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.

Process

If the proposed use meets all of the above criteria, treating physicians should first contact the drug manufacturer (or IND holder) to confirm that the drug is available for emergency use, and to obtain their agreement to provide the drug. After confirming that the manufacturer can provide the drug, the treating physician must call the FDA's Division of Drug Information (DDI) to obtain authorization for the emergency use. The DDI representative will request supporting documentation from the manufacturer and/or treating physician, including—but not limited to—FDA Form 3926 and a Letter of Authorization from the manufacturer. FDA will review these materials and will issue an Emergency IND number if it determines that the request meets the criteria for emergency use. (Contact information for DDI and a more detailed description of FDA emergency use requirements are available here.)

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 following documents should be attached to that email:

- Emergency IND approval from the FDA
- Consent form (if applicable). If it was not possible to obtain consent from the patient or their legally authorized representative prior to treatment, the treating physician and an

independent, uninvolved physician must certify in writing that the criteria for emergency use without consent were met.
- Investigator's brochure (if available)
- Protocol/treatment plan (if available)
- FDA Form 3926 (if used)

After review by an IRB Chair, COMIRB will send the treating physician an email formally acknowledging the emergency use.

Tracking and Reporting

In parallel, COMIRB Management will create an electronic submission, identified by a unique COMIRB number, in InfoEd for purposes of documenting the emergency use and storing the documents listed above. Following the IRB Chair's acknowledgment of the emergency use report, COMIRB Management will change the status of the emergency use submission to "Closed."

Treating physicians are responsible for reporting any event that may meet the definition of an Unanticipated Problem or Serious and/or Continuing Noncompliance to COMIRB within 5 days, in accordance with COMIRB Policies and Procedures, Sections 19 and 20. An Unanticipated Problem is any adverse event that is related or possibly related to the test article, was unexpected—either in severity or nature—and placed the patient at an increased risk of harm than was previously known or recognized. Examples of Serious and/or Continuing Noncompliance include, but are not limited to:

- Emergency use of an unapproved test article without an Emergency IND or authorization to ship from the FDA;
- Failure to report emergency use of an unapproved test article to COMIRB within 5 business days; or
- Any other failure to comply with the terms of the Emergency IND and FDA regulations.

In some cases, a drug approved for emergency use under an Emergency IND may never actually be used, e.g., if the patient does not survive or their condition changes such that emergency use is no longer necessary. In that scenario, please notify COMIRB when the request to withdraw the Emergency IND has been submitted to the FDA. At that point, COMIRB will administratively close the InfoEd record for the emergency use.

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
- FDA: Emergency IND Timeline
- COMIRB Unanticipated Problem Submission Guide