Guidance for the IRB Submission of a Compassionate or Emergency use of an Unapproved Medical Device (including those not under an IDE[i])

The guidance below is for use of an unapproved medical device to treat a patient outside an IDE protocol, or even if the unapproved device is not under an IDE yet. Please follow the relevant instructions below, based on whether the use is considered a "compassionate use", or an emergency use (both are types of Expanded Access uses).

For information about expanded access including what would qualify and submission to FDA, follow this link. For additional instructions on how to submit an Expanded Access use request to the FDA, please review the IRB P&Ps. The FDA also has a Q&A at this link.

If you need assistance with the submission to the FDA, please contact the Office of Research Compliance at orc@emory.edu or at (404) 727-2398.

Treatment (compassionate) use of an unapproved medical device (non-Emergency): What information needs to be submitted to the IRB?

FDA approval and IRB concurrence/approval is required **before** the use of the device. The submissions to the FDA and IRB can occur simultaneously, but both are needed before use.

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**. The submission should include the following:

- Consent form: Emory Expanded Access (IND/IDE)/HIPAA Template (ver. 1-16-15)
  Please, do not tamper with the header, but please do add a version date at the bottom of the form.
- Device information (including device manual) under the "Devices" section in the smartform.
- Description of why this use is needed. Don't include patient identifiers, but do describe the medical condition of the patient.
- Copy of an uninvolved physician's assessment of use (any qualified physician who is not participating in the treatment use protocol).
- IDE protocol with description of device and name of IDE holder.
- Copy of authorization from IDE holder (sponsor).
- Information submitted to the FDA (including FDA approval if already obtained).

NOTE: If you are not providing PHI to the IDE sponsor, the HIPAA related questions in the smartform should be skipped.

Under the "Biomedical Research" section of the new study submission form, click on "Investigational Device or Investigational Use of Approved Device". This will allow you to provide the device information in a following section.

Emergency use of unapproved medical device: What information needs to be submitted to the IRB?

Unlike treatment ("compassionate") use, the use under an emergency situation **does not** need IRB or FDA approval before use. Emergency use of an unapproved device to save a patient's life may occur when:

- An IDE does not exist OR

- 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.
    - Consent form: Emory Expanded Access (IND/IDE)/HIPAA Template (ver. 1-16-15)
- In the "Devices" section:
    - Device information (including device manual)
    - Copy of authorization from IDE holder (sponsor).
- In the "Research Design" section:
    - 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.
    - IDE protocol with description of device and name of IDE holder, if this exists.
    - Copy of an uninvolved physician's assessment of use.
    - Information submitted to the FDA (including FDA acknowledgement if already obtained).

Expanded Access Mechanism	Regulatory Authority	Criteria for Use	When Can It Be Used?	Number of Patients to be Treated	FDA Approval Needed?	How is FDA Approval Obtained?	Patient Protection Measures
Emergency Use	"Guidance for the Emergency Use of Unapproved Medical Devices" 21 CFR 812.35(a)	1. Life-threatening condition 2. No alternative and 3. No time to obtain FDA approval	Before or after initiation of clinical trial	Limited to few patients	No; sponsor submit report to FDA following device use	Not applicable	1. Independent assessment by uninvolved doctor 2. IRB chairperson's concurrence 3. Institutional clearance 4. Informed consent
Compassionate Use	21 CFR 812.35(a)	1. Serious disease or condition 2. No alternative	During clinical trial	Individual patient or small groups of patients	Yes	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	1. Independent assessment by uninvolved doctor 2. IRB concurrence/review 3. Institutional clearance 4. Informed consent

From FDA website

REFERENCES

- 21 CFR § 812
- Guidance on IDE policies and Procedures, IDE Staff, January 20, 1998.
- IRB policies and procedures
- FDA information at http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf

[i] IDE: Investigational Device Exemption. The FDA requires an IDE when doing research with an unapproved medical device. For more information, please follow this link.