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 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 1
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:
   - Rationale for use of the drug including a list of available therapeutic options that were tried;
   - Description of the patient’s disease or condition, including recent medical history and previous treatments;
   - Proposed method of administration of the drug, dose, and duration of intervention;
   - 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.

**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
   *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 1
4. Form 3 for the device 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 or compassionate use that the criteria for the exception from informed consent were met as per 21 CFR 50.24.
6. Brief specific protocol that includes:
   - Rationale for use of the device including a list of available therapeutic options that were tried;
   - Description of the patient’s disease or condition, including recent medical history and previous treatments;
   - Proposed method of implanting the device, and duration of intervention;
   - Description of clinical procedures, or monitoring needed to evaluate the effects of the device and to minimize its risks
7. The Operator’s Manual for the device.
8. 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.
9. A statement from the FDA that it has approved the proposed emergency or compassionate use of the device in this patient.
10. A letter of support from Tufts Medical Center leadership that the proposed emergency or compassionate use of the device is supported by the institution. This should be obtained from the Chief Medical Officer (CMO). The CMO may also designate a content expert to provide this.