

Emergency Use

Overview:

This guidance is specific to the emergency use of an unapproved investigational drug, biologic, or device. **All** of the following conditions must exist to justify the emergency use of an unapproved investigational drug, biologic, or device:

1. The patient has a condition that is life-threatening (i.e., the likelihood of death is high) or severely debilitating (i.e., may cause irreversible morbidity, such as blindness, loss of limb, paralysis, or stroke) that requires immediate treatment
2. No generally acceptable alternative for treating the patient is available
3. Because of the immediate need to use the drug or device, there is not sufficient time to obtain approval at a convened IRB meeting
4. There has been no prior emergency use of this specific investigational drug, biologic or device,.
Note: the FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

Requirements for Emergency Use:

General Requirements:

1. It is the physician's responsibility to determine whether the criteria for emergency use have been met, to assess the potential for benefits from the emergency use of the drug or device, and to have substantial reason to believe that benefits will exist.
2. The physician may not conclude that an "emergency" exists in advance of the time when the treatment may be needed, solely on the expectation that IND or IDE approval procedures require more time than available.
3. Physicians should be aware that the FDA expects them to exercise reasonable foresight with respect to potential emergencies and to make appropriate, advance arrangements under Expanded Access, Treatment IND, or IDE procedures to avoid creating a situation where such arrangements are impracticable.


Investigational Drug or Biologic:

1. Physicians should contact the manufacturer of the investigational drug or biologic to determine if it can be provided under an existing IND. If this is not available from the manufacturer, contact the FDA for an Emergency IND.

Investigational Device:

1. The emergency use of an unapproved investigational device does not require an IDE for such use, provided that the physician subsequently provides written justification to the FDA that an emergency actually existed.
2. The device manufacturer must be notified of the intended emergency use.
3. The requesting physician must notify the FDA of the emergency use of the investigational device (i.e., within 1 working day).

Procedures for Investigational Drug or Biologic:

1. Contact the manufacturer of the investigational drug or biologic to determine if the manufacturer has an IND in place that will permit emergency treatment of the patient outside of a controlled clinical trial.
 - a. If YES, request inclusion of the patient under the existing IND, request a supply (or a replacement supply if currently available under a controlled clinical study) of the drug for the emergency use, and obtain the IND number.
 - b. If NO, inquire if the manufacturer will provide a supply (or replacement supply) of the drug subsequent to obtaining FDA approval of the emergency use (i.e., if there is currently an approved IND for the drug or biologic) or an Emergency IND number (i.e., if there is no approved IND for the drug or biologic).
 - c. Note that the manufacturer will likely require the attending physician to contact the FDA to obtain emergency use of Emergency IND approval, with subsequent notification of the manufacturer. To facilitate this process, request that the manufacturer identify the specific FDA Division which is currently reviewing the drug or biologic.
2. Call the main IRB office number at (412) 383-1480 during normal working hours and for after hours, follow the instructions on the audix message to contact the IRB Chair or Medical Director.
 - a. This notification should occur prior to implementation of the emergency use. Provide the IND number under which this use is authorized (e.g., Expanded Access, Treatment IND, other currently approved IND, or Emergency IND)
3. Submit the request in OSIRIS (www.osiris.pitt.edu)
 - a. Create a new submission
 - i. Question T.1: select New Emergency Use Application (not research) and complete the application
 - ii. This application should be submitted by the treating physician but unlike a research study, a designee appointed by the treating physician is permitted to submit the application and follow-up documentation. The treating physician is responsible for the validity of all information and documents submitted
 - b. IRB Chair or designee will review and send an email to concur with the request or contact you for additional information
 - c. All the required documentation must be submitted within 5 working days
 - i. Follow-up reports can be submitted using  located under My Activities

4. If the unapproved investigational drug or biologic emits ionizing radiation, the Radiation Safety Office (412-624-2728) must also be notified.

Considerations:

- University of Pittsburgh IRB policies require that the IRB be notified prior to emergency use when feasible. However, this notification of the IRB will NOT result in an IRB approval. FDA regulations do not provide for expedited IRB approval in emergency situations. An IRB must either convene and give “full board” approval of the emergency use or, if the conditions of 21 CFR 56.104(c) are met and there is not time to convene a meeting, the IRB will issue an acknowledgement letter.
- Results from an emergency use of an unapproved investigational drug, biologic or device cannot be used as research data.
- The FDA emergency use exemption from IRB review cannot be used to circumvent the requirement for a convened IRB review.

Consent Requirements:

Written informed consent from the patient or the patient’s legally authorized representative must be obtained prior to the emergency use unless a waiver of informed consent is approved. If time permits, the IRB should review the consent form prior to consenting the patient.

The regulations do, however, provide for a waiver of informed consent if both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

- the subject is confronted by a life-threatening situation necessitating use of the test article
- informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject
- time is not sufficient to obtain consent from the subject’s legal representative
- no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject’s life.

If, in the investigator’s opinion, there is not sufficient time to obtain an independent physician’s determination that the four criteria are met, the investigator should make the determination and subsequently obtain (i.e., within 5 working days) a review of his/her determination by a physician not participating in the investigation. Documentation of this process should be submitted to the IRB within 5 working days.

Required Reporting:

Within 5 working days of initial notification of the IRB Chair or Medical Director, the following must be submitted to the IRB Office.

- Emergency Use application submitted in OSIRIS

- Unsigned copy of Emergency Use consent form signed by the patient or the patient's legally authorized representative or written documentation from both the investigator as well as a physician independent of the clinical investigator that a waiver of consent was necessary based on the four points noted above
- Required follow-up documentation

Additional Information:

U.S. Food and Drug Administration (www.fda.gov)
[Emergency Use of an Investigational Drug or Biologic](#)
[Emergency Use of an Investigational Device](#)