EMERGENCY USE

IRB Member & Staff Training

August 2023
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/


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