1. **Gilead’s Restriction of Emergency Use of Remdesivir:**

Gilead Sciences, Inc. has suspended access to experimental coronavirus treatment Remdesivir as it works to transition the process of emergency access to remdesivir from individual compassionate use (emergency use) requests to other types of expanded access programs. As stated on Gilead’s website, “Gilead is currently in the process of transitioning the provision of emergency access to remdesivir from individual compassionate use requests to expanded access programs.” Gilead also states that, “. . . Due to overwhelming demand over the last several days, during this transition period we are unable to accept new individual compassionate use requests, with the exception of requests for pregnant women and children less than 18 years of age with confirmed COVID-19 and severe manifestations of disease . . .”

VHA is communicating with Gilead and other companies on using VA sites for clinical trials. ORD also expects other opportunities for expanded access options for other investigational drugs and biologics related to COVID-19.

2. **FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID019 Pandemic:**

The U.S. Food and Drug Administration announced that it has issued a guidance for industry, investigators, and institutional review boards conducting clinical trials during the coronavirus (COVID-19) pandemic. As stated in their announcement, “. . . Although the impact of COVID-19 on trials will vary depending on many factors, including the nature of disease under study, the trial design and in what region(s) the study is being conducted, the FDA outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity. Considerations recommended include, among others, sponsors evaluating alternative methods for assessments, like phone contacts or virtual visits and offering additional safety monitoring for those trial participants who may no longer have access to investigational product or the investigational site.”


3. **NCI Central IRB Information about COVID-19:**

The NCI Central IRB (CIRB) has developed a single collection page for all COVID-19 information to help the research community when addressing the outbreak of COVID-19 within the context of the NCI CIRB approved clinical trials. This page includes a set of frequently asked questions, and both a memorandum and guidance related to patients on NCI CIRB approved clinical trials. This page is located at [https://www.ncicirb.org/content/nci-cirb-information-about-covid-19](https://www.ncicirb.org/content/nci-cirb-information-about-covid-19).