UTAH DEPARTMENT OF HEALTH

INFORMED PATIENT CONSENT
PHYSICIAN REFERRAL FOR COVID-19 TREATMENT
Bamlanivimab or Casirivimab/Imdevimab (Regeneron)

I hereby certify that I have explained the risks, benefits, alternatives, and possible modes of treatment to this patient. We have jointly arrived at the decision to proceed with the administration of the selected monoclonal antibodies (Bamlanivimab or Casirivimab & Imdevimab) which is currently authorized for emergency use by the Food & Drug Administration (FDA) and made available through the State of Utah COVID-19 Response.

_____	_____	_____
Signature of Physician	**Date**	**Time**

Attention Health Care Professional: Either medication may be administered and have similar safety and side effect profiles and treatment outcomes. The on-site Mobile Infusion Strike Team (MIST) shall mark in the box below the therapy the patient will receive for a one-time infusion. The particular therapy chosen is based upon availability. The printed materials provided to the patient and marked below shall be specific to the therapy the patient receives.

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

Attention MIST: I hereby certify that I have provided the Patient with the following printed materials:

☐ Monoclonal Antibodies Frequently Asked Questions

☐ Fact Sheet For Patients, Parents And Caregivers Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19)

☐ Fact Sheet For Patients, Parents And Caregivers Emergency Use Authorization (EUA) of Casirivimab and Imdevimab for Coronavirus Disease 2019 (COVID-19)

_____	_____	_____
Signature of MIST Member	**Date**	**Time**

- 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.

TREATMENT

- **In order for you to be treated with the therapy offered by the State Mobile Infusion Strike Team (MIST), 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; and**

- **to authorize the Mobile Infusion Facility (MIF), your medical provider, the MIST providers and /or their designee to administer monoclonal antibodies for the purpose of treating COVID-19, and to perform such additional procedures as are considered necessary to monitor and care for you while participating in this treatment course.**

- The Infusion Team will annotate the monoclonal therapy available for your encounter.
- The particular therapy chosen is based upon availability.
- You will be provided a patient informational handout regarding the specific monoclonal antibody infusion before or shortly after the infusion begins.
- **You have the right to refuse to take this treatment(s) for any reason.**

BACKGROUND

Bamlanivimab and Regeneron 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

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, so you 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.

Possible side effects/risks may include: **Nausea** (3%)* **Dizziness** (3%) **Headache** (3%) **Pruritus** (itchy skin) (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 consult with 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.

PATIENT CERTIFICATION AND CONSENT

I hereby certify that my health care provider has answered all my questions and explained to me the reasons why use of the above named medications is considered desirable or necessary, its advantages and possible complications, if any, as well as possible alternative modes of treatment. Some of the known risks of these medications explained to me include, but are not limited to allergic reactions, fever, chills, nausea, headache, shortness of breath, low blood pressure,

wheezing, swelling of my lips, face, or throat, rash, including hives, itching, muscle aches and dizziness. These can happen during and after the infusion and should be reported to my healthcare provider right away. These are not all the possible side effects. Serious and unexpected side effects may happen.

I acknowledge that monoclonal antibodies (Casirivimab & Imdevimab and Bamlanivimab) are still under investigation. Therefore, there may be risks, side effects, and/or long-term effects that are related to this treatment but are unknown at this time.

I have been advised of risks and possible benefits, although no guarantee or assurance has been made as to the results to be obtained.

This treatment has been carefully explained to me. Additional printed material specific to my drug therapy has been reviewed and given to me. I received and reviewed the Monoclonal Antibodies Frequently Asked Questions with links to the Fact Sheets For Patients, Parents And Caregivers Emergency Use Authorization (EUA) of Bamlanivimab and Casirivimab and Imdevimab for Coronavirus Disease 2019 (COVID-19). This permission is based on knowledge and understanding of the elements of the therapy and an awareness of the risks, consequences, and discomforts.

I will self-isolate and use infection control measures (e.g. wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and perform frequent hand washing) according to CDC guidelines.

I understand clearly that I can stop my participation in treatment at any time and that such a discontinuation will not prejudice my future medical care.

I, the undersigned, hereby consent to proceed with the use of these medications.

☐ I agree to sign this form electronically.

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: _____

Relationship to Patient: _____ Date: _____ Time: _____

Name of Witness: _____

Signature of Witness: _____ Date: _____ Time: _____

Witness to complete for translations (if applicable): _____

Translated by: _____ Language Used: _____

By typing your name in the "Signature" fields above, it will be considered the legal equivalent of your signature. A copy of this consent will be provided upon your request.