UTAH DEPARTMENT OF HEALTH

INFORMED PATIENT CONSENT PROVIDER REFERRAL FOR COVID-19 NOVEL THERAPEUTIC TREATMENT

Treatment to be given (based on availability):

- □ **Paxlovid (oral medication)**
- □ **Casirivimab/Imdevimab (Regeneron)**
- □ **Bamlanivimab + Etesevimab**
- □ **Sotrovimab**

HEALTH CARE PROFESSIONAL:

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 therapeutic marked above, 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 Health Care Professional	**Credentials (must be RN level or higher)**	**Date & Time**

Healthcare Facility Point of Contact:

_____	_____	_____
Name & Credentials	Title / Facility Role	Mobile phone number

UDOH HEALTHCARE ASSOCIATED INFECTIONS (HAI) TEAM MEMBER:

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

- □ Fact Sheet For Patients, Parents And Caregivers for the selected therapeutic medication
- □ Emergency Use Authorization (EUA) if requested

_____	_____	_____
Signature of HAI Member	**Date**	**Time**

ATTENTION PATIENT:

- As your provider 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 UDOH Healthcare Associated Infections (HAI) 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; and

- **o to authorize the HAI nurse practitioner, your medical provider, and /or their designee to prescribe and/or administer the therapeutic medication indicated above 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.**
- Treatment medications are scarce, and therefore you will only receive it if you qualify under a clearly defined Risk Score and if medications are available.
- You will be provided a patient informational handout regarding the medication when it is prescribed or dispensed to you.
- **You have the right to refuse to take this treatment(s) for any reason.**

BACKGROUND

Novel therapeutic medications are investigational medicines 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 medication 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.

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.

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, so you should discuss with your care provider if you need to wait before receiving 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: **Altered sense of taste** (6%)* **Diarrhea** (3%) **Hypertension** (1%) **Muscle Aches** (1%).

For more information about risks and side effects, please consult with your provider. Please be advised that not all risks and side effects in the context of COVID-19 are known. Your provider 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 a health care provider has answered all my questions and explained to me the reasons why use of the above named medication 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, altered sense of taste, diarrhea, hypertension (increased blood pressure) and muscle aches. 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 Paxlovid and other novel therapeutics 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 Paxlovid Fact Sheet and/or Emergency Use Authorization (EUA) for Coronavirus Disease 2019 (COVID-19) given to me. 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.

Consent to Release of Medical Information

I understand that some therapeutic medications should not be used in conjunction with some other medications or when some medical conditions are present; therefore, I will be forthright about other medications and treatments I am currently undergoing.

I, the undersigned, authorize my care providers to disclose any information and records to the UDOH Healthcare Associated Infections team that may assist in determining which therapeutic medication is right for me. This may include, but is not limited to: medical findings, diagnosis, treatment, treatment summaries, pharmacy records or any other health information necessary. Information will be kept protected, and only used in determining the best course of treatment for me.

Consent to Blood Draw

I, the undersigned, consent to the drawing of a complete metabolic panel (CMP) blood sample for the purpose of verifying whether or not I am a good candidate for therapeutic medications. Data gained from this sample will be kept confidential, and only used in determining the best course of treatment for me. .

Consent to Treatment

I, the undersigned, hereby consent to proceed with the use of the Paxlovid medication. 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 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.