Informed Consent for Administration of Monoclonal Antibodies for Treatment of COVID-19

You are consenting to receive a classification of medicine called **monoclonal antibodies** for the treatment of coronavirus disease 2019 (COVID19). Your physician should have already explained the risks, benefits, and any potential alternative treatments prior to you signing this consent. This consent contains information to help you understand the potential risks and potential benefits of taking monoclonal antibodies, which you may receive. It is your choice to receive monoclonal antibodies or stop it at any time.

What is a monoclonal antibody? A group of investigational medicine 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. Monoclonal antibodies are investigational because they are still being studied. There is limited information known about the safety or effectiveness of using monoclonal antibodies to treat people with COVID-19. The approve medications are Bamlanivimab or Regen COV 2 (casirivimab and imdevimab).

You will be receiving: ☐ **Regen COV 2 (casirivimab and imdevimab)**

What is Emergency Use Authorization (EUA)? The FDA has authorized the emergency use of monoclonal antibodies for the treatment of COVID-19 under an Emergency Use Authorization (EUA). Monoclonal antibodies have not undergone the same type of review as an FDA-approved product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. The FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic.

How will I receive monoclonal antibodies?

- You will receive one dose of monoclonal antibodies by subcutaneous injections (Four 2.5 ml Injections) with 1 hour observation period

Possible side effects of monoclonal antibodies are:

- Allergic reactions can happen during and after infusion with monoclonal antibodies. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: **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.**
- The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

If you have mild side effects from monoclonal antibodies, you may be given additional medication for nausea, mild pain, or itching. You will be monitored during treatment, and medical care will be provided if needed because of a reaction to the medicine. A record of treatment will be shared with the referring health care provider and/or your primary care provider.

These are not all the possible side effects of monoclonal antibodies. Not a lot of people have been given monoclonal antibodies and they are still being studied, so it is possible that all of the risks are not known at this time. Serious and unexpected side effects may happen. It is possible that monoclonal antibodies could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, monoclonal antibodies may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Ask your doctor if you have questions about these risks.

There is no charge for the monoclonal antibodies medicine itself. There may be a charge for additional medications or medical attention if those services are needed.

What other treatment choices are there?
The FDA may allow for emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19.

It is YOUR DECISION whether to be treated with monoclonal antibodies. You can decide NOT to receive it or to STOP receiving it at any time.

I have read and understand the information above. I have received a copy of Churchill County's Notice of Privacy Practices and the EUA Fast Sheet for Patients, Parents, and Caregivers. I have been advised of the risks and benefits of receiving monoclonal antibodies, and about other choices I can make, including the risks and benefits of those. I understand that this is a new treatment, the results are not guaranteed, and that unknown and unexpected side effects can occur. I have had the chance to ask questions and have them answered. I accept the risks and I voluntarily consent to receive this medication.

Patient / Guardian Signature	Date / Time	Witness	Date / Time