Quick Reference Guide for Emergency and Compassionate Use

This guide is a supplement to the Emergency and Compassionate Use Guide on the IRB website.

Please note: This guidance relates to use of investigational products (not approved by the FDA for commercial use). Off-label use of FDA-approved (commercially available) drugs, biologics, and devices does not require consultation with the IRB.

When can you use an investigational 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
- No standard treatment is available
- There is no time to obtain IRB approval
- Compassionate use situation: circumstance that the FDA recognizes that the investigational device is the only option available for a patient faced with a serious, albeit not life-threatening disease or condition

What do you need to do in order to use an investigational product in an emergency?

Drug or Biologic
- Contact the manufacturer to obtain their approval of the plan
- A physician not involved in the patient’s care must evaluate the patient’s clinical status and the proposed emergency or compassionate use and provide a letter stating that no other standard acceptable treatment is available for this patient

Submit the following:
1. Written notification of the emergency use
   *Confirm this is documented in patient’s medical record*
2. Letter of support from a physician not involved in the patient’s care
   *Confirm this is documented in patient’s medical record*
3. Form 3
4. Form 2 for the drug that will be used
5. An informed consent form (ICF) tailored for this single use OR certification by the Principal Investigator and a physician unaffiliated with this emergency use that the criteria for the exception from informed consent were met as per 21 CFR 50.24.
6. Brief specific protocol that includes:
   o Rationale for use of the drug including a list of available therapeutic options that were tried;
   o Description of the patient’s disease or condition, including recent medical history and previous treatments;
   o Proposed method of administration of the drug, dose, and duration of intervention;
   o Description of clinical procedures, or monitoring needed to evaluate the effects of the drug and to minimize its risks
7. The Investigator’s Brochure for the drug
8. A statement from the drug manufacturer that it is aware of the proposed emergency use and supports the use of the drug in the patient.
9. A statement from the FDA that it has approved the proposed emergency use of the drug in this patient.
10. A letter of support from Tufts Medical Center leadership that the proposed compassionate use of the device is supported by the institution.

Device
- Contact the manufacturer to obtain their approval of the plan
- For a compassionate use, once the manufacturer’s support is secured, please speak to the FDA, since the FDA must approve all compassionate uses before they occur.
- A physician not involved in the patient’s care must evaluate the patient’s clinical status and the proposed emergency or compassionate use and provide a letter stating that no other standard acceptable treatment is available for this patient

Submit the following:
1. Written notification of the emergency or compassionate use
2. *Confirm this is documented in patient’s medical record*
3. Letter of support from a physician not involved in the patient’s care
   *Confirm this is documented in patient’s medical record*
4. Form 1
5. Form 3 for the device that will be used.
6. An informed consent form (ICF) tailored for this single use OR certification by the Principal Investigator and a physician unaffiliated with this emergency or compassionate use that the criteria for the exception from informed consent were met as per 21 CFR 50.24.
7. Brief specific protocol that includes:
   o Rationale for use of the device including a list of available therapeutic options that were tried;
   o Description of the patient’s disease or condition, including recent medical history and previous treatments;
   o Proposed method of implanting the device, and duration of intervention;
   o Description of clinical procedures, or monitoring needed to evaluate the effects of the device and to minimize its risks
8. The Operator’s Manual for the device.
9. A statement from the device manufacturer that it is aware of the proposed emergency or compassionate use and supports the use of the device in the patient.
10. A statement from the FDA that it has approved the proposed emergency or compassionate use of the device in this patient.
11. A letter of support from Tufts Medical Center leadership that the proposed compassionate use of the device is supported by the institution.