**[INSERT LOGO/FACILITY/ORGANIZATION NAME HERE]**

CONSENT FOR EMERGENCY USE OF AN FDA INVESTIGATIONAL AGENT: BAMLANIVIMAB

**INFORMATION ABOUT AUTHORIZED EMERGENCY USE TREATMENTS**

We have determined that you have a COVID-19 infection, which potentially could be a life-threatening disease. While this treatment may be helpful, no currently used medication treatments are likely to prolong your life or cure a COVID-19 infection. Bamlanivimab is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it’s safe and effective. Because bamlanivimab is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use; however, the FDA has authorized emergency use of the drug in cases of COVID-19 infection pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3..

I understand that [ FACILITY/ORGANIZATION NAME ] will be administering the medication according to my attending physician’s orders. I understand when I request care for my medical condition I am generally consenting to other medical treatments such as x-ray examinations, laboratory test and additional medications that may be necessary prior infusion, during infusion, or post treatment infusion. I also understand that a physician’s medical judgment is required to make the determination about treatment, because severe and even fatal adverse events may occur. The medical team at the facility will be responsible for the evaluation of the patient, establishing a medical history, including present illness and past medical history. The physician will evaluate the information specific to the resident prior to medication administration. I understand that no guarantees have been made to me regarding the results of this treatment and that it may or may not improve my condition.

Monoclonal antibodies are laboratory-made proteins that mimic the immune system’s ability to fight off harmful antigens such as viruses. Bamlanivimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus’ attachment and entry into human cells.

This came from here: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19>

**Before you sign this form, be sure you understand how bamlanivimab relates to your condition, as well as the risks and possible benefits of using it.**

**SPECIFIC INFORMATION ABOUT THE TREATMENT**

**Why is bamlanivimab treatment being recommended?**

Bamlanivimab is a monoclonal antibody used to treat COVID-19 infections in non-hospitalized patients with mild to moderate symptoms who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization.

**What can I expect when I receive this treatment?**

An IV will be started. The medication will be prepared specifically for you. The infusion will take approximately one hour, during which time you will be closely monitored. After the infusion is complete, you will continue to be monitored for a minimum of one hour.

**What other treatments are available for patients who have this type of disease or condition?**

There is no adequate, approved, and available alternative to bamlanivimab for patients who have mild to moderate COVID-19 who are at high risk for progressing to severe COVID-19 and/or hospitalization. You should discuss all available treatment options with your treating physician.

**HOW INFORMATION ABOUT YOU WILL BE SHARED**

If you give us permission to use bamlanivimab, we will provide the following information about you to Eli Lilly and Company (the manufacturer or supplier of bamlanivimab):

 • Any problems that occur when you are treated with bamlanivimab.

**RISKS AND BENEFITS**

**What are the risks of being treated with bamlanivimab?**

Allergic reactions can happen during and after the infusion. Signs and symptoms may include fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness. Side effects of receiving any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. It is possible that new, unanticipated, different, or worse symptoms will result from using bamlanivimab, including, but not limited to, death.

**What are the possible benefits of being treated with bamlanivimab?**

Expected benefit is that the patient will experience a decreased possibility of progressing from mild to moderate COVID-19 symptoms to severe symptoms and/or the need for hospitalization.

**What is the most likely outcome of being treated with bamlanivimab?**

Unknown, as this drug is experimental and there is not information available at this time as to likely outcomes related to its use.

You are free to stop the bamlanivimab infusion at any time; your treatment is voluntary. You should notify your nurse if you wish to stop the infusion and he/she can contact your doctor. You should discuss your choice with your doctor, as stopping its use may pose additional risks to you that your doctor may need to manage.

**CONSENT FOR EMERGENCY USE OF AN FDA INVESTIGATIONAL AGENT**

I understand the information printed on this form. I have discussed treatment with bamlanivimab, its risks and potential benefits, and my other choices with my Attending Physician. I agree with my physician that there are no approved or commonly used treatments for my COVID-19 infection, but that other treatment options are unlikely to be as helpful as bamlanivimab and are unlikely to prolong my life. I understand bamlanivimab is not yet FDA approved for general use in treating COVID19 infection, but that it is FDA authorized solely for emergency use as determined by the Attending Physician. I understand that no guarantees have been made to me regarding the results of this treatment and that it may or may not improve my condition. My questions so far have been answered. I understand that if I have more questions or concerns, I may speak with my Attending Physician. If bamlanivimab makes me sick or causes me injury, I understand that I or my estate will be responsible for the costs of treatment. I understand that I will receive a copy of this consent and the FDA Fact Sheet regarding bamlanivimab at the time I sign it. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued treatment.

Legal Name of Patient/Authorized Representative, If Patient Cannot Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to Patient: Parent Spouse Child Sibling Legal Guardian Other (If “Other,” explain:)

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Additional information: <https://www.lilly.com/news/media/media-kits/bamlanivimab-covid19>





