

## Quick Reference Guide

### Emergency Treatment Use of an FDA-Regulated Product

*This guide is a supplement to **SOP HRP-180: Emergency and Compassionate Uses** and **WORKSHEETS HRP-451: Emergency Use Drugs and Biologics**, **HRP-452: Emergency Use Devices**, and **HRP-453: Compassionate Use Devices**.*

#### 1. 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 and needs immediate treatment, diagnosis, or monitoring
- No generally acceptable alternative for 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

You can use an **FDA-approved** drug, biologic, or device in an unapproved way (“off-label”) to treat a patient without any special permission. You do not need to consult the IRB or FDA.

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

##### Drug or Biologic

1. Contact the manufacturer and obtain permission to pursue emergency use
2. Obtain an emergency IND from the FDA
3. If time, email the following to the IRB (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 (start with the Treatment Use template on the IRB Forms website) or justification for why informed consent will not be sought.
  - Any available documentation from the FDA regarding the emergency IND.
4. Obtain informed consent of the patient or patient’s LAR, unless consent is not feasible (see HRP-451 for criteria)

##### Device

1. If feasible, contact the manufacturer and obtain permission for emergency use
2. If time, email the following to the IRB (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 concurs (may copy the physician and have them respond to the email)
  - A proposed consent form for treatment use (start with the Treatment Use template on the IRB Forms website)
  - Any available documentation from device manufacturer/sponsor
  - If available, clearance from institutional department
3. If feasible, obtain informed consent of the patient or patient’s LAR.

The IRB Chair will notify you by email as soon as possible whether the emergency use meets the regulatory criteria. **If the patient’s condition warrants it, you may proceed with treatment before you receive confirmation from the IRB Chair.** Following the emergency use, you will receive an official memo from the IRB stating that the use was reported and did or did not meet the applicable regulatory criteria.

See the applicable **WORKSHEETS** for more details regarding the above requirements. Call the IRB office if you have questions.

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

Generally, yes.

**Drugs and Biologics:** You will need to obtain an Expanded Access 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.

**Devices:** 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 a new study application in the eIRB and upload 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 (clinical HIPAA rules apply – separate authorization is not required)
- FDA concurrence with the use
- If an IDE exists, authorization for the use from the sponsor
- Clearance from the appropriate institutional representative (signed electronic or paper PPQ is sufficient)
- The opinion of an independent physician concurring that the applicable criteria have been met

The IRB Chair will verify that the proposed use meets the applicable criteria and will notify you by issuing an “approval” of your submission and a memo through the eIRB. Additional compassionate uses of the same device can be processed as modifications to the initial submission.