

## Guidance for the IRB Submission of an Expanded Access IND (Treatment or Emergency use) of an Unapproved Drug

The guidance below is for use of an unapproved drug to treat a patient or patients, outside of a clinical trial. 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). The FDA must authorize any type of expanded access use in advance, even Emergency use for individuals, via an IND (Investigational New Drug). The Emory IRB also must approve in advance any Expanded Access use, *except* for emergency use situations in which it is not possible to obtain prospective IRB review.

For information about what would qualify as treatment use, follow this [link](#). For instructions on how to submit an Expanded Access use request to the FDA, please review the [IRB P&Ps](#), or this [FDA webpage](#). The FDA also has a Q&A at this [link](#) and specific draft guidance at this [link](#).

**If you need assistance with the expanded access submission to the FDA, please contact the Office of Compliance at [compliance@emory.edu](mailto:compliance@emory.edu) or at (404) 727-2398.**

### **Emergency use of an unapproved drug: What information needs to be submitted to the IRB?**

Unlike non-emergency use, the use in an emergency situation does not need IRB approval, as long as the FDA has authorized this use. The IRB should receive a report within 5 business days of the expanded access emergency use. This should be done via a new submission in eIRB. For assistance with this process, you may want to review this [instructional video](#) or contact the [IRB Education and QA team](#). You will find that several sections do not apply to your situation, please fill in these fields with “N/A” and the IRB will alert you if additional information is required.

The eIRB submission should include the following:

- A copy of the informed consent that was used, if applicable. Please use our template, which can be found [here](#).
- If consent was not obtained before use, please let us know why. 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.
- A copy of all information submitted to the FDA in connection with the Expanded Access use request, especially:
  - Reason for intended treatment use of the Investigational New Drug.
  - List of available therapeutic options that would usually be tried before using the Investigational New Drug OR an explanation of why the Investigational New Drug is preferable to available therapies.
  - Criteria for patient selection for Expanded Access if the use is for more than one individual OR a description of patient’s disease/condition, medical history and previous treatment for Expanded Access for an individual patient.
  - Dose and method of administration for the Investigational New Drug and duration of therapy.

- Description of the clinical procedures, laboratory test or other monitoring necessary to evaluate the effects for the drug and minimize its risks.
- Drug information under the “Drugs” section. This is triggered by selecting “Investigational drug or investigational use of an approved drug” in the “Biomedical Research” section of the smartform.
- Documentation of FDA approval for the Expanded Access Use request.

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.

**Treatment or “Compassionate” use of an unapproved drug (non-Emergency): What information needs to be submitted to the IRB?**

You will 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. You will find that several sections do not apply to your situation; please fill in these fields with “N/A” and the IRB will alert you if additional information is required.

The eIRB submission should include the following:

- A clean copy of the informed consent form on the required [template](#). Please, do not tamper with the header, but please do add a version date at the bottom of the form.
- In the “Research Design” section:
  - Documentation of FDA approval for the Expanded Access Use request.
  - A copy of all information submitted to the FDA in connection with the Expanded Access use request, especially:
    - Reason for intended treatment use of the Investigational New Drug.
    - List of available therapeutic options that would usually be tried before using the Investigational New Drug OR an explanation of why the Investigational New Drug is preferable to available therapies.
    - Criteria for patient selection for Expanded Access if the use is for more than one individual OR a description of patient’s disease/condition, medical history and previous treatment for Expanded Access for an individual patient.
    - Dose and method of administration for the Investigational New Drug and duration of therapy.
    - Description of the clinical procedures, laboratory test or other monitoring necessary to evaluate the effects for the drug and minimize its risks.
- Drug information under the “Drugs” section. This is triggered by selecting “Investigational drug or investigational use of an approved drug” in the “Biomedical Research” section of the smartform.

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.

**REFERENCES**

- 21 CFR Parts 312
- IRB policies and procedures
- FDA draft guidance at:  
[http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM432717.pdf?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM432717.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery)