

Guidance for the IRB Submission of a Treatment Use (“Compassionate”) or Emergency use of an Unapproved Medical Device (Including those not under an IDE¹)

The guidance below is for use of an unapproved medical device to treat a patient outside an IDE protocol, or use of an unapproved device not under an IDE. Please follow the relevant instructions below, based on whether the use is considered a non-emergency treatment “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 Compliance at compliance@emory.edu or at (404) 727-2398.**

Please follow the relevant instructions below, based on the type of Expanded Access: whether the use is considered a non-emergency “compassionate use”, or an emergency use.

Treatment (compassionate) use of an unapproved medical device (non-Emergency)

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

You are no longer required to create a new submission in eIRB. Instead, you need to contact a member of the [Education and QA team](#) to help you with obtaining IRB Chair concurrence before the use. In order to secure IRB chair concurrence, please email us the following information:

- Consent form. Please use our template: [Emory Expanded Access \(IND/IDE\)/HIPAA Template](#)
- A description of the circumstances necessitating the use.
- IDE protocol with description of device and name of IDE holder.
- Copy of uninvolved physician’s assessment of use.
- Copy of authorization from IDE holder.
- Timeline for FDA submission

Our staff will email our IRB chair this information and let you know if there are any changes required before the IRB concurrence letter can be issued. After receiving this letter, you will be required to:

- Notify the IRB about the patient status within 5 days after treatment started
- Provide a copy of the FDA communication agreeing with the use

The IRB staff will create a shell in eIRB with this information for reference.

Emergency use of unapproved medical device

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

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](#).

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- Patient does not qualify for the IDE protocol or 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. Use our template to create this document: [Emory Expanded Access \(IND/IDE\)/HIPAA Template](#)
 - If consent was not obtained before use, please let us know why, and upload in the informed consent process section instead the informed consent form. The physician and a licensed physician who is not participating in the medical care protocol must certify in writing that:
 - The patient was under a life-threatening situation.
 - There was an inability to communicate with or obtain legally effective informed consent from the patient.
 - There was not sufficient time to obtain informed consent from the subject or legally authorized representative.
 - There was no available alternative method of FDA-approved or generally recognized therapy that provided an equal or greater likelihood of saving the patient's life.
- 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 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. In this case, you need to create a new submission in eIRB. We can provide you with a pre-populated submission if requested. **If you want assistance, you may want to review this [instructional video](#) or contact the [IRB Education and QA team](#) for assistance.**

NOTE: If you are not collecting information for research, the initial HIPAA related questions in the smartform may be answered "no," allowing you to skip further HIPAA questions.

Please include the following information in your submission:

- In the Informed Consent Process section:
 - 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 (as explained above), and upload your justification under the informed consent process section instead of the informed consent. For example, if there was not

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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 template: [Emory Expanded Access \(IND/IDE\)/HIPAA Template](#)

- In the “Medical 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	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	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; submit report to FDA following device use	Not applicable	1. Independent assessment by uninvolved doctor; 2. IRB chairperson's concurrence; 3. Institutional clearance; and 4. Informed consent
Compassionate Use	1. Serious disease or condition and 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; and 4. Patient protection measures.	1. Independent assessment by uninvolved doctor; 2. IRB chairperson's concurrence; 3. Institutional clearance; and 4. Informed consent.

From FDA [website](#)

REFERENCES

- 21 CFR § 812
- [FDA Webpage Expanded Access for Medical Devices](#), IDE Staff, 1/16/2018.
- Emory IRB policies and procedures
- FDA information at <http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf>
- FDA Expanded Access for Medical Devices Guidance at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm>
- FDA Presentation: Emergency Use and Compassionate Use of Unapproved Devices at <https://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf>