

Compassionate Use Request for Remdesivir

Inclusion Criteria:

- Pregnant or < 18 years old
- Confirmed COVID-19
- Severe disease

Adult patients with COVID-19 may be eligible for remdesivir through a different expanded access program.

Process to obtain drug:

1. Physician complete Gilead Request Form at <https://rdvcu.gilead.com/>
 - a. You will be asked to provide physician contact information, pharmacy contact information, and patient information. Please remember to only use patient initials when providing patient information.

Pharmacy contact information:

Hospital Name	Kapi'olani Medical Center for Women and Children	Wilcox Medical Center
Pharmacist	Len Yonemura	Danita Narciso
Address	1319 Punahou Street Inpatient Pharmacy Honolulu, HI 96826	3-3420 Kuhio Hwy Inpatient Pharmacy Lihue, HI 96766-1099
Email	Len.yonemura@kapiolani.org	Danitadee.narciso@wilcoxhealth.org
Phone	808-983-8126	808-245-1008
Cell Phone	808-349-0881	808-333-6697

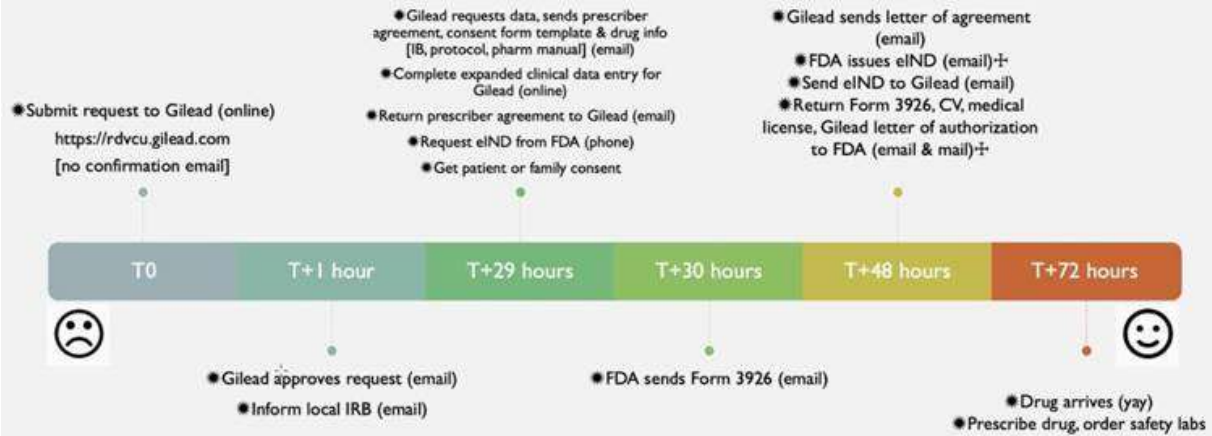
2. Physician contact Pharmacist and Research, inbasket patient
 - a. Research contact: Andrea Siu, andrea.siu@hawaiiipacifichealth.org
 - b. For KMCWC only, additional pharmacy contact: Jan Vita, jan.vita@kapiolani.org
3. Physician receive Gilead approval and documents to complete
4. Physician send Gilead documents to Research
5. Physician contact FDA to obtain IND. This can be done as soon as Gilead approves.
 - a. FDA Business hours (8am-4:30pm EST) 301-796-3400
 - b. FDA Emergency Request outside of business hours 866-300-4374
 - c. FDA Office of Infectious Diseases 301-796-1300
 - d. FDA Expanded access contact info <https://www.fda.gov/news-events/expanded-access/fdas-expanded-access-contact-information>
6. Research contact IRB, complete FDA Form 3926 (physician will need to sign)
7. Research complete and return Gilead, FDA, and IRB paperwork
8. Physician consent patient, provide copy of signed consent to HIM for scanning into patient medical record
9. Pharmacy receive drug
10. Physician prescribe drug and order safety labs
11. Pharmacy check for consent form and prepare drug
12. Pharmacy maintain drug accountability log

Research contact: Andrea Siu (andrea.siu@hawaiiipacifichealth.org, 808-535-7169)

Research pharmacist: Jan Vita (jan.vita@kapiolani.org, 808-983-6266)



72 HOURS TO REMDESIVIR COVID-19 COMPASSIONATE USE



†Note that Form 3926, CV, medical license usually returned to FDA first before eIND granted but not in this case

ANOTHER PCH GRAPHIC

Credit to Dr. Peter Chin-Hong from UCSF