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?

<table>
<thead>
<tr>
<th>Drug or Biologic</th>
<th>Device</th>
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</thead>
<tbody>
<tr>
<td>Patient is in a life-threatening or severely debilitating situation</td>
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<tr>
<td>No standard treatment is available</td>
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<td>There is no time to obtain IRB approval</td>
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<tr>
<td>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</td>
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### 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
2. Letter of support from a physician not involved in the patient’s care
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.
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. Letter of support from a physician not involved in the patient’s care
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 compassionate use of the device is supported by the institution.