COMMONSPIRT 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:

IRB	Contact	Phone	Email
CHIRB - *All CHI Facilities*	Jared Rowe	844-626-2299	chirb@catholichealth.net
Arizona - *East Valley Facilities*	Julie Lynk	480-782-3582	julie.lynk@dignityhealth.org
Arizona *St. Joseph's Hospital & Medical Center*	Julie Barton	480-570-1546	julie.barton@dignityhealth.org
	Kim Hedden	602-406-3195	kim.hedden@dignityhealth.org
Dignity Health California & Nevada Facilities	Russell Stolp	831-295-0610	russell.stolp@dignityhealth.org
	Mary Rydman	801-910-2792	mary.rydman@dignityhealth.org

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.

Treating Physicians Name and Title		**Degree/Credentials**
Mailing Address	**Phone Number(s)**	**Email**
	Office:	
	Cell:	
	Other:	
Alternate Contact Name	**Phone Number**	**Email**

Investigational Agent Name	IND/IDE # or HDE#

Manufacturer/Sponsor Name

Holder of IND or IDE (e.g., Manufacturer/Sponsor or Treating Physician)

Did the Manufacturer/Sponsor approve the Emergency Use?	
☐ YES	☐ NO

Did the Manufacturer/Sponsor provide a protocol for the emergency use?	
☐ YES (attach and submit)	☐ NO

Did the FDA give permission (or approve) for the use of this agent in this subject?
☐ YES, Emergency IND/IDE Letter is attached to this submission
☐ 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.
☐ 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.
☐ Other (e.g., off-label use or Humanitarian Use Device)

If you selected "other," please explain below:

Location Investigational Agent was Administered	
Date Investigational Agent was Administered	**Date a CommonSpirit Health IRB was Notified**

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 <u>was</u> 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 <u>elements of informed consent</u> and state that there is <u>no guarantee of benefit; the treatment is experimental and not approved by the FDA.</u>*
☐	**Informed Consent <u>was not</u> 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 a 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