UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-015
AAHRPP:	Element I.7.A., Element I.7.B., Element I.7.C. & Element II.4.C.
Date Adopted:	04/11/2019
Last Updated:	1/24/2022
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Emergency Use

1.0 Objective

1.1. To describe the policies and procedures for the use of a Food and Drug Administration (FDA) regulated investigational drug, biologic, or device in a single subject.

2.0 General Description

2.1. The need for an investigational drug, biologic, or device may arise in an emergency situation that does not allow time for submission of an investigational new drug (IND) application or investigational device exemption (IDE) in accordance with federal regulations.

2.2. Principal Investigators (PIs) must obtain prior review and confirmation that use of the article meets FDA criteria by the IRB Chair, or designee, in these situations.

2.3. In accord with FDA regulations, investigators who administer an investigational treatment in an emergency situation, without IRB approval, must submit a report of the use to the IRB within five working days.

2.4. Any subsequent use of the test article in another subject must first receive full IRB review.

2.5. PIs may not use data related to emergency use of a test article in any report of a research activity.

2.6. If use is for a life-threatening or severely debilitating situation but time is sufficient to obtain IRB approval, PIs must follow procedures in the Medical Device SOP.

3.0 Definitions

3.1. **Emergency Use** is the use of a test article (e.g., investigational drug, biologic, or device) on a human subject in a life-threatening or severely debilitating situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

3.2. **Life-threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

3.2.1. Life-threatening situations include diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.

3.2.2. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death.

3.2.3. The subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

3.3. **Severely debilitating** means diseases or conditions that cause major irreversible morbidity.

3.3.1. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

4.0 Responsibility

4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this SOP.

5.0 Procedure

5.1. PI Responsibilities

5.1.1. Before administering the test article, the PI submits an emergency use request directly to the IRB Chair, including:

5.1.1.1. Justification to administer the test article;
5.1.1.2. A copy of the informed consent document and an explanation that the following emergency use conditions are met:
5.1.1.3.1. The subject was confronted by a life-threatening or severely debilitating situation necessitating the use of the test article;
5.1.1.3.2. No alternative method of approved or generally recognized therapy was available that would have provided an equal or greater likelihood of saving the subject's life; and
5.1.1.3.3. Time was not sufficient to obtain IRB approval.

5.1.2. If the IRB Chair is not available, the PI should contact the RCA, or ORIO staff, to identify an appropriate IRB member to serve as the IRB Chair's designee.

The RCA forwards the request to the IRB Vice Chair or a physician member as available.

5.1.3. If the immediate use of the test article is, in the healthcare provider's opinion, required to preserve the life of the patient and time is not sufficient to obtain assessment by the IRB Chair or designee, then the PI proceeds and submits an emergency use request report to the RCA in writing within five (5) working days, including:

5.1.3.1. Justification to administer the test article;
5.1.3.2. A copy of the informed consent document;
5.1.3.3. An explanation that the following emergency use conditions are met:
5.1.3.3.1. The subject was confronted by a life-threatening or severely debilitating situation necessitating the use of the test article;
5.1.3.3.2. No alternative method of approved or generally recognized therapy was available that would have provided an equal or greater likelihood of saving the subject's life; and
5.1.3.3.3. Time was not sufficient to obtain IRB approval.

5.1.4. If the PI proposes to administer the test article in an emergency use situation without informed consent, then the PI proceeds and submits an emergency use request report to the IRB Chair, including:

5.1.4.1. Justification to administer the test article;
5.1.4.2. An explanation that the following emergency use conditions are met:
5.1.4.2.1. The subject was confronted by a life-threatening or severely debilitating situation necessitating the use of the test article;
5.1.4.2.2. No alternative method of approved or generally recognized therapy was available that would have provided an equal or greater likelihood of saving the subject's life; and
5.1.4.2.3. Time was not sufficient to obtain IRB approval.
5.1.4.3. An explanation that the following waiver of informed consent conditions are met:
5.1.4.3.1. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the subject; and
5.1.4.3.2. Time is insufficient to obtain consent from the subject's legal representative.
5.1.4.4. An assessment from a physician who is not participating in the clinical investigation and is qualified in the appropriate medical specialty;
5.1.4.4.1. If the immediate use of the test article without informed consent is, in the healthcare provider's opinion, required to preserve the life of the patient and time is not sufficient to obtain the independent determination by qualified

physician, then the independent evaluation must be provided to the IRB Chair within five (5) working days.

5.1.5. Within five (5) working days of the emergency use, the PI must submit a report to the IRB regarding the emergency use of the test article, including:

5.1.5.1. A brief description of the life-threatening or severely debilitating situation;
5.1.5.2. Justification for use of the test article;
5.1.5.3. Signed consent form or justification for administration without informed consent;
5.1.5.4. Statement of review and evaluation of the situation by a physician who is not participating in the clinical investigation and is qualified in the appropriate medical specialty (if administered without informed consent);
5.1.5.5. Describe the process to control investigational drugs and/or devices so that they are used only in approved research protocols and under the direction of approved Principal Investigator, and;
5.1.5.6. A description of outcome of administration.

5.1.6. Consent will be obtained in accordance with FDA regulations including disclosure of all required and appropriate additional elements of consent, and consent is appropriately documented.

5.1.7. Under FDA regulations, 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 to be reported in a marketing application.

5.2. IRB Responsibilities

5.2.1. The IRB Chair or designee may withhold confirmation or determine the PI can proceed if the following emergency use criteria are met:

5.2.1.1. The subject was confronted by a life-threatening or severely debilitating situation necessitating the use of the investigational drug, biologic, or device;
5.2.1.2. No alternative method of approved or generally recognized therapy was available that provides an equal or greater likelihood of saving the subject's life; and
5.2.1.3. Time was not sufficient to obtain IRB approval.

5.2.2. The IRB Chair or designee forwards the request and their response to the RCA and the RCA processes the request.

5.2.3. At a convened IRB meeting, the RCA informs the IRB that the IRB Chair or designee has assessed a request for emergency use using the regulatory

definition, and the convened IRB verifies the following criteria to approve the emergency use:

5.2.3.1. The subject was confronted by a life-threatening or severely debilitating situation necessitating the use of the investigational drug, biologic, or device;
5.2.3.2. No alternative method of approved or generally recognized therapy was available that provides an equal or greater likelihood of saving the subject's life; and
5.2.3.3. Time was not sufficient to obtain IRB approval.

5.2.4. If the PI fails to submit a request involving emergency use of an investigational test article to the IRB for review and confirmation prior to initiation, or fails to submit the report justifying the emergency use within five (5) working days, the IRB retrospectively reviews the situation.

5.2.4.1. The IRB determines if the test article administration met the regulatory definition and whether failure to comply with this SOP meets the IRB definition of noncompliance.

6.0 References

6.1. 21 CFR 56.102(d);

6.2. 21 CFR 56.104(c);

6.3. 21 CFR 50.23;

6.4. 21 CFR 312.310