

Department: UAMS Institutional Review Board
Policy Number: 18.3
Section: Drugs and Devices
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SUBJECT: Emergency Use of a Test Article

I. Purpose

The purpose of this policy and procedure is to explain the limited circumstances where prior IRB approval is not required in the emergency use of a test article.

II. Definitions

A. Emergency Use means the use of a test article on a patient 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.

B. Test Article means any drug, biological product or medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

C. Life Threatening. Life threatening includes the scope of both life threatening and severely debilitating, as defined below:

Life threatening means 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 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 means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

III. Policy

The IRB acknowledges that there will be certain limited circumstances where IRB approval will not be obtainable prior to the first use of a test article. FDA requirements for emergency use must be met, and the IRB requires prior notification of test article use where possible. The IRB will acknowledge this one time use and require a follow up report within 5 days of the use of the test article.

Any subsequent use of the test article in a new patient will require full IRB review and approval prior to use. Submission of a protocol for review by the convened IRB is required within 30 days as a condition of emergency use.

If a test article has previously been acknowledged under the emergency use provisions, no subsequent uses in a new patient will be acknowledged without an approved protocol. Failure to submit a protocol within 30 days and any additional use of the test article will be treated as continuing non-compliance. For the safety of future patients, submit a protocol immediately after the first use.

Under FDA regulations, emergency use of a drug or biological product is considered a clinical investigation and the patient is considered to be a subject. The FDA may require data from an emergency use to be reported in a marketing application.

Under DHHS regulations, emergency use of a test article is not considered Human Research. Therefore, data from an emergency use cannot be used in any report of research activity subject to DHHS regulations.

IV. Procedures

An Investigator who intends to treat a patient with a test article in an emergency situation should:

A. Confirm situation meets the following emergency use requirements:

1. The patient is in a life-threatening situation
2. There is no standard acceptable treatment available
3. There is not sufficient time to obtain IRB approval.

B. Confirm test article status.

1. Drugs – Contact manufacturer to see if the drug can be made available for emergency use under the company's IND. If that is not an option, contact the FDA who may authorize shipment prior to IND Submission. The Research Support Center will provide assistance if needed.
2. Devices – FDA authorization is not required prior to the emergency use of an unapproved device. However, the manufacturer should be informed of the use in order to meet their IDE reporting requirements.

C. Consent Process. The Investigator should obtain consent from the patient or the legally authorized representative of the patient unless the PI and a physician who is not otherwise participating in the clinical investigation both make all of the following assurances, in writing:

1. Patient is in a life threatening situation;
2. All other available treatments are either unproven or unsatisfactory;
3. Patient is unable to give consent due to their medical condition ; and
4. There is no time to obtain consent from LAR.

If it is the Investigator's opinion that immediate use of the test article is necessary to save the patient's life and time does not permit seeking the opinion of a physician not otherwise involved, the Investigator should make the above determinations and proceed with the use. Within 5 working days after the use of the article, the Investigator must have the use of the test article reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

D. IRB Notification and Follow-up Report.

1. Notification. If possible, notify the IRB when a situation arises that calls for the emergency use of test article. The IRB will ask for confirmation that the situation meets the regulatory requirements for an emergency use. Information that may be requested includes the diagnosis, test article to be used, proposed use, and location of use. The IRB will acknowledge the intended use.

2. Follow-up Report. Within 5 days of the use of test article, the Investigator should submit a follow up report to the IRB that includes

- a. Name of test article used and date of IRB acknowledgement, if applicable
- b. Date, time and location of use
- c. Patient's diagnosis and outcome if known
- d. Any adverse events or unanticipated problems
- e. Copy of the signed informed consent. If consent was not obtained, provide the assurance letters from the Investigator and the independent physician as outlined in section C above.

3. IRB Review. The IRB will review the follow-up report to determine whether FDA regulatory requirements were met. If FDA regulations were not met, the matter will be handled according to IRB policies and procedures for non-compliance.

E. Protocol Submission. Within 30 days of first use, the Investigator must submit a New Protocol Submission in ARIA for review by the convened IRB.