COVID-19 RESEARCH
EMERGENT DRUG USE GUIDANCE

New Edition: May 13, 2020
Replaces: April 22, 2020

The purpose of this document is to provide a single source of COVID-19 guidance to the CommonSpirit Health research community regarding research emergent drug use.

For questions contact Amanda Trask (AmandaTrask@catholichealth.net)

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Distributed by:
Amanda Trask, System SVP Clinical Institutes and Service Lines.

May 13, 2020

DISCLAIMER: COVID-19 information is rapidly changing and documents will be updated accordingly
COVID-19 Guidance – Research Operations

Although there is no FDA approved treatment for COVID-19, there are some medications being used. In an effort to keep you informed on experimental research opportunities and industry activities in response to COVID-19, the CommonSpirit Research Institutes have developed the following guidance documents:

- Convalescent Plasma Access and Permission for Treatment Form
- Remdesivir
- Hydroxychloroquine Guidance
- Leronlimab Guidance and Consent Form
- CommonSpirit Health COVID-19 IRB Emergency Use Report Form

The IRB will facilitate a conversation with the IRB Chair about emergent cases. IRB Contacts for CommonSpirit Health facilities are as follows:

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As more information becomes available, we will continue to update this guidance document for distribution. Thank you for your commitment to our patients and research mission in this unprecedented time.
COVID Convalescent Plasma

Background
COVID Convalescent plasma (CCP) is being explored as a treatment for COVID-19 and is overseen by the FDA. Outlined below are some recommendations and guidelines for obtaining, administering and identifying donors for CCP.

Patient Recipient Criteria
Generally, for a patient to receive CCP they must be 18 years or older, be hospitalized with a lab confirmed diagnosis of infection with SARS CoV-2 and have severe or life threatening COVID-19 or at risk for progression to severe or life threatening COVID-19.

How to Obtain COVID Convalescent Plasma for Patients
There are two options available to CommonSpirit Health physicians and principal investigators (PI)

- **Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19 (Recommended)**
  The National Expanded Access Treatment Protocol Is being overseen by Mayo Clinic (Rochester). Information can be found at: [www.uscovidplasma.org](http://www.uscovidplasma.org). Each hospital must enroll individually and notify your IRB

- **Emergency Investigational New Drug (eIND)**
  Individual physicians or principal investigator (PI) must enroll each patient with the FDA and notify your IRB

Preparing Your Site for COVID Convalescent Plasma
- Notify your CommonSpirit IRB, who can provide information and guidance on the process.
- If using the Mayo Clinic Expanded Access Protocol, review the protocol workflows found at [www.uscovidplasma.org/#physicians](http://www.uscovidplasma.org/#physicians).
- Work with local blood donor center to confirm plasma is available with appropriate blood type.

Ordering Convalescent Plasma for Patients
- CCP given under expanded access protocol will be coded as plasma given in clinical trial. There are charge and tracking implications so you must note that it is CCP.
- Until specific electronic orders are implemented the recommendation is to order CCP through traditional FFP workflow and indicate that is CCP in the comments section.
- Electronic orders for our various EHRs are either available (Dignity Health Cerner) or currently being developed to order CCP. Check with your local clinical informatics team if you have questions.

Administering Convalescent Plasma Following the Mayo Clinic Protocol to Patients That Meet Criteria
- Obtain patient consent and keep a signed copy ([www.uscovidplasma.org](http://www.uscovidplasma.org))
- Register your patient using the Patient Enrollment Form
- Order Convalescent Plasma
- Administer plasma per institutional guidelines for plasma administration.
- When CCP transfusion has been completed the treating physician/PI must complete the trial 4-hour report with (1) CCP unit number and (2) patient medical record number. This must be done even if the plasma is not given. If not given you must provide an explanation of why it was not given.
- Physician/PI must also complete a 7-day form (30-day form if patient remains hospitalized).

Identifying and Recruiting Convalescent Plasma Donors
- Discuss CCP donation with all COVID-19 patients upon discharge.
- To qualify to donate plasma, patients must have had a laboratory confirmed positive COVID-19 test and have complete resolution of symptoms for ≥14-27 days with a negative test for SARS-CoV-2 or have complete resolution of symptoms for ≥28 days.
- Please advise patients to reach out to local blood donation centers and make an appointment specific for convalescent plasma donation.
- Hospitals or providers can refer patients for donation. Forms are available on local blood donations website.
- If you want to proactively create a donor registry and contact patients recently confirmed with COVID-19 please contact your local IRB or the local Privacy Officer. They will work with you to get a waiver of authorization to contact patients.
Investigational COVID-19 Convalescent Plasma

Hospitalized patients meeting the following criteria:
- >= 18 Years of age
- Lab confirmed dx of infection with SARS CoV-2
- Admitted for treatment of COVID-19 complications
- Severe or life threatening COVID-19 or at risk for progression to severe or life threatening

Severe:
- SOD/Dyspnea
- RR >= 30/min
- Blood Saturation <= 93%
- $\text{PaO}_2$/FiO$_2$ ratio < 300
- Lung infiltrates >50% within 24-48 hours

Life Threatening:
- Respiratory failure
- Septic shock
- Multi-organ dysfunction or failure

Order ABO typing

Expanded Access Option (preferred)
- Notify designated CSH IRB to ID necessary structure
- Register site with Mayo Clinic
  - www.uscowivplasma.org
- Notify Research Coordinator to Assist with Protocol Follow-up Compliance

Single Patient Access (eIND)
- Notify FDA
  - https://www.fda.gov/media/98646/download
- Notify designated CSH IRB to ID necessary structure
- Contact FDA by completing form FDA 3926 and submitting via email to: CBER_eIND_Covid19@fda.hhs.gov
- Complete Fill out CommonSpirit Health IRB Emergency Use Form and submit to CommonSpirit Research Institute

Sourcing Plasma
- If your regular supplier is not the American Red Cross, your supplier can work with the Red Cross to obtain convalescent plasma.
- The federal programs will reimburse regardless of the convalescent plasma blood bank source.

Hospital blood bank places order & obtains plasma from traditionally used hospital supplier, based upon the ABO type of the recipient
- Hospital blood bank receives and processes plasma and informs care team of its availability
- Transfusion order placed and plasma transfused
- Treating physician/PI completes 4-hour report with (1) unit number and (2) patient medical record number.
- Physician/PI completes 7 day form (10 day form if patient remains hospitalized)

Report each expanded access use to CSH IRB

Process Step

Questions?
Contact your CommonSpirit Research Institute IRB
Hospitalized patients meeting the following criteria:
- > 18 Years of age
- Lab confirmed dx of infection with SARS CoV-2
- Admitted for treatment of COVID-19 complications
- Severe or life threatening COVID-19 or at risk for progression to severe or life threatening

Confirmed COVID patient
Patient experiencing SOB/Dyspnea
Oxygen needs SL NC or >

Consider
COVID Convalescent Plasma

If patient not in ICU Consider transfer to ICU
Order Blood Type and Cross Match
Contact Institutional PI to enroll patient in Mayo CP study through expanded access option

Contact local IRB to identify facility Primary Investigator (PI)

Obtain Convalescent Plasma Informed Consent

Obtain IRB approved CP informed consent from facility PI

- Transfuse 1-2 units of ABO compatible Covid-19 convalescent plasma per institutional guidelines
- Recommended administration rate for plasma administration is 100 to 250 mL/hr (total volume of plasma to be administered approximately 200-500 mL) over 1-2 hours

Monitor vital signs and assess patient per facility guidelines. Assess for adverse events

Complete transfusion and complete post transfusion research protocol documentation

- Allergic reaction
- Blood borne infections (bacterial, viral, parasitic)
- Hospital acquired infection
- Febrile reactions
- Hemolysis
- Cardiac Events
- System inflammatory response syndrome (SIRS)
- Multiple organ systems failure (MOSF)
- Transfusion related acute lung injury (TRALI)
- Circulatory volume overload (TACO)
- SOB/dyspnea
- RR ≥ 30/min
- Blood Saturation ≤ 93%
- PaO2/FiO2 ratio < 300
- Lung infiltrates >50% within 24-48 hours
- Respiratory failure
- Septic shock
- Multi-organ dysfunction or failure
MEMORANDUM

To: Practicing Providers, Pharmacy Leadership, Hospital Leadership; Quality Leadership; Research Leadership

From: Candace Fong, System VP Medication Safety

CC: Barbara Pelletreau; Amanda Trask; Tracy Sklar

Date: May 11, 2020

Subject: Urgent HHS Data Request for Allocation of Remdesivir

The purpose of this memo is to address the Urgent HHS Data Request for Allocation of Remdesivir issued today with a deadline of tomorrow, May 12 at 8pm ET.

The COVID-19 Response Integration Surveillance and Insights System (CRISIS) team will be managing this data submission from a system level. The initial data due by 8pm ET tomorrow, May 12, 2020, will be submitted as well as the weekly data requirements that follow. It is NOT necessary for the individual hospitals to submit this data. This data will assist HHS in understanding the use of the donated Remdesivir as well as determining allocations. If you have questions, please contact Simon Dorval; simon.dorval@dignityhealth.org.

On May 11, 2020, the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) announced the allocation plan for Remdesivir. State health departments will distribute the doses to appropriate hospitals in their states because state and local health departments have the greatest insight into community-level needs in the COVID-19 response, including appropriate distribution of a treatment in limited supply. Healthcare providers interested in administering the donated experimental drug should contact their state health department. Candidates for the donated doses must be patients on ventilators or on extracorporeal membrane oxygenation or who require supplemental oxygen due to room-air blood oxygen levels at or below 94 percent. Public health experts from the Federal government have been in contact with state health departments regarding these allocations.

An initial allocation was sent to the following seven states: Indiana (38 cases), Massachusetts (117 cases), New Jersey (94 cases), New York (565 cases), Rhode Island (30 cases), Tennessee (7 cases) and Virginia (33 cases). Beginning on the evening of May 7, 2020, the process was initiated to deliver cases of the drug to the following states: Connecticut (30 cases), Illinois (140 cases), Iowa (10 cases), Maryland (30 cases), Michigan (40 cases) and New Jersey (110 cases). Each case contains 40 vials of the donated drug.


Please contact Candace Fong, System VP Medication Safety; Candace.Fong@DignityHealth.org if you have additional questions.
Strategic National Stockpile: Access to Hydroxychloroquine

The FDA has issued a fact sheet regarding the emergency authorization of hydroxychloroquine from the Strategic National Stockpile:

https://www.fda.gov/media/136537/download

This authorization allows use of hydroxychloroquine to treat adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.

It is important to note that hydroxychloroquine does not have an FDA indication for COVID-19. Because COVID-19 is a novel virus, there is very limited evidence available.

To request hydroxychloroquine under Emergency Use Authorization, the local or state health department should be contacted. Healthcare providers must report all medication errors and serious adverse events related to its administration. Adverse event reporting instructions, as well as additional information, are in the FDA link provided above.

A fact sheet for patients is provided by the FDA at:
https://www.fda.gov/media/136538/download

For questions, please contact the System P&T Co-Chairs:

- Karen McConnell, PharmD, System Director of Clinical Pharmacy Services
  - KarenMcConnell@catholichealth.net
- Bruce Bethancourt, MD, CMO Dignity Health Medical Group
  - Bruce.Bethancourt@DignityHealth.org
- Ben Chaska, MD, System SVP Physician Enterprise Operations Midwest/Fargo Divisions
  - BenjaminChaska@catholichealth.net
Instructions for those using *Leronlimab* for the treatment of COVID-19

Although there is no FDA approved treatment for COVID-19 there are some treatments being used. One investigational treatment being explored involves the use of *Leronlimab*, which binds to protein CCR5. The drug does not kill the novel coronavirus; however, acts as a CCR5 antagonist by blocking pro-inflammatory cytokines, which prevents cytokine storm and thus could be useful in treatment of COVID-19.

The FDA is facilitating access to *Leronlimab* for use in patients with confirmation of coronavirus disease by polymerase chain reaction or other commercial or public health assay from any sampling source and is hospitalized with a new onset respiratory illness through the process of single patient emergency Investigational New Drug Applications (eINDs).

To request individual expanded access use of *Leronlimab*, please first contact the drug manufacturer, CytoDyn to obtain permission and work with them to complete FDA form 3926 and to obtain an eIND: [https://www.cytodyn.com/expanded-access](https://www.cytodyn.com/expanded-access).

The CommonSpirit Health IRBs have provided a form to facilitate and help clinicians navigate access.

- Whenever possible, the treating physician should contact a CommonSpirit Health IRB prior to an Emergency Use. The IRB will facilitate a conversation with the IRB Chair about the emergent case. IRB contacts for CommonSpirit Health facilities are as follows:

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<td><a href="mailto:mary.rydman@dignityhealth.org">mary.rydman@dignityhealth.org</a></td>
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- If it’s not possible to contact the IRB before the test article is used, the attached Emergency Use Report Form must be completed and submitted to the IRB within 5 business days of the initiation of its use.
- If your drug use request is *NOT EMERGENT* and there is sufficient time for prospective IRB review and approval, our team will provide you further instructions on obtaining the necessary facility and IRB approvals.
- There will be no IRB fees for submissions related to COVID-19.

Please contact Amanda Trask if you have any questions by email at AmandaTrask@catholichealth.net.
COVID-19 RESEARCH FORMS

Forms Follow on Next Pages
Leronlimab Consent Form for Treatment Only

TITLE: Leronlimab for the Treatment of Coronavirus Disease 2019 (COVID-19) Expanded Access IND

PHYSICIAN: <physician name> <insert phone number>

SUPPORTED BY: CytoDyn, Inc.

INTRODUCTION:
Your doctor has told you that you have coronavirus disease 2019 (COVID-19) and you are hospitalized with a new onset respiratory illness. Your doctor thinks that it would be best to treat this disease with Leronlimab (PRO 140).

Leronlimab (PRO 140) belongs to the monoclonal antibody class of medicines. Monoclonal antibodies are synthetic versions of the disease-fighting proteins (antibodies) that are naturally produced by the body. Antibodies that are normally circulating in the blood typically react to any foreign organisms or materials that enter our body. However, leronlimab (PRO 140) binds to a protein (CCR5) that is present on the surface of one kind of our blood cells.

In the disease COVID-19, the body may respond to the viral infection by overproducing immune cells and their signaling molecules in a dangerous phenomenon called cytokine storm, which is often associated with a surge of activated immune cells into the lungs. This can lead to acute respiratory distress syndrome (ARDS).

In ARDS, fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. The fluid keeps your lungs from filling with enough air, which means less oxygen reaches your bloodstream. This deprives your organs of the oxygen they need to function. ARDS has known to be one of the main reasons for death in patients with COVID-19.

Leronlimab (PRO 140) does not kill the novel coronavirus. It acts as a CCR5 antagonist by blocking pro-inflammatory cytokines, which prevents cytokine storm and thus could be useful in treatment of COVID-19.

The Food and Drug Administration (FDA) has not approved this drug for treating this condition. The use of the drug is experimental.

This drug is being provided under an expanded access program. Expanded access, sometimes called "compassionate use," is the use of an investigational drug (a drug that is not approved by the FDA) outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition that has no comparable or satisfactory alternative treatment options. For more information about expanded access to investigational drugs, see the FDA website at:
Please take your time to make your decision about taking part. You can discuss your decision with your friends and family. You can also discuss it with your health care team or another doctor. If you have any questions, ask the physician who is named at the top of this form.

PROCEDURES:

If you agree to participate in this treatment and sign this consent form, you will be given the experimental treatment (Leronlimab) weekly for two weeks. The experimental drug used for this treatment (Leronlimab) will be injected via a very thin needle slightly below the surface of your skin in your stomach. You will receive two injections of 2mL of Leronlimab each week, one on each side of your abdomen.

While receiving Leronlimab, the physician may conduct procedures as per the standard of care treatment:
- You may be asked to report any symptoms that you experienced.
- You may be asked if there have been any changes to the medications you are taking.
- Your vital signs (pulse rate, respiratory rate, temperature, and blood pressure) may be assessed.
- The physician may give you a physical exam based on any changes reported in your health.
- A series of blood tests will be performed. The amount of blood needed for these tests is about 3-4 teaspoons.
  - A blood test for general health screening, such as chemistry and complete blood count.
  - A blood test to check the levels of certain proteins and substances in your blood cells.
  - A blood test to check the acidity and levels of oxygen and carbon dioxide in your blood.
- The physician may assess the injection site for any pain, tenderness, etc.
- Your study doctor will assess your clinical symptom score by evaluating signs of fever, muscle pain, breathing difficulties, and cough.
- Your doctor will determine your National Early Warning Score 2 (NEWS2) by checking your blood oxygen levels as well as assessing your breathing, your need for oxygen, heart and breathing rate, and your consciousness level.
- Your doctor may determine your PaO2/FiO2 ratio (ratio of oxygen moving in your lungs to inhaled oxygen).
- Your doctor will do an test to check your heart (electrocardiogram).
- A urine sample will be needed for lab tests.
- An assessment to test your requirement for breathing or oxygen assistance or any hospital stay.

Your treatment with Leronlimab may be temporarily withheld if you experience a side
effect that is severe or medically significant (but not life-threatening). Treatment can be resumed once the condition becomes mild and is no longer medically significant.

**RISKS AND DISCOMFORTS:**

There is a risk that you could have side effects from Leronlimab. A side effect is anything a drug does to your body that is not part of how the drug treats disease.

Here are important points about side effects:

- The physician does not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.
- You may have some side effects we do not expect because we are still learning about Leronlimab.
- There may be unanticipated risk to an embryo or fetus if you become pregnant.
- You may not have symptoms for some of these side effects, but you will be monitored by the physician to check for any changes throughout the treatment.

Here are important points about how you and the physician can make side effects less of a problem:

- Tell the physician if you notice or feel anything different so they can see if you are having a side effect.
- The physician may be able to treat some side effects.
- The physician may adjust the Leronlimab to try to reduce side effects.

You will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information.

**Side effects that you could experience during or after leronlimab (PRO 140) treatment:**

- The most common potential Leronlimab-related side effect that has been seen using the drug formulation that you will be using is mild headache. Other side effects likely to be related to the drug include mild to moderate diarrhea, nausea, and fatigue. There may be other side effects associated with leronlimab (PRO 140) that we do not know about.
- Injection site reaction such as pain or discomfort, redness at the site where the drug is given.
- Leronlimab (PRO 140) belongs to the monoclonal antibody class of drugs. Monoclonal antibodies are sometimes associated with allergic reactions (fatigue, diarrhea, fever, vomiting, headache, nausea, pain at the site of injection, low blood pressure, rash, itching, and chills) or flu-like reactions such as fever, chills, and aches. These events usually do not last long if they occur at all. Severe allergic reactions, however, can be life-threatening.
• Rare severe acute hypersensitivity reactions or anaphylaxis can occur. If anaphylaxis or severe allergic reactions occur, therapy with leronlimab (PRO 140) will be permanently discontinued and appropriate medications (e.g., epinephrine) and supportive care will be provided.

• A hypersensitivity reaction is an allergic reaction that may include a rash, hives, fever, difficulty breathing, and low blood pressure. Although usually reversible with treatment, it can be severe or life-threatening.

• Anaphylaxis is a life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

• People who take leronlimab (PRO 140) or other monoclonal antibodies can also develop an immune response that may impact whether they can receive or benefit from monoclonal antibodies in the future.

• Side effects that may be associated within a short period of time after receiving drugs similar to leronlimab (PRO 140) through an injection include chills, headache, backache, overall feeling of being ill, fever, skin rash, nausea, tingling and high blood pressure. The physician may give you medicine to help with these side effects.

• People who lack a functional CCR5 gene are at increased risk for severe infection by West Nile virus. Please ask <insert physician name> about this.

• Local pain, redness, tenderness, bruising, itching and rarely, an infection might occur at the site of injection in your stomach or at the site of the needle stick in your arm for blood draws or you may faint when blood is taken.

• In addition to these risks, this treatment may harm you in unknown ways.

Let the physician know of any questions you have about possible side effects. You can ask the physician questions about side effects at any time.

**Other Types of Risk**

**Blood Draw**
We will draw blood from a vein in your arm. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting.

**Interactions with Other Medications**
Leronlimab may change how your body reacts to some other drugs, which could stay in your body longer than usual. While you are taking part in this treatment, you might need to stop some medications or replace them with other medications. If you can’t stop taking these medications, the physician might need to change how much you take. The physician might also need to watch your health more closely while you are taking part in this treatment.

**Non-Physical Risks**
Because of side effects or the time required for tests and clinic visits while you are on this treatment, you may be unable to keep up with your normal daily activities.
ALTERNATIVES:
Taking part in this treatment is voluntary. You have other options which may include the following:
• Other standard supportive care to help relieve symptoms
• Take part in another research study being explored for antiviral treatment

Please talk to the physician about your options before you decide whether you will take part.

CONFIDENTIALITY:
All of the records related to your treatment will be placed in your medical record as usual. If there is a problem with your treatment (such as a side effect), the physician may be required to report the problem to the Institutional Review Board (IRB), CytoDyn, Inc., and the Food and Drug Administration (FDA). They may review and copy the parts of your medical record related to your treatment with this drug. No one else will be allowed to see your medical records unless permitted by law or unless you give permission.

COSTS:
The drug will be provided to you at no cost. You or your insurance company will be responsible for the remaining costs related to this treatment. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

LIABILITY:
If you believe you have been injured or harmed while participating in this treatment and require immediate medical care, contact <physician name> at <insert phone number> or the <site name> Operator at <insert phone number> and ask for the oncologist-on-call.

If you are injured or harmed by the drug, you will be treated. <site name> does not offer any financial compensation or payment for the cost of medical care if you are injured or harmed as a result of participating in this treatment. Therefore, any medical care you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the treatment.

If you have questions on this subject, please call <insert phone number>.

PARTICIPATION:
Your participation in this treatment is voluntary. If you do start the treatment and later change your mind, you have the right to quit at any time. If you choose not to have this treatment or change your mind later, there will be no penalty or loss of benefits to which
you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to your doctor if you want to stop the treatment. You may need additional medical care to ensure your safety.

We will give you any new information we learn during the course of the treatment that might change the way you feel about receiving the treatment. <physician name> at <insert phone number> has offered to answer any other questions you may have about this treatment.

Your signature below shows that you have read this form and agree to this treatment.

______________________________________________
Patient’s signature     Date

I discussed this treatment with the above named patient or legal representative. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this treatment protocol.

________________________________    __/__/____ _____
Signature of Person Obtaining Consent    Date   Time

Printed Name

If patient is unable to sign:

State reason patient is unable to sign: _____________________________________

___________________________________________  __/__/____
Signature of Legally Authorized Representative (LAR)  Date

Printed Name

Relationship to Patient: ________________________________________________

___________________________________________  __/__/____
Signature of Witness      Date

Printed Name

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant. The patient freely consented to participate in this investigational treatment.
Permission for Treatment with an Experimental Item

Dr. _____ is offering to treat you, your child (in which case the word “you” will refer to “your child” throughout this document), or the person you represent (in which case the word “you” will refer to the person you are representing) with convalescent plasma because you have a serious condition called COVID-19 (coronavirus) and there are no standard acceptable options.

What you should know about this experimental treatment

This treatment has not been approved by the Food and Drug Administration.
This treatment is considered experimental.
Someone will explain this treatment to you.
You volunteer to get this treatment.
Whether or not you get this treatment is up to you.
You can choose not to get this treatment.
You can agree to get this treatment now and later change your mind.
If you do change your mind, contact your doctor right away.
Whatever you decide it will not be held against you.
Feel free to ask all the questions you want before you decide.

How long will this experimental treatment last?

We expect that the experimental treatment may last as long as you are an inpatient.

What happens if I get this experimental treatment?

We anticipate the antibodies in the convalescent plasma will help you to fight the virus.

Is there any way this experimental treatment could be bad for me?

This treatment may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.
If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown.
Getting this treatment may lead to added costs to you. Insurance may not pay for this treatment because it is considered experimental.

Can this experimental treatment help me?

We cannot promise that this treatment will help you. The goal of this treatment is to help you recover from COVID-19.
**What else do I need to know?**

Efforts will be made to limit your personal information, including medical records, to people who have a need to review this information. Organizations that may inspect and copy your information include appropriate representatives from Dignity Health and the Food and Drug Administration.

If you are injured or made sick from taking part in this treatment, medical care will be provided. Generally, this care will be billed to you or your insurance. However, it is possible that your insurance will not pay for the care, because the treatment is experimental. Contact your doctor for more information.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the treatment has hurt you, you can talk to Dr. _______________ at ________________.

This treatment is subject to oversight by the Dignity Health Institutional Review Board. If you have questions about your rights or any unresolved questions, concerns or complaints, please call them at ________________.

Your signature documents your permission to take part in this experimental treatment.

---

**Signature of Adult Patient** (over 18 years of age)

___________________________

Date

___________________________

Printed Name

---

**If patient is unable to sign (or is under 18 years of age):**

State reason patient is unable to sign: ____________________________

___________________________

Date

___________________________

Printed Name

Relationship to Patient: ____________________________
I discussed this treatment with the above named patient or legal representative.

Signature of **Person Obtaining Consent**

Date ___/___/____

Time ___

Printed Name

Signature of **Witness** (if applicable)

Date ___/___/____

Printed Name

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the patient. The patient freely consented to accept this experimental treatment.
COMMONSPIRIT HEALTH COVID-19 IRB EMERGENCY USE REPORT FORM

Preferably before administration and no later than five (5) business days after the emergency use occurrence, the treating physician is required to submit a written report to the IRB Office containing the information below. For additional information or questions please contact:

<table>
<thead>
<tr>
<th>IRB</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHIRB - All CHI Facilities</td>
<td>Jared Rowe</td>
<td>844-626-2299</td>
<td><a href="mailto:chirb@catholichealth.net">chirb@catholichealth.net</a></td>
</tr>
<tr>
<td>Arizona - East Valley Facilities</td>
<td>Julie Lynk</td>
<td>480-782-3582</td>
<td><a href="mailto:julie.lynk@dignityhealth.org">julie.lynk@dignityhealth.org</a></td>
</tr>
<tr>
<td>Arizona St. Joseph’s Hospital &amp; Medical Center</td>
<td>Julie Barton</td>
<td>480-571-1546</td>
<td><a href="mailto:julie.barton@dignityhealth.org">julie.barton@dignityhealth.org</a></td>
</tr>
<tr>
<td></td>
<td>Kim Hedden</td>
<td>602-406-3195</td>
<td><a href="mailto:kim.hedden@dignityhealth.org">kim.hedden@dignityhealth.org</a></td>
</tr>
<tr>
<td>Dignity Health California &amp; Nevada Facilities</td>
<td>Russell Stolp</td>
<td>831-295-0610</td>
<td><a href="mailto:russell.stolp@dignityhealth.org">russell.stolp@dignityhealth.org</a></td>
</tr>
<tr>
<td></td>
<td>Mary Rydman</td>
<td>801-910-2792</td>
<td><a href="mailto:mary.rydman@dignityhealth.org">mary.rydman@dignityhealth.org</a></td>
</tr>
</tbody>
</table>

For investigational drugs/biologics that have not yet been approved or cleared by the FDA, prior FDA authorization must be initially requested and authorized by telephone or other rapid means of electronic communication. Treatment may start immediately upon FDA Authorization. A written submission to the FDA will be required. Please contact the FDA for more information. A CommonSpirit Health IRB should be notified of the Emergency Use as outlined above.

For investigational devices that have not yet been approved or cleared by the FDA, FDA approval is not required prior to the Emergency Use if there is an emergency that requires the patient to be treated and the criteria for emergency use are satisfied:

- The patient is in a life-threatening or severely debilitating situation;
- There was no acceptable standard treatment available; and
- There was not sufficient time to obtain prospective IRB approval.

For investigational devices that have not yet been approved or cleared by the FDA, FDA approval is not required prior to the Emergency Use if there is an emergency that requires the patient to be treated and the criteria for emergency use (cited below) are satisfied. A follow-up report to the FDA will be required. Please contact the FDA for additional information. A CommonSpirit Health IRB should be notified of the Emergency Use as outlined above.
<table>
<thead>
<tr>
<th>Investigational Agent Name</th>
<th>IND/IDE # or HDE#</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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<table>
<thead>
<tr>
<th>Manufacturer/Sponsor Name</th>
</tr>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Holder of IND or IDE (e.g., Manufacturer/Sponsor or Treating Physician)</th>
</tr>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Did the Manufacturer/Sponsor approve the Emergency Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
</tr>
<tr>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Did the Manufacturer/Sponsor provide a protocol for the emergency use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES (attach and submit)</td>
</tr>
<tr>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Did the FDA give permission (or approve) for the use of this agent in this subject?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES, Emergency IND/IDE Letter is attached to this submission</td>
</tr>
<tr>
<td>YES, FDA Authorization was obtained via telephone or other rapid form of communication and a formal written report will be submitted to the FDA. The FDA’s approval letter will be submitted to a CommonSpirit Health IRB once obtained.</td>
</tr>
<tr>
<td>NO, this is a request for an emergency use of a drug or device. Due to the emergent need to use the drug/device, time was not sufficient to use existing procedures to obtain FDA approval for the use. The FDA’s approval letter will be submitted to a CommonSpirit Health IRB once obtained.</td>
</tr>
<tr>
<td>Other (e.g., off-label use or Humanitarian Use Device)</td>
</tr>
</tbody>
</table>

If you selected “other,” please explain below:

<table>
<thead>
<tr>
<th>Location Investigational Agent was Administered</th>
</tr>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Investigational Agent was Administered</th>
<th>Date a CommonSpirit Health IRB was Notified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

Emergency Use Certification:

The subject was in a life-threatening or severely debilitating situation.

Explain what the life-threatening or severely debilitating situation was and why the use of the investigational agent was necessary:

There was no acceptable standard treatment available.

Explain what, if any, treatment options were available for this subject:

There was not sufficient time to obtain prospective IRB approval.

Explain why there was not sufficient time to obtain prospective IRB approval:
## Summary of the subject’s case and the outcome of the emergency use of the test article

Note: If information about the subject’s outcome is not available within the initial reporting period (5 business days), results are requested to be reported to a CommonSpirit Health IRB within 10 business days of the occurrence.

## Provide a description of adverse events associated with the use of the test article

### Informed Consent was obtained from the subject or their legally authorized representative and a copy of this informed consent document has been appended to this submission

**Note:** The informed consent form should include all the relevant elements of informed consent and state that there is no guarantee of benefit; the treatment is experimental and not approved by the FDA.

### Informed Consent was not obtained from the subject or their legally authorized representative and the following conditions have been met:

- The subject was confronted by a life-threatening or severely debilitating situation necessitating the use of the test article.
- Informed consent could not be obtained because of an inability to communicate with or obtain legally effective consent from the subject.
- Time was insufficient to obtain consent from the subject’s legal representative.
- There was no alternative method of approved or generally recognized therapy available that will provide an equal or greater likelihood of saving the subject’s life.

**Independent certification from a physician not involved in the use of the test article of the following:**

**Note:** This certification must be obtained in writing and should be obtained prospectively when possible and if not, within 5 business days after the emergency use of the test article.

- The subject was confronted with a life-threatening or severely debilitating situation.
- The treating physician could not communicate with the subject.
- Time was not sufficient to obtain consent from the subject’s legally authorized representative.
- There was no alternative method of approved or generally recognized therapy available that provides equal or greater likelihood of saving the subject’s life.

**Name of independent physician (printed)**

**Signature of independent physician's certification**

**Date independent physician completed this certification**

**Comments on details surrounding the informed consent process:**
**Treating Physician Attestation**

This application must be sent to a CommonSpirit Health IRB by the treating physician/clinician only after the treating physician/clinician has reviewed and determined that all information is accurate. The treating physician/clinician assumes responsibility for ensuring that (please check all):

- The information provided in this application, and the accompanying materials, is complete and correct. All required materials have been uploaded as part of this submission.
- I agree to comply with all CommonSpirit Health IRB policies and procedures, as well as with all applicable federal, state, and local laws.
- I agree to report all adverse events associated with this investigational agent to a CommonSpirit Health IRB and the sponsor or U.S. Food and Drug Administration (as applicable), and to submit continuing review reports to a CommonSpirit Health IRB.
- I acknowledge that I do not have any perceived, potential, or actual conflict of interest with respect to the manufacturer/sponsor of the investigational agent and if any such interest exists, it has been reported to a CommonSpirit Health IRB and any other appropriate parties.
- I acknowledge that it is my responsibility to secure any local institutional or departmental approvals prior to utilizing this investigational agent.

---

**Treating Physician’s Signature**

---

**Date**

---

**Please upload:**

a) Consent form (if applicable)
b) Investigator’s Brochure/Instructions for Use (if available)
c) Product description/labeling
d) Protocol/Treatment Plan (if available)
e) Previous safety data (if available)
f) FDA Authorization/Approval Letter
g) CV for all treating physicians/clinicians
COVID-19
Convalescent Plasma
Donate to Save Lives

What You Need to Know

Convalescent Plasma is currently being studied as a possible new treatment for COVID-19 patients. Plasma provides many important functions in the body including helping the body to fight diseases. COVID-19 convalescent plasma is plasma that is collected from patients who have recovered from COVID-19. This plasma is rich in antibodies which are important for fighting infections and is being studied to determine if it will help other patients recover from the disease. The use of convalescent plasma has been effective in the treatment of other viral infections. (FDA.gov)

How you can help? After you have recovered from COVID-19 you can donate your plasma to help others still suffering from this severe illness. One patient’s donation provides multiple units of plasma that can be used to help other patients. Currently there is limited supply of this plasma so your donation could have an immediate impact and help those who are severely ill. (FDA.gov)

Convalescent Plasma Donation

You can donate your plasma if:
You have had a laboratory confirmed positive COVID-19 test
And
You have been free from symptoms (fever, cough, shortness of breath) for at least 28 days
Or
You have been free from symptoms for at least 14 days and have a negative COVID-19 test.

How do you donate?
If you think you meet the criteria contact your local blood donation center and request an appointment to donate COVID-19 Convalescent Plasma.

Your recovery journey from COVID-19 can help others. Thank you!
COVID-19
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Dignity Health.