimab-imdevimab is voluntary. You can refuse to receive it or stop taking it at any time without giving a reason. There will be no penalty or loss of benefits to you. If you decide to stop casirivimab-imdevimab at any time, it will not affect medical care that you otherwise may receive. Your doctor may decide for your medical safety to stop casirivimab-imdevimab as well. If casirivimab-imdevimab is stopped for any reason, your doctor will closely monitor your overall health.

**What is the recuperative process following treatment?**
It is not expected that there will be additional recuperative time or processes after receiving casirivimab-imdevimab compared to that required following COVID-19 infection. However, it is possible that you may have side effects of casirivimab-imdevimab that will require additional treatment.

**How much will the treatment cost you?**
Casirivimab-imdevimab is temporarily being provided free of charge to health care facilities, but there are charges related to the medical care you receive during and after the infusion of casirivimab-imdevimab. If there is a cost to the medication or the infusion, it will be billed to your usual health care payer.

When you sign this form, you are agreeing to the following:
- You have carefully read and understand the information in this document.
- The purpose and procedures of this treatment have been fully explained to you.
- You were able to ask questions and all of your questions were answered to your satisfaction.
- You have been informed that casirivimab-imdevimab is an investigational antibody treatment that is not approved by the FDA, but is authorized by the FDA through the Emergency Use Authorization to be administered to certain patients being treated for COVID-19 outside of the hospital.
- You have received the "Fact Sheet for Patients and Parents/Caregivers: Emergency Use Authorization of Casirivimab-imdevimab for Coronavirus Disease 2019 (COVID-19)."
- There are risks involved with this treatment and with associated procedures. You have been informed of possible risks as a result of receiving to casirivimab-imdevimab that could happen to you from both known and unknown causes.
- You are free to withdraw your consent and to stop casirivimab-imdevimab at any time.
- The possible effect on your health, if any, of stopping the casirivimab-imdevimab early has been explained to you.
- You understand stopping casirivimab-imdevimab will not impact your other medical care and other treatment options.
- You agree that any remaining tissue(s), bodily substances, and/or fluids may be used for research and education not specifically related to my care. If such material identifies you, research use will occur only with your permission.
Patient, Legally Authorized Representative, Parent or Guardian of a Child:

Printed Name and relationship if other than patient ___________________________  Signature ___________________________  Date __________  Time __________

Signature of Attending Physician (or Authorized Professional) providing treatment:

Printed Name and Title ___________________________  Signature ___________________________  Date __________  Time __________

Signature of Witness to Patient’s Consent (if applicable):

Witness Printed Name ___________________________  Signature ___________________________  Date __________  Time __________

Interpreter Identification Number (if services used)