LLUH IRB Tip Sheet for requesting REMDESIVIR from Gilead through an Emergency Individual Patient IND Expanded Access

Support is available as needed to complete submissions to the IRB and to the FDA. Please contact Lila Dalton or Melissa Rundquist (contacts below) should support be needed.

1. Confirm Criteria: https://rdvcu.gilead.com/
2. Request a letter of Authorization from Gilead
    a. Treating physicians will need to submit expanded access requests on behalf of an individual patient to Gilead through their portal: https://rdvcu.gilead.com/
3. Request FDA Emergency Use Authorization
    a. Contact FDA's Emergency Call Center at 866-300-4374
4. Obtain Informed Consent from the patient or their legally authorized representative.
    a. Gilead will provide you with the appropriate consent to be used.
    b. If consent is unable to be obtained from the patient or their legally authorized representative, an exception to the informed consent requirement may occur if both the treating physician and a physician not otherwise involved in the emergency use certify in writing that all of the following criteria are met (certification to be done on the IRB Emergency Use Report Form (see step 8 below):
        - The prospective recipient is confronted by a life-threatening situation necessitating the use of the test article.
        - Informed consent cannot be obtained from the recipient because of an inability to communicate with, or obtain legally effective consent from, the recipient.
        - Time is not sufficient to obtain consent from the recipient's legal representative.
        - There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the recipient.
5. Authorization of Emergency Use from FDA
    a. Authorization will be received by an FDA official by telephone, fax or email. Document that authorization is received in the patient's medical record.
6. The drug will be shipped to the Investigational Pharmacy.
    a. At LLUMC-Please contact Desiree Wallace, PharmD, Rph for further guidance:
    Email: dwallace@llu.edu Pager: dwallace@my2way.com or 1505 Phone: ext 83773 or
    Norm Hamada, PharmD Email: nhamada@llu.edu Pager: nhamada@my2way.com or 5839 Phone: ext. 47386
    b. At LLUMC- Murrieta- contact Long Vinh Pharm D for further guidance:
    Email: lvinh@llu.edu Phone: (951) 704-1952
7. Begin Treatment
8. Notify the LLUH IRB within 5 business days of treatment initiation
    a. Submit the Emergency Use Report to IRB: https://researchaffairs.llu.edu/sites/researchaffairs.llu.edu/files/docs/responsible-research/irb-emergency-questionnaire-and-irb-report.doc to the form may be emailed to: irb@llu.edu
9. Submit Form FDA 3926 to the FDA within 15 business days of FDA Emergency Use Authorization
    a. Link to Form FDA 3926 : https://www.fda.gov/about-fda/individual-patient-expanded-access-investigational-new-drug-application-ind-pdfnote-best-form
    b. Instructions for Completing form FDA 3926: https://www.fda.gov/about-fda/individual-patient-expanded-access-investigational-new-drug-application-ind-instructions
10. Submit Follow-up Expanded Access Reports using FDA Form FDA3926 (Link in Step 8 above).
    a. Safety Reports – As soon as possible but in no case later than 15 calendar days
    b. Summary Reports- Following completion of treatment

Adapted from FDA.gov Guidance

Questions? Concerns? Please contact:

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