PATIENT CONSENT FORM FOR COVID-19 TREATMENT PURPOSE OF INFORMED CONSENT

Bamlanivimab, Bamlanivimab/Etesevimab or Casirivimab/Imdevimab (Regeneron)

As your physician has discussed with you, you have been diagnosed with COVID-19 (or SARS-CoV-2). At the present time, there are few Food and Drug Administration (FDA) approved, or clinically proven therapies for treatment of COVID-19. As new clinical data emerges, local treatment guidelines have been developed and will be updated as new information becomes available. CDC guidelines reflect what is known about therapies that may work against the SARS-CoV-2 virus, have been used to treat other coronaviruses, or may theoretically target the underlying causes of virus- related severe lung conditions that make breathing difficult.

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies in patients with confirmed or suspected COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization

TREATMENT

In order for you to be treated with the therapy by the Infusion Team, you must sign this form to show that you agree to the use of investigational or off label treatments, that you have been informed of the benefits and risks of taking such therapies as well as the benefits and risks of declining or refusing such use. The Infusion team will annotate the monoclonal therapy available below for your encounter and the particular therapy chosen is based upon availability. You will be provided a patient informational handout regards the specific monoclonal antibody infusion before the infusion begins. **You have the right to refuse to take this treatment(s) for any reason.**

Attention Health Care Professional:

Either Medication may be Administered and have similar safety and side effect profiles and treatment outcomes.
The Medication Checked Below is the One You will Receive for your One Time Infusion

☐ **Bamlanivimab**	☐ **Bamlanivimab+ Etesevimab**	☐ **Casirivimab/Imdevimab (Regeneron)**

BACKGROUND

Bamlanivimab, Regeneron, and Bamlanivimab+ Etesevimab are investigational medicines which are monoclonal antibodies used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. The FDA has issued an Emergency Use Authorization (EUA) to permit the use of this unapproved medication. Clinical trials are ongoing to study its safety and efficacy.

POSSIBLE BENEFITS

It is possible that the medications listed above may help to control your symptoms, slow or stop the growth of the virus, shorten the duration or lessen the severity of the illness in you. Possible benefits primarily include improvement in lung function (ability to breathe without assistance) and normalization of blood pressure. However, there is the possibility that these medications may be of NO direct medical benefit to you. Your condition may get worse.

POSSIBLE RISKS AND KNOWN SIDE EFFECTS

It is possible that the medication prescribed may not improve your symptoms and not shorten the duration nor severity of the illness. It is possible that the medication will unexpectedly interfere with your ability to improve, hasten damage to the lungs or other organs, and shorten your life.

***Bamlanivimab / Regeneron/ or* Bamlanivimab+ Etesevimab**

There is limited clinical data available for these treatments and unexpected adverse events may occur that have not been previously reported. Side effects may include allergic reactions and injection site reactions. It is possible that these treatments could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. These treatments may also reduce your body's immune response to a vaccine for SARS-CoV-2. If you receive this therapy, it could reduce or delay your response to any COVID-19 vaccine for up to 90 days following the infusion and should consider waiting 90 days for a COVID-19 vaccine. *Alternatives*: There are few approved therapies for the treatment of COVID-19 specifically. Medical care relies on helping the patient through the many complications. Most hospitalized patients survive their disease with standard medical care

List side effects/risks: **Nausea** (3%)* **Dizziness** (3%) **Headache** (3%) **Pruritus** (2%) Immediate nonserious hypersensitivity (2%) **Diarrhea** (1%)* **Vomiting** (1%). Serious side effects: anaphylaxis (<1%), Low Blood Pressure (<1%), Wheezing (<1%).

For more information about risks and side effects, please ask your physician. Please be advised that not all risks and side effects in the context of COVID-19 are known. Your physician may give you medication to help lessen the side effects. Some side effects are temporary. In some cases, side effects can be serious and can last a long time. Sometimes they never go away.

CERTIFICATION AND SIGNATURES

I have read this informed consent form and all of my questions have been answered to my satisfaction by my physician. I understand that I have the right to refuse to take this medication(s) for any reason. If I choose not to take this medication(s), this decision will not otherwise affect my status as a patient. I voluntarily consent to take the monoclonal antibody medication by infusionas discussed with my physician, and infusion team members as described in this consent form.

CONSENT

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies in patients with confirmed or suspected COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization.

Patient Name: _____

Patient Signature: _____ Date: _____ Time: _____

If patient is a minor; or is unable to sign, Indicate reason (ex: patient in COVID isolation):

Name of Person Signing for Patient: _____

Signature of Person Signing for Patient: _____ Date: _____ Time: _____

Name of Witness: _____

Signature of Witness: _____ Date: _____ Time: _____

Witness to complete for translations (if applicable): _____

Translated by: _____ Language Used: _____

Relationship to Patient: _____ Date: _____ Time: _____

By typing your name in the "Signature" fields above, it will considered the legal equivalent of your signature.