



EMERGENCY USE

*IRB Member & Staff
Training*



EXPANDED ACCESS

- Use of an investigational drug, biologic, or medical device
- Used to treat a patient with a serious disease or condition when there is no other comparable or satisfactory alternative treatment available
- The intent is to provide direct benefit to the patient
 - 21 CFR 312 subpart I for drugs and biologics
 - 21 CFR 812.35 and 812.36 for medical devices

EXPANDED ACCESS

- Emergency Use
- Non-Emergency Use



EXPANDED ACCESS

Emergency Use

- Single patient
- The patient is in an immediately life-threatening situation
- One time use of an investigational drug
- Informed consent is required unless it isn't feasible in the situation

Non-Emergency Use

- Single patient or group
- The patient/group has a serious condition and is not in an immediately life-threatening situation.
- Involves a treatment plan
- Informed consent is required
- Requires full committee review
 - Under certain circumstances a single patient application may undergo chair review for concurrence

IRB ROLE IN EXPANDED ACCESS

Emergency Use

- IRB receives notification of physician's use of the drug or device
- The full IRB committee is notified at the following IRB meeting

Non-Emergency Use

- The chair concurs with the physician's use of the drug or device

OR

- The committee reviews the use of the drug or device

Resources

USC HRPP Webpage for Emergency Use/Expanded Access

<https://hrpp.usc.edu/emergency-use/>

USC HRPP Policies and Procedures, Chapter 16.7: Emergency Use of a Test Article

<https://hrpp.usc.edu/policies/chapter-16-fda-regulated-research/>

Institutional Review Board Management and Function, 3rd edition, Bankert, et.al.

FDA Guidance: Emergency Use of an Investigational Drug or Biologic

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic>

FDA Webpage for Expanded Access: Information for Patients, Physicians and Industry

<https://www.fda.gov/news-events/public-health-focus/expanded-access>