We have a patient who tested positive for COVID-19 and want to pursue an Emergency Use of a Test Article. What do we do?

The procedures for a single patient emergency use of an investigational drug or device remain unchanged during this time. The policy for Emergency Use of an Investigational Drug or Device follows FDA Guidance. The FDA has published a dedicated page for Emergency Investigational New Drug (EIND) Applications for Antiviral Products https://www.fda.gov/drugs/investigational-new-drug-ind-application/emergency-investigational-new-drug-eind-applications-antiviral-products?wptouch_preview_theme=enabled

I: Contact the sponsor/manufacturer to ensure they are willing to provide the investigational product for EIND use.

II: If the sponsor/manufacturer agrees to provide the drug call or email the FDA for authorization for the EIND use.

III: Call the IRB to discuss the circumstances and to confirm that criteria to be considered Emergency Use are met.

IV. Use the following format for a proposed emergency use formal submission and email it as instructed below.

1. The initial submission to the IRB should be by email. In the text of the email confirm that the following criteria for emergency use are met:
    - The patient is confronted by a disease or condition that is life-threatening or severely debilitating, or the patient is confronted by a life-threatening disease or a serious condition requiring immediate use of an unapproved drug or device.
    - The situation necessitates the use of the test article (drug, biologic, device).
    - No generally acceptable alternative for treating the patient is available.
    - There is insufficient time to obtain IRB approval. (Or if there is time for review at the next IRB meeting, indicate this and the information will be added to the agenda.)
    - Note: The above findings for emergency use must also be noted in the medical record.
2. Attach the following materials to the email as supporting documentation:
    - Document or email that describes the patient's medical condition and the reason for the use of the test article. (Do not include any identifiers in documents.)
    - Correspondence to and from the FDA with the investigational new drug (IND) number or investigational device exemption (IDE) number, if available. (For a single-patient IND or compassionate IDE, submit the number when it is available).
    - Correspondence to and from the sponsor regarding use of the test article.
    - Protocol or detailed treatment plan for this patient.
    - Investigator's brochure or drug package insert, or device information.
    - Emergency use informed consent form to be used.
3. Send the email and all subsequent communications about the emergency use to IRB Director and the general IRB office email as well as any other persons involved in coordinating the use (this may include but is not limited to other treating clinicians, research or regulatory coordinators or Scientific Centers Administrators).
4. Keep the IRB office informed about the status of a proposed use to proceed or if circumstances change.
5. By close of business within five days after the use of the device or first administration of the drug/biologic, submit to the IRB via the eIRB system written notification of the emergency use of a test article in a life-threatening situation, and include a copy of the signed consent document used (or provide certification by the treating physician and an uninvolved physician that the criteria for the exception from informed consent were met).