

Emergency Single-Case Use of an Investigational Device, Drug or Biologic Product

Scope

Mayo Clinic Human Research Protection Program

Relying Organizations for which the Mayo Clinic IRB is the IRB of Record

Purpose

Federal regulations do not limit or interfere with the authority of a clinician to provide emergency medical treatment using an investigational device, drug or biologic product for one patient in a life-threatening medical emergency, where there is no standard acceptable treatment available and insufficient time to obtain IRB approval. In this circumstance, Federal regulations grant an exemption from prior review and approval by the IRB.

Policy/Procedure

- The emergency use of a test article is permitted provided a patient is in a life-threatening situation in which no standard acceptable treatment is available, and when there is not sufficient time to obtain IRB review and approval.
- The clinician will consult with an independent clinician (not involved in the patient's care) and obtain a written assessment from him/her that the emergency use criteria specified in this document have been met.
- At the earliest opportunity, and no later than **3 working days** following the emergency use, the clinician will notify the IRB of his/her intent to use, or of his/her completed use of a test article in an emergency.
- Informed consent will be obtained from the patient or his/her legally authorized representative unless the Federal requirements for exception from the informed consent requirement are satisfied, as noted below in this policy.
- The clinician must report the emergency use to the IRB within **3 working days** of the emergency use in order to meet the FDA and IRB reporting requirements. **Three working days includes the day of the emergency use and the day of submission to the IRB.** The clinician will complete and submit the Emergency Use Report in the IRB's electronic system (IRBe) within 3 working days of the emergency use.
- A convened IRB will review the IRB Emergency Use Report to assess compliance with emergency use requirements. The clinician will report the emergency use to the holder of the product's IND, IDE or HDE. The holder is responsible for reporting the emergency use, as required, to the FDA.
- The clinician will consult with the Mayo Clinic Office of Research Regulatory Support (ORRS) to identify and fulfill Federal regulatory requirements following the Emergency Use. The Mayo Clinic Office of Research Regulatory Support (ORRS) can be contacted by phone at 507-266-0022 [internal: (77)6-0022], or by email: ORRS@mayo.edu .

- The Mayo Clinic IRB and FDA acknowledge that it is inappropriate to deny emergency treatment to a second qualified individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue. Any emergency treatment to a second qualified individual must follow the same process as a first-time emergency use.

Exception from Informed Consent Requirement

FDA regulations permit emergency use of a test article without informed consent where the clinician and an independent physician certify in writing:

1. The patient is confronted by a life-threatening or severely debilitating situation, necessitating the use of the test article.
2. Informed consent cannot be obtained from the patient (because the patient cannot communicate or is incompetent to give consent).
3. Time is not sufficient to obtain consent from the patient's legally authorized representative, and
4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient's life.

If, in the clinician's opinion, immediate use of the test article is required and if time is not sufficient to obtain the independent physician determination, the clinician should make the determination and, **within 3 working days** after the use of the article, have the determination reviewed and evaluated in writing by an independent physician. This is in addition to submitting the Emergency Use Report to IRB **within 3 working days** of the use of the test article.

Clinician Responsibilities

The clinician must determine the following:

- The patient to be treated has a serious or immediately life-threatening disease or condition;
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
- The potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated;
- The probable risk to the person from the test article is not greater than the probable risk from the disease or condition; and
- The provision of the test article for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

Prior to Emergency Use

1. The clinician is responsible for contacting the manufacturer or sponsor to determine if the test article can be made available for the emergency use under the test article's IND (drug, biologic product), or IDE or HDE (device).

2. If the manufacturer does not permit use of the test article under their IND/IDE, the clinician may request emergency use from the FDA by telephone, facsimile, or other means of electronic communication.

Mayo Clinic clinicians may contact the Office of Research Regulatory Support (ORRS) if assistance is needed with the Emergency IND or IDE submission to the FDA. The ORRS may be contacted by internal telephone (77)6-0022 or email to ORRS@mayo.edu.

3. The clinician notifies an IRB on-call Chairperson to inform him/her of the intended emergency use (prior to the emergency use if possible) and, as may be required by the manufacturer, request an Emergency Use Letter to Manufacturer from the IRB.
 - To notify the on-call IRB Chairperson, call the Mayo Clinic (Rochester) main number at 507-284-2511 or (77) 4-2511 requesting the IRB chairperson on-call.

Prior to the use of the test article, the clinician is responsible to obtain a written assessment from a physician not involved in the emergency use as documentation that the proposed emergency use is appropriate (i.e. the conditions for emergency use are met). Note: The physician's independent assessment must be included in the Emergency Use Report submitted to the IRB via the IRB electronic system within **3 working days** of the emergency use of the product. **Three working days includes the day of the emergency use and the day of submission to the IRB.**

4. When informed consent can be obtained, the clinician uses the Emergency Use Authorization form to document authorization from the patient or their legally authorized representative (LAR). The clinician provides a copy to the patient or his/her legally authorized representative.
5. When informed consent cannot be obtained, both the clinician and an independent physician, who is not otherwise participating in the patient's clinical care and management, must certify in writing all of the following [21 CFR 50.23(a)]:
 - The subject is confronted by a life-threatening situation necessitating the use of the test article.
 - Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
 - Time is not sufficient to obtain consent from the subject's legal representative.
 - No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.
6. If, in the clinician's opinion, immediate use of the test article is required to preserve the patient's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinician should make the determination and, **within 3 working days** after the use of the test article, have the determination reviewed and evaluated in writing by a physician who is not participating in the patient's clinical care and management.

After Emergency Use

The clinician completes the IRB Emergency Use Report and submits it to the IRB within **3 working days** of the emergency use of the test article. **Three working days includes the day of the emergency use and the day of submission to the IRB.**

1. The IRB Emergency Use Report will include:
 - The independent physician's assessment of the patient's need for emergency treatment with the test article.
 - Confirmation of permission from the manufacturer/sponsor for the Emergency Use of the test article, if applicable.
 - Signed Emergency Use Authorization form (unless the Exception from Informed Consent Requirement is met).
 - If applicable, written certification from the clinician and an independent physician who is not otherwise participating in the patient's clinical care and management, documenting that the Exception from Informed Consent Requirement is met.
2. The clinician reports any unanticipated adverse event or problem related to the emergency use of the test article to the IRB in the Emergency Use Report.

Use of Patient Data - Drug or Biologic Product

Emergency use of the investigational drug or biologic product is limited to a single patient and data from the single patient use may not be used as part of a prospective research study conducted by the clinician or sponsor of the drug or biologic without IRB approval (Mayo Clinic Legal communication: 12/16/2009).

However, when following FDA regulations and guidance, the emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a participant and the FDA may require data from an emergency use reported in a marketing application (AAHRPP I.7.C).

Use of Patient Data - Device

Emergency use of the investigational device is limited to a single patient and data from the single patient use may not be used as part of a prospective research study conducted by the clinician or sponsor of the device without IRB approval (Mayo Clinic Legal communication: 12/16/2009).

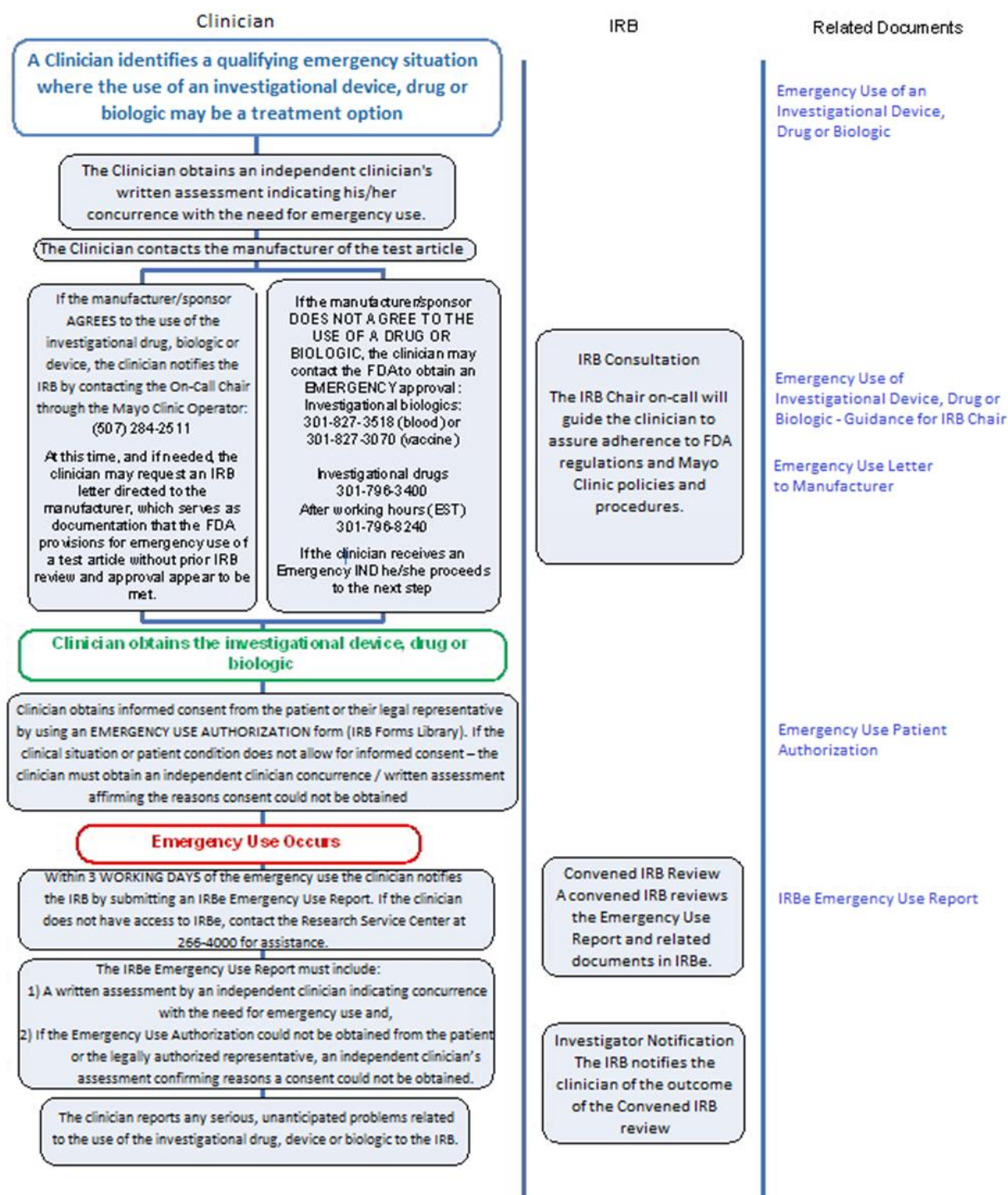
Assistance

The clinician may contact the on-call IRB chairperson for guidance by calling Mayo Clinic Rochester at 507-284-2511 (internal: (77) 4-2511) and requesting the IRB chairperson on-call.

The clinician may contact the Mayo Clinic Office of Research Regulatory Support (ORRS) at 507-266-0022, (77)6-0022, or ORRS@mayo.edu for assistance.

The clinician may contact the IRB Service Center at 507-266-4000, Monday-Friday, 8 am - 5 pm central time.

EMERGENCY USE OF AN INVESTIGATIONAL DEVICE, DRUG or BIOLOGIC



Policy Notes

N/A

Related Procedure(s)

N/A

Related Document(s)

[Emergency Single Case Use of an Investigational Device, Drug or Biologic - Guidance for the IRB Chair](#)

[Emergency Use IRB Letter to Manufacturer \(IRB10048\)](#)

[Emergency Use Authorization Form - Patient or Legally Authorized Representative \(10346\)](#)

[IRB Emergency Use Follow-up application](#)

Definitions

Test Article: Any investigational drug, biologic product, such as blood or a vaccine, or medical device for human use.

Clinician: Licensed physician or other licensed authorized prescriber with a regular (standing) institutional appointment. Requirements at Mayo Clinic are defined in the [“Eligibility as Principal Investigator Policy”](#)

Emergency Use: Use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)].

- Life-threatening includes both life-threatening and severely debilitating diseases or conditions where likelihood of death is high unless the course of the disease is interrupted, and diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival.
- The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened IRB meeting is feasible.

- Severely debilitating: Diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

Investigational New Drug (IND): Investigational New Drug (IND): Application document submitted to the FDA proposing human clinical research to study an unapproved drug, or an approved product for a new indication or in a new patient population in a research study.

New drugs that have not yet been approved by the FDA or approved drugs that have not yet been approved for a new use, and are in the process of being tested for safety and effectiveness. This FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

Investigational Device Exemption (IDE): Application document submitted to the FDA proposing human clinical research to study an unapproved significant risk device, or a cleared or approved device for use other than its approved indication or intent. FDA grants permission so a device that otherwise would be required to comply with a performance standard or to have pre-market approval can be shipped lawfully for the

purpose of conducting investigations of that device. This FDA permission is evidenced by the assignment of an IDE number.

References

[FDA Guidance](#): Emergency Use of an Investigational Drug or Biologic

[FDA Device Advice](#): Comprehensive Regulatory Assistance

[21 CFR 50.23](#) – Exception from general requirements for informed consent

[21 CFR 56.102\(d\)](#) – Emergency Use definition

[21 CFR 56.104\(c\)](#) – Exemptions from IRB Requirement

[21 CFR 812.36](#) – Treatment Use of an Investigational Device

Owner

Pam Kwon on behalf of the Office for Human Research Protections

Contact

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Revision History

Date	Synopsis of Change
September 6, 2017	Minor revision. Updated the following definitions per Glossary review: Emergency Use, Investigational Device Exemption (IDE), Investigational New Drug (IND), and Test Article.
May 22, 2017	Changed the reporting requirement to the IRB from 5 working days to 3 working days and defined 3 working days. Clarified definition of “clinician”. Added that the IND, IDE, or HDE holder is responsible for reporting emergency use, as required, to the FDA. Updated the flowchart embedded in the policy. Updated to the new Policy template.