INVESTIGATOR GUIDANCE: Emergent & Non-Emergent Use of Test Articles

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I. When can I use an investigational (not approved by FDA) drug, biologic, or device in an emergency situation to treat a patient?

Drug or Biologic

- Patient is in a life-threatening or severely debilitating situation
- No standard treatment is available
- There is no time to obtain IRB approval

Device

- Patient is in a life-threatening or severely debilitating situation
- Patient needs immediate treatment, diagnosis, or monitoring
- No generally acceptable alternative or the condition exists
- There is substantial reason to believe the patient will benefit from the use of the device
- There is no time to obtain FDA approval of an IDE

II. What do I need to do in order to use an investigational product in an emergency?

Drug or Biologic

- Contact the manufacturer and obtain permission to pursue emergency use
- Obtain an emergency IND from the FDA
- If time, submit the following to the IRB using **HRP-222 FORM: Emergency Use Report** (if no time, submit within 5 days after the emergency use):
  - Description of case and treatment plan, including justification of the above criteria
  - A proposed consent form for treatment use (see **HRP-502 TEMPLATE: Consent for Emergency Use**) or justification for why informed consent will not be sought
  - Any available documentation from the FDA regarding the emergency IND
- Obtain informed consent of the patient or patient's LAR, unless consent is not feasible

Device

- If feasible, contact the manufacturer and obtain permission for emergency use.
- If time, submit the following to the IRB using **HRP-222 FORM: Emergent Use Report** (if no time, submit within 5 days after the emergency use):
  - Description of case and treatment plan, including justification of the above criteria
  - Documentation that an independent physician (not involved with any associated research studying the device) concurs
  - A proposed consent form for treatment use (see **HRP-502 TEMPLATE: Consent for Emergency Use**)
  - Any available documentation from device manufacturer/sponsor
  - If available, clearance from institutional department
- Obtain informed consent of the patient or patient's LAR, unless consent is not feasible
- No FDA notification is required

The IRB Chair or designated IRB member will review the submission of **HRP-222 FORM: Emergency Use Report** and notify you via IRBNet as soon as possible whether the emergency use meets the regulatory criteria.

III. Can I use an investigational product to treat a patient outside of a research study if it is not an emergency?

Generally, yes. The table below summarizes the differences in the regulations between emergency use and the other types of treatment use (non-research) options.

Emergency Use	Single Patient IND *	Expanded Access **	Compassionate Use ***
•Life threatening or severely debilitating situation •Applies to **drugs & devices** •**Drugs:** Emergency IND required •**Devices:** If feasible, obtain permission from manufacturer •If possible, give IRB prior notice; Fully notify the IRB within 5 days after use •Obtain consent of subject or LAR, unless not feasible per applicable regulatory criteria •May require an independent physician's assessment	•Non-emergent •Applies only to **drugs** •IND required •IRB Chair review and concurrence prior to use •Consent required	•Non-emergent •Applies only to **drugs** •IND required •IRB review and approval prior to use •Consent required	•Non-emergent •Applies only to **devices** •FDA concurrence with use is required; FDA may require a full IDE be submission •IRB Chair review and concurrence prior to use •Consent required

***Single Patient IND:** You will need to obtain an IND from the FDA and submit your plan for the proposed use to the IRB. Convened IRB review of Single Patient INDs can be waived, but IRB Chair concurrence with the use is required. To obtain this, submit the following documentation:

- **HRP-200 FORM: Initial Review Application** (including documents according to the Submission Requirements section)
- Completed FDA form 3926: Individual Patient Expanded Access IND Application

****Expanded Access:** You will need to obtain an IND from the FDA and submit a new study application to the IRB. The IRB will review the application just like a research study. If the situation is urgent but does not rise to the level of an Emergency Use, let the IRB know and we will do our best to review the submission quickly. Additional Expanded Access INDs involving the same drug can be processed as modifications to the initial submission.

*****Compassionate Use:** The non-emergency treatment use of a device is called Compassionate Use. You must contact the FDA to obtain their concurrence with the use, as well as concurrence from the device manufacturer and or IDE sponsor, as applicable. The FDA may require you to submit an IDE if none exists. The IRB does not perform a full review of Compassionate Uses, but IRB Chair concurrence with the use is required. To obtain this, submit the following documentation:

- Treatment plan, including an explanation of why the criteria in **HRP-453 WORKSHEET: Compassionate Use Devices** are met
- Treatment use consent form or alternative explanation of how consent will be obtained
- FDA concurrence with the use
- Clearance from the appropriate institutional representative

- The opinion of an independent physician (who is not involved with any associated research studying the device) concurring that the applicable criteria have been met

Additional compassionate uses of the same device can be processed as modifications to the initial submission.

This guidance is a supplement to the following:

- *https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm*
- *HRP-451 WORKSHEET: Emergency Use Drugs and Biologics*
- *HRP-452 WORKSHEET: Emergency Use Devices*
- *HRP-453 WORKSHEET: Compassionate Use Devices*
- *CW ACH 233 SOP: IRB Review of Emergency and Compassionate Use*