

Emergency Use of a Test Article (Investigational Drug, Device, or Biologic)	Effective Date	06.08.03
	Revisions Date	7.1.2019

1.0 Purpose: This standard operating practice (SOP) establishes guidelines for emergency use of an investigational drug, device, or biologic according to federal guidelines and in accordance with ECU’s University and Medical Center Institutional Review Board (UMCIRB) practice. This SOP will address physician/investigator responsibilities in the emergency use of an investigational drug, device, or biologic as well as IRB responsibility for review of the emergency use of investigational drugs, devices, or biologics.

2.0 Persons Affected:

2.1 Physicians/investigators who wish to utilize an investigational drug, device, or biologic in an emergency situation when there is not sufficient time to obtain IRB review and approval.

3.0 SOP: The emergency use of an investigational drug, device, or biologic must meet applicable federal and institutional IRB criteria for such use and the IRB must be notified within no more than five business days by the physician/investigator (or their designee) when such use occurs.

4.0 Definitions:

- 4.1 Test article: refers to any drug, biologic, or medical device for human use subject to federal regulation.
- 4.2 Emergency use: is defined as the use of a test article with a human participant in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain UMCIRB approval
- 4.3. Life-threatening: refers to diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted, and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening does not require the condition be immediately life-threatening or to immediately result in death. Rather, the participants must be in a life-threatening situation requiring intervention before review at a convened meeting of the UMCIRB is feasible.
- 4.4 Severely debilitating: refers to diseases or conditions that cause major irreversible morbidity; examples being; blindness, loss of limb, loss of hearing, paralysis or stroke.

5.0 Responsibilities:

- 5.1 Physician/Investigator (or designee) responsibilities include:
 - 5.1.1 consultation with the IRB prior to use of the test article, if time allows;
 - 5.1.2 documentation of the emergency use of a test article via [worksheet](#) on UMCIRB website;
 - 5.1.3 notification of the IRB within no more than five (5) business days of the use of the test article;
 - 5.1.4 notification of the IRB within no more than five (5) business days of the use of waiver of informed consent in an emergency use of a test article (if applicable);
 - 5.1.5 obtaining informed consent of the participant or the participant’s legally authorized representative;
 - 5.1.6 submission of application for prospective IRB review and approval for any subsequent use of the test article;
 - 5.1.6.1 Although Emergency Use provisions are designed to permit only a single

emergency use of a test article for the treatment of an individual within an institution, the regulation is not intended to limit the authority of a physician to provide emergency care in a subsequent life-threatening situation.

5.1.7 providing assurance that no data has been collected for research purposes.

5.2 University and Medical Center Institutional Review Board (UMCIRB) responsibilities include:

5.2.1 Acknowledging the use of the test article meets the federal criteria for emergency use in accordance with FDA regulations;

5.2.2 Verifying that emergency use of a test article without prior UMCIRB review and approval will neither be considered research nor the data from the use be included in any report of a research activity.

5.3 UMCIRB Administrative Director or designee responsibilities include:

5.3.1 ensuring compliance with this SOP;

5.3.2 ensuring appropriate tools/resources are available for review of emergency use of test articles based on new and evolving applicable regulations and guidelines;

5.3.3 assisting the UMCIRB committee/chair in the review of Emergency Use material as needed.

5.3.4 providing written documentation of IRB determinations.

5.4 The IRB Chairperson or designee responsibilities include:

5.4.1 reviewing Emergency Use documentation material to be shared with the convened UMCIRB.

5.4.2 Providing acknowledgement for use if required by manufacturer of test article.

6.0 Procedures:

6.1 The physician/investigator (or designee) identifies the need for emergency use of a test article;

6.1.1 When there is insufficient time, this use can be without prior notification to the UMCIRB office, the IRB Chairperson or designee and without IRB approval;

6.1.2 FDA regulations allow this provided the following criteria are met:

6.1.2.1 the patient is in a life-threatening situation for which no standard acceptable treatment is available, and

6.1.2.2 there is not sufficient time to obtain IRB approval, and

6.1.2.3 the use will be reported to the IRB within no more than five (5) working days by contacting the UMCIRB office and completing the *Emergency Use Worksheet* on the UMCIRB website, and

6.1.2.4 no subsequent use of the test article should occur without prospective IRB review and approval.

6.2 The physician/investigator is required to obtain informed consent of the participant or the participant's legally authorized representative (LAR) unless both the investigator and a physician who is not otherwise participating in the emergency use certify, in writing, all of the following:

6.2.1 the participant is confronted by a life-threatening situation necessitating the use of the test article;

6.2.2 informed consent cannot be obtained because the participant's medical or psychological condition precludes an ability to communicate with or obtain legally effective consent from the participant;

6.2.3 time is not sufficient to obtain consent from the participant's LAR;

6.2.4 no alternative method of approved or generally recognized therapy is available that

- provides an equal or greater likelihood of saving the subject's life.
- 6.3 If immediate use of the test article is required to save the participant's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above are met; the physician/investigator should make the determination, and within no more than five (5) working days after the use of the test article, have the determination reviewed and evaluated in writing by an independent physician who did not participate in the emergency use;
 - 6.4 The participant and/or the participant's LAR must be notified of the emergency use and consent to continue should be obtained for those procedures that require continued or repeated administration;
 - 6.5 The physician/investigator (or designee) will notify the UMCIRB of any reportable events that occur as a result of the emergency use of the test article and the outcome of the patient receiving the test article;
 - 6.6 The emergency use of a test article will be reviewed by the Chairperson (or designee) as it is received and subsequently reported to the full committee at the next convened UMCIRB meeting.
 - 6.7 The UMCIRB office will keep a file of all Emergency Use event reported to the UMCIRB committee.

Revision History:

Date	Change	Reference Section(s)
11.12.14	Revised Format	All sections
7.1.2019	Updated office name throughout from ORIC to UMCIRB; clarify UMCIRB and UMCIRB Chair responsibilities; clarify procedures and update references	All sections, 5.0, 6.7, References

References

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

FDA, Regulations for Institutional Review Boards, Definitions, Emergency Use, [21 CFR 56.102\(d\)](#)

FDA, Regulations for Institutional Review Boards, Exemptions from IRB Requirement, [21 CFR 56.104](#)