Guidance for the IRB Submission of a Compassionate or Emergency use of an Unapproved Medical Device (including those not under an IDE)
• Patient does not qualify for the IDE protocol of the physician wants to use the device in a way not approved under an IDE OR
• Physician is not an investigator under an IDE.

In order for the use of an unapproved device to qualify as Emergency use, the following conditions must exist:

• The patient has a life-threatening or serious disease or condition AND
• There is no generally acceptable alternative treatment AND
• There is no time to obtain FDA approval for the use because the unapproved medical device needs to be used in the patient immediately

Before using the device, the physician should take as many of the following patient protection measures as possible, and provide the following information in the submission:

• Obtain a written independent assessment of the use of the device by an uninvolved physician.
• Obtain documented informed consent from the patient or patient’s legally authorized representative.
• Obtain documented authorization from the holder of the IDE for the Investigational Medical Device, if an IDE exists.
• Notify the Emory IRB (via call or email), and provide the Emory IRB with a written description of the circumstances necessitating the use of the device, along with copies of the uninvolved physician’s assessment, informed consent, and the IDE’s holder’s authorization.

Prior FDA approval for shipment or use of the device is not necessary but emergency use needs to be reported to the FDA and IRB. The information to the FDA should be submitted by the sponsor (IDE holder). If the unapproved medical device is not under an IDE, the investigator should submit the information directly to the FDA.

Report the emergency use to the Emory IRB in writing within five business days. Similar to the treatment (“compassionate”) use application, you need to create a new submission in eIRB. If you have never done that before, you may want to review this instructional video or contact the IRB Education and QA team for assistance. Please include the following information in your submission:

• A copy of the informed consent that was used. If a consent form was not used, please let us know why consent was not obtained. For example, if there was not time to consent the subject, please explain how the subject (or legally authorized representative) was informed after the use. You may submit an unsigned copy of the informed consent, so you can obtain documentation of consent after the IRB reviews the use.
  o Consent form: Emory Expanded Access (IND/IDE)/HIPAA Template (ver. 1-16-15)
• In the “Devices” section:
  o Device information (including device manual)
  o Copy of authorization from IDE holder (sponsor).
• In the “Research Design” section:
  o A description of the circumstances necessitating the use. Don’t include patient identifiers, but do describe the medical condition of the patient and why the device is needed.
  o IDE protocol with description of device and name of IDE holder, if this exists.
  o Copy of an uninvolved physician’s assessment of use.
  o Information submitted to the FDA (including FDA acknowledgement if already obtained).
<table>
<thead>
<tr>
<th>Expanded Access Mechanism</th>
<th>Regulatory Authority</th>
<th>Criteria for Use</th>
<th>When Can It Be Used?</th>
<th>Number of Patients to be Treated</th>
<th>FDA Approval Needed?</th>
<th>How is FDA Approval Obtained?</th>
<th>Patient Protection Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emergency Use</strong></td>
<td>&quot;Guidance for the Emergency Use of Unapproved Medical Devices&quot; 21 CFR 812.35(a)</td>
<td>1. Life-threatening condition 2. No alternative and 3. No time to obtain FDA approval</td>
<td>Before or after initiation of clinical trial</td>
<td>Limited to few patients</td>
<td>No; sponsor submit report to FDA following device use</td>
<td>Not applicable</td>
<td>1. Independent assessment by uninvolved doctor 2. IRB chairperson's concurrence 3. Institutional clearance 4. Informed consent</td>
</tr>
<tr>
<td><strong>Compassionate Use</strong></td>
<td>21 CFR 812.35(a)</td>
<td>1. Serious disease or condition 2. No alternative</td>
<td>During clinical trial</td>
<td>Individual patient or small groups of patients</td>
<td>Yes</td>
<td>IDE supplement with: 1. Explanation of circumstances constituting need for the device 2. Reasons alternatives not acceptable 3. Deviations from protocol, if any 4. Patient protection measures</td>
<td>1. Independent assessment by uninvolved doctor 2. IRB concurrence/review 3. Institutional clearance 4. Informed consent</td>
</tr>
</tbody>
</table>

From FDA [website](http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf)

**REFERENCES**

- 21 CFR § 812
- IRB policies and procedures

1 IDE: Investigational Device Exemption. The FDA requires an IDE when doing research with an unapproved medical device. For more information, please follow this [link](http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf).