UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE CHATTANOOGA/ ERLANGER HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD
EMERGENCY USE

I. PURPOSE

To document the policy and procedures for a submission regarding emergency use of a drug, biologic or device

II. SCOPE

This SOP applies to the IRB administrator, Board members, investigators and sponsor

Personnel Responsible

IRB administrator. Board members, investigators and sponsors

III. BACKGROUND

The FDA recognizes that situations arise in which an investigational drug, biologic or device may be used on an emergency basis in a manner inconsistent with an approved protocol, in the absence of an approved protocol, or by a physician who is not an investigator on a clinical study.

The FDA definition of the conditions under which emergency use is permissible involves two essential components:

1. The presence of a life-threatening situation in which no standard acceptable treatment is available; and
2. Insufficient time to secure prior IRB approval.

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.

Drug/Biologic: The emergency use of an unapproved investigational drug or biologic normally requires an existing IND. If medical circumstances require its use outside an approved protocol, the physician must contact the sponsor to determine if the drug or biologic can be made available for emergency use under the IND. The need for an investigational drug or biologic may also arise in an emergency situation that does not allow time for submission of an IND. In such a case, the FDA may authorize shipment of the test

article in advance of the IND submission. Requests for such authorization may be made by telephone or by other rapid communication method to the FDA.

Device: The FDA recognizes that emergencies arise where an unapproved device may offer the only possible life-saving alternative, but the device must be administered outside an approved IDE and/or protocol. Using its enforcement discretion, the FDA has not objected if a physician chooses to use an unapproved device in a situation that satisfies the conditions for permissible emergency use. The physician must subsequently provide documentation to the FDA that an emergency actually existed.

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.

In accordance with:

21 CFR 50(a)-(c); 21 CFR 56.102(d); 21 CFR 56.102(1); 21 CFR 56.104(c)

FDA Guidance on Emergency Use of an Investigational Drug or Biologic located at http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html-emergency

FDA Guidance on Emergency Use of Unapproved Medical Devices located at http://www.fda.gov/oc/ohrt/irbs/devices.html-emergency

Definitions

Emergency use: 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: 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 meeting of the IRB is feasible.

Severely debilitating: 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: An unapproved investigational drug, biological or device for human use, including human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act.

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

Full Board approval is normally required for emergency use of a test article. If it is not feasible to convene a quorum before the treatment must be administered and the treatment will be administered in a UTCOMC/EHS facility, then the emergency use may proceed only if the IRB Chair and the EHS Chief Medical Officer (who will notify the appropriate institutional officials, as appropriate) concur in its use. If the treatment will be administered in any other institution, emergency use may proceed without IRB approval only if the IRB Chair concurs and the investigator obtains institutional clearance or approval according to the institution's policies and procedures. IRB approval using an expedited review procedure is not allowed.

2. IRB approval or concurrence for emergency use of a drug or biologic will occur only if all of the following conditions are satisfied (specified at 21 CFR 56.102(d)):
   a. The patient has a life-threatening condition requiring treatment before review at a convened meeting of the IRB is feasible;
   b. There is no generally acceptable alternative treatment available; and
   c. There is not sufficient time to submit a protocol/amendment to the IRB for approval.

3. IRB approval or concurrence for emergency use of a medical device will occur only if all of the following conditions are satisfied:
   a. The patient is in a life-threatening condition that needs immediate treatment;

b. There is no generally acceptable alternative treatment available; and
c. Because of the immediate need to use the device, there is no time to use existing procedures to secure FDA approval for use.

4. If approved

If the IRB approves or the Chair concurs with the emergency use, then:

a. The IRB Chair will notify the physician seeking emergency use approval or concurrence;
b. The IRB 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.

5. Informed consent

For any emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative (LAR) unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following (21 CFR 50.23(a)):

a. The subject is confronted by a life-threatening situation necessitating the use of the test article;
b. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject;
c. Time is not sufficient to obtain consent from the subject's legally authorized representative; and
d. 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. Use without IRB approval

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 specified in (5) above apply, the clinical investigator should make the determination and have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation within five working days.

The investigator must submit written documentation regarding the decision to proceed without informed consent to the IRB within five working days after the use of the test article [21 CFR 50.23(c)].

7. Post-Use reporting

The investigator must provide a report on the use of the test article and the outcome for the patient to the IRB within five days as required by 21 CFR 56.104(c) and again at one month after use of the test article. All correspondence and documentation relevant to the use of the test article must be submitted to the IRB as soon as possible, but no later than five days after notification of the use.

8. Sponsor requirements

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, the UTCOMC/EHS IRB will provide such correspondence upon request.

9. Sponsor notification

After emergency use of a medical device, the investigator must notify the sponsor of the emergency use if an IDE for the particular use exists. If an IDE does not exist, the investigator must notify the FDA of the emergency use and provide the FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results. Copies of the correspondence should be submitted to the IRB.

10. Full Board review

If the emergency use of the test article has occurred without approval of the full Board, the Chair will review the documentation submitted and report to the full IRB at the next convened meeting after the documentation is received.

11. IRB correspondence

The IRB will include in its correspondence to the investigator/physician a statement indicating that any subsequent use of the test article at the institution requires prospective IRB review and approval.

12. Record retention

If the emergency use involves a test article utilized in an IRB- approved study, a copy of all correspondence and documentation concerning the emergency use will be kept in the IRB files