PATIENT CONSENT FORM FOR COVID-19 TREATMENT

PURPOSE OF INFORMED CONSENT

As your physician has discussed with you, you have been diagnosed (or diagnosis is highly suspected) 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. Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) 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

❑ **Bamlanivimab**

Other therapies offered at VCMC & SPH for COVID-19 are considered "off-label", meaning they have been approved by the FDA to treat other diseases and conditions, but not COVID-19. Once a medication is approved by the FDA, it depends on doctors to exercise professional judgment in prescribing that medication in a way that is beneficial to the patient. The FDA does not prohibit the use of medications in an "off-label" manner.

The following medications are being considered for off-label use for COVID-19:

❑ **Dexamethasone** ❑ **Tocilizumab**

❑ **Other:**_____

In order for you to be treated with the therapy(ies) listed above, 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. **You have the right to refuse to take this treatment(s) for any reason.**

The evidence at this time is not clear as to whether the proposed treatment will be beneficial. If you decline this investigational or off-label use of the recommended medication(s), you will still be provided all standard treatments, but your condition may deteriorate despite use of standard treatments. Even with the recommended proposed treatment, your condition may deteriorate. However, due to the serious nature of COVID-19, few FDA approved treatments, and little availability of clinical trials, investigational therapies and off-label medications are offered in the hope it could benefit you.

BACKGROUND

Bamlanivimab is an 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 syumptoms 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.

Dexamethasone is a corticosteroid medication that is approved for a variety of conditions for its anti-inflammatory and immunosuppressant effects. It has been tested in clinical trials and may have benefit for those with COVID-19. Dexamethasone is not approved by the FDA for treatment of COVID-19.

Tocilizumab is an antibody (immune system protein) that blocks certain inflammatory processes in your body. By inhibiting or blocking these inflammatory processes, these medications may limit the damage COVID-19 causes to your lungs. Tocilizumab is an FDA- approved medication for the treatment of rheumatoid arthritis. It has not been approved by the FDA for the treatment of COVID-19.

For other medications: list background rationale below:

_____

_____

_____

You will be monitored for improvement or worsening in COVID-19 symptoms, for any signs of new infections, and for signs of latent tuberculosis infection. It is anticipated that blood will be drawn on a daily basis to monitor your condition. Your liver function will be monitored at least weekly.

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: There are limited clinical data available for bamlanivimab 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 bamlanivimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Bamlanivimab may also reduce your body's immune response to a vaccine for SARS-CoV-2.

Dexamethasone: Corticosteroids can result in elevated blood sugar, high blood pressure, water retention, and difficulty sleeping. They may also increase the risk of other infections with bacteria, fungus, and reactivation of tuberculosis.

Tocilizumab: Many patients receive tocilizumab on a long-term basis for chronic conditions such as rheumatoid arthritis. As your physician is advising that you take only a single dose of this medication, side effects of a single dose of these medications are expected to be limited, but may include: injection site reactions, headache, high blood pressure, impaired liver function, reduced blood cell counts, perforation of the intestines and development of other infections including tuberculosis (TB) which may be serious or life-threatening. Additionally, the FDA advises that testing for latent TB be conducted prior to administration of the medication and that if the test is positive, that treatment for latent TB be initiated prior to administration of the medication. This is to prevent development of active TB. As your physician has discussed with you, due to the severity of your COVID-19 symptoms, by agreeing to this off-label use you agree to administration of tocilizumab prior to the availability of your test results for latent TB. You further agree and understand that should test results for latent TB turn out to be positive, treatment for TB will then be initiated after tocilizumab may have been administered.

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.

Other: list side effects/risks below

_____

_____

_____

_____

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 medication(s) indicated on the first page of this document as discussed with my physician and as described in this consent form.

Name of Patient: _____

Signature of Patient: _____ Date: _____ Time: _____

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

Name of Person Signing for the Patient: _____

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

Name of Witness: _____

Signature of Witness: _____ Date: _____ Time: _____

Witness to complete for translation (if applicable):

Translated by: _____ Language used: _____

Relationship to Patient: _____ Date: _____ Time: _____