Department: **UAMS Institutional Review Board**

Policy Number: **18.3**

Section: **Drugs and Devices**

Effective Date: **July 31, 2002**

Revision Dates: **February 8, 2005; August 26, 2004; March 5, 2008**

SUBJECT: Emergency Use of a Drug or Biologic (Source *FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update*)

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 an investigational drug or biologic.

Definitions:

Emergency Use means the use of a test article on 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.

Test Article. A test article is defined as any drug, biological product or medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act. As used hereafter, it shall only apply to investigational drugs or biological products. Emergency Use of a Medical Device is addressed in Policy 18.4.

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.
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> 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.

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. The IRB will acknowledge this one time use and require a follow up report. Any subsequent use of the test article will require full IRB review and approval prior to use. However, FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had time to convene a meeting.

Warning: Submission of a standing protocol is required within 30 days as a condition of emergency use

Warning: No new emergency uses will be granted without the protocol and failure to submit a protocol within 30 days will be treated as continuing non-compliance. For your patient's safety, please submit a protocol immediately.

Under FDA regulations emergency use of a test article is considered research. Under DHHS regulations emergency use of a test article is not research because it is not a systematic investigation designed to generate or contribute to generalizable knowledge. To maintain this distinction data from an emergency use cannot be used in any report of a prospectively conceived research activity.

Procedure:

1. Principal Investigator will:

1.1 Obtain an IND (Investigational New Drug) number from the manufacturer, if possible, or if the manufacturer elects not to name the PI on the IND, the PI should then contact the FDA directly for an IND or obtain evidence of an IND Exemption.

1.2 Notify the IRB, verbally, when a situation arises that calls for the emergency use of an investigational drug or biologic without an approved study protocol to obtain a determination from the IRB chair that the situation meets the regulatory requirements for an emergency use, and submit a letter to the IRB stating the following;

a. The participant was in a life-threatening situation
b. There is no standard acceptable treatment available
c. There is not sufficient time to obtain IRB approval.
d. The diagnosis, test article to be used and proposed use, and hospital.

1.3. Obtain the consent of the participant or the legally authorized representative of the participant unless the PI and a physician who is not otherwise participating in the clinical investigation both make all of the following assurances:

a. Participant in a life threatening situation
b. All other available treatments are either unproven or unsatisfactory
c. Participant unable to give consent due to their medical condition
d. There is no time to obtain consent from LAR

1.4. If in the PI's opinion, immediate use of the test article is necessary to

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

1.5 Within 5 days of the use of test article, the PI should submit a follow up report to the IRB that includes

a. Name of test article used, detailed conditions of use and date of IRB verbal acknowledgement
b. Date, time and location of use
c. Participant's diagnosis and outcome if known
d. Any adverse events or unanticipated problems

e. Copy of the signed informed consent OR letters from the PI and the independent physician stating:

i.. The participant was in a life threatening situation
ii. All other available treatments were either unproven or unsatisfactory
iii. The participant was unable to give consent due to their medical condition
iv. There was no time to obtain consent from a LAR

1.6 Evaluate the likelihood of needing to use the test article again. If additional use is anticipated, immediately submit protocol and consent for full IRB review under separate ARIA submission

2. IRB Chair or Vice Chair will:

2.1 Evaluate the Investigator's notice of intent to use a test article under these guidelines to determine whether FDA regulatory requirements are met.

2.2 Request the information listed in 1.2, assessment of consent process, or any other materials that will aid in the evaluation.

2.3 Provide initial verbal acknowledgement and shortly thereafter, written acknowledgement, through ARIA, of intent to use test article.

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

2.5 Arrange for full committee notification on next available agenda.