

**UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
EMERGENCY USE**

I. PURPOSE

To document the review procedures for a submission regarding Emergency Use of a drug, biologic or device

II. SCOPE

This SOP applies to the IRB administrative staff, IRB members, investigators and sponsors

Personnel Responsible

University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) administrative staff, members, investigators and sponsors

III. BACKGROUND

FDA recognizes that situations arise in which there could be a need to use an investigational drug, biologic or device in a manner inconsistent with the approved protocol or by a physician who is not an investigator on the clinical study. The criteria for emergency use are defined at 21 CFR 56.102(d). The emergency use provision is an exemption from prior IRB review and approval as specified at 21 CFR 56.104(c). While this exemption allows use of a test article in one subject without prospective IRB review, any subsequent use requires prospective review and approval.

The emergency use of an unapproved investigational drug or biologic requires an IND. Should conditions require its use for a subject who does not meet inclusion /exclusion criteria for a protocol, the investigator must contact the sponsor to determine if the drug or biologic can be made available for emergency use under the IND. FDA may also authorize shipment of the test article in advance of an IND submission.

When emergency care is initiated without IRB review or approval, the patient may not be considered a research subject. Such emergency care may not be claimed as research, nor can the outcome be included in any report of a research activity.

Definitions

Emergency Use means the use of an investigational drug or biological product with 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.

Life Threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted, as well as diseases or conditions with potentially fatal outcomes. The criteria for a life-threatening disease or condition 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 means diseases or conditions that cause major irreversible morbidity including blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

Test Article means an unapproved investigational drug, biologic or device.

In Accordance With:

45 CFR 46; 21 CFR 56

Emergency Use of an Investigational Drug or Biologic located at
<http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html>

Emergency Use of Unapproved Medical Devices at
<http://www.fda.gov/cdrh/devadvice/ide/early.shtml#emergencyuse> .

Compassionate Use at
<http://www.fda.gov/cdrh/devadvice/ide/early.shtml#compassionateuse>

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. Full Board approval is required for emergency use or, if it is not possible to convene a quorum within the time available, the Chairperson of UTGSM IRB may concur with the emergency use and the use may proceed without IRB approval. Expedited approval is not allowed.
2. UTGSM IRB will acknowledge of emergency use of a test article, or the Chairperson will concur with the emergency use, or the investigator may proceed without either IRB approval or concurrence of the Chairperson only if all conditions specified at 21 CFR 56.102(d) are satisfied. These conditions are as follows:
 - a. The patient has a life-threatening or serious disease condition requiring immediate treatment.
 - b. There is no generally acceptable alternative for treatment available.
 - c. There is not sufficient time to submit a protocol / amendment to the IRB for approval.

3. If the IRB or the Chairperson concurs with the emergency use, then
 - a. The IRB Chairperson will notify the IRB Assistant Director/designee of his/her action.
 - b. The IRB Assistant Director/designee will use the date of concurrence to initiate tracking to ensure the investigator provides a report to the IRB within five days as required by 21 CFR 56.104(c).
4. If the Sponsor requires a written statement that the IRB is aware of the proposed use and considers the use to meet the requirements of 21 CFR 56.104 (c) in order to approve shipment of the test article, UTGSM IRB will provide such correspondence upon request.
5. UTGSM IRB requires the following patient protection procedures be followed:
 - a. Before the test article is used, the physician will:
 - i. obtain approval of the full IRB or the chairperson's concurrence,
 - ii. obtain informed consent from the patient or his/her legally authorized representative
 - iii. obtain authorization / approval from the sponsor or manufacturer
 - iv. obtain institutional clearance or approval per the individual institution's policies and procedures
 - v. if a medical device is used and does not have an IDE, a report must be submitted directly to the FDA that contains a summary of the conditions constituting the emergency, patient protection measures taken (informed consent), and the results.
 - vi. determine if the test article is likely to be used again; if so, the physician must be designated as an investigator and obtain full IRB approval of an appropriate protocol prior to such subsequent use.
 - vii. Submit all above correspondence and documentation to the IRB as soon as possible, but no later than 5 days after notification of the use.
 - b. Submit a follow-up report within 5 days of the use per 21 CFR 56.104(c) on the patient's condition
 - c. Include the emergency use in the continuing review report for the study as a separate line item
6. The Chairperson will review the documentation submitted and report to the full IRB at the next convened meeting.
7. UTGSM IRB will include in its correspondence to the investigator / physician a statement that "any subsequent use of the investigational product (test article) at the institution requires prospective IRB review and approval."
8. UTGSM IRB requires that, for each situation in which a test article is to be administered and informed consent cannot feasibly be obtained:
 - a. The investigator and a physician who is not otherwise involved in the clinical investigation must certify in writing to the IRB that:
 - i. the subject is confronted by a life-threatening situation necessitating the use of the test article;

- ii. informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject;
 - iii. time is not sufficient to obtain consent from the subject's legally authorized representative; and
 - iv. no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.
 - b. If, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.
9. A copy of all correspondence and documentation concerning the said emergency use will be kept in the IRB files for the study.