Dear Hospital Representative,

As you likely are aware, the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of remdesivir for the treatment of COVID-19. The FDA has provided the state with an allotment of remdesivir and the state is distributing it to hospitals such as yours.

In order to receive an allocation of remdesivir, you must agree to the following:

- The hospital will review the EUA and comply with its terms.
- Remdesivir will only be used as authorized under its EUA.
  - All ordering clinicians will review a copy of the Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734)
- The ordering clinician will review the Oregon Health Authority’s document, Oregon’s Federal Remdesivir Allocation: Patient Criteria and Hospital Distribution and comply with its terms.
- Doses requested are for patients that meet clinical criteria eligibility.
- Written informed consent must be obtained from any patient or the patient’s legally authorized representative prior to administering remdesivir, that makes clear that remdesivir is an experimental drug. If English is not the patient’s primary language, a certified health care interpreter must be used during the informed consent process. The written consent must be included in the patient’s medical record.
- A patient must be provided with the following, translated into the patient’s primary language:
  - FDA Fact Sheet for Patients and Parent/Caregivers – EUA of Remdesivir For Coronavirus Disease 2019 (COVID-19)
- Complete and submit information to the State of Oregon regarding nonidentifying basic demographic and clinical information on each patient receiving the remdesivir as supplied by the State of Oregon.
- Adverse events related to the administration of remdesivir will be reported as specified in the Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734).
- All necessary clinical care will be provided to a patient who is administered remdesivir.
- Notify and return to the Oregon Health Authority any medication not used within 48 hours of determining the hospital no longer has a need for the medication.

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1 https://www.fda.gov/media/137564/download
The federal Public Readiness and Emergency Preparedness Act (PREP Act) immunity from liability (except for willful misconduct) applies to any claims of loss caused, arising out of, relating to, or resulting from the administration or use of covered countermeasures like remdesivir, for entities and individuals involved in the distribution, administration, and use of such countermeasures. The state assumes no liability related to the distribution or administration of remdesivir.

If you agree to the terms above, please sign and date this letter and return a signed copy to ORESF8.LogisticsChiefs@dhsoha.state.or.us. Once we receive the signed copy, the hospital will receive your requested allocation of remdesivir.

If you have clinical questions about remdesivir, please call 971.673.1111.

Signature

Printed Name and Title

Date

You can get this document free of charge in other languages, large print, braille or a format you prefer. Contact Mavel Morales at 1-844-882-7889, 711 TTY or OHA.ADAModifications@dhsoha.state.or.us.