
MEMORANDUM

To: CommonSpirit Health Leadership

From: Amanda Trask, SVP Clinical Institutes and Service Lines

CC: Barbara Pelletreau, SVP Patient Safety
Roy Boukidjian, System VP Infection Prevention

Date: March 23, 2020

Subject: **Gilead Sciences Statement on Access to Remdesivir Outside of Clinical Trials**

Gilead announced on 3/22/2020 that Remdesivir is no longer available for single Compassionate Use [exceptions will be made only for pregnant women or children less than 18 years of age with confirmed COVID-19 and severe manifestations of disease].

You can review the full announcement at the following link:
<https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-access-to-remdesivir-outside-of-clinical-trials>

Gilead will no longer accept new “Compassionate Use” requests and instead shift their focus to seeking regulatory approval for “Expanded Access” programs that will both accelerate access to Remdesivir for severely ill patients and enable the collection of data from all participating patients. All compassionate use requests that were submitted up to the publication of this notice (prior to 3/22/2020) will be honored by Gilead and our CommonSpirit Institutional Review Board staff will continue to assist our sites for this purpose.

Our CommonSpirit Research Institutes will continue to monitor this situation very closely and immediately issue new guidance and instructions to obtain Remdesivir once available under an Expanded Access program. If you have any questions about Compassionate Use requests and this guidance from Gilead, please contact your IRB leadership listed below.

IRB	Contact	Phone	Email
CHIRB - All CHI Facilities	Jared Rowe	844-626-2299	chirb@catholichealth.net
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Arizona <i>St. Joseph's Hospital & Medical Center</i>	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
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