

Emergency Use of an Investigational Drug Guidance for Investigators

This guidance is specific to the “Emergency Use” of an investigational drug. Do not follow this guidance if you will be using an investigational drug under a “Single-Patient IND,” “Intermediate IND,” or “Expanded Access” (see below). Email COMIRB@ucdenver.edu if you have any questions.

Under FDA Emergency Use provisions, the use of an investigational drug without prior IRB approval is allowed if the following criteria are met:

1. The patient has a life-threatening or severely debilitating condition.
2. No standard, acceptable treatment is available.
3. There is not sufficient time to obtain prospective IRB review and approval.
4. The emergency use is reported to the IRB within five working days.
5. Consent will be sought and documented from the patient or legally authorized representative.
6. The treatment is not part of a systematic investigation designed to develop or contribute to generalizable knowledge.

While the IRB does not need to approve the emergency use of the drug, an emergency IND must be obtained from the FDA prior to use of the drug, and the IRB must be notified of the use within 5 days of treatment. If the proposed use meets all of the above criteria, treating physicians should contact the manufacturer (or IND holder) to inquire if the drug is available for emergency use. If so, the manufacturer may release the drug under an existing emergency use IND, or they may contact the FDA to obtain an emergency use IND. The manufacturer may also require the treating physician to obtain their own emergency use IND.

After obtaining the emergency IND, the treating physician may proceed with treatment. The treating physician or delegate must notify COMIRB of the use within 5 days of treatment by sending an email to COMIRB@ucdenver.edu. The investigator’s brochure, letters of authorization from the FDA and manufacturer, and the consent form, should all be submitted to COMIRB via InfoEd within five days of treatment. After review by an IRB Chair, COMIRB will issue a letter to the treating physician.

Expanded Access and Single-Patient INDs

If the manufacturer requires that the patient be enrolled in an existing expanded access protocol in order to receive the drug, the protocol will require prior review and approval by an IRB. If the manufacturer and/or FDA determine that the proposed use does not fulfill the criteria for an emergency IND, the treating physician may request a Single Patient IND. For more information on this pathway, please visit the [CRSC’s FDA Submission Support webpage](#).

Links to More Information

- [FDA: Emergency Use of an Investigational Drug or Biologic](#)
- [FDA: Expanded Access](#)