Department: **UAMS Human Research Advisory Committee**
Policy Number: **18.3**
Section: **Drugs and Devices**
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SUBJECT: Emergency Use of a Test Article

In a clinical investigation, emergency use of a test article is exempt from the requirement of HRAC review, provided that such emergency use is reported to the HRAC within 5 working days. Any subsequent use of the test article at the institution is subject to HRAC review (21CFR56.104c; 45CFR).

Emergency Use. Emergency use is defined as 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 HRAC approval (21CFR56.102d; 45CFR).

Test Article. A test article is defined as any drug (including a biological product for human use), 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 [42USC262 and 263b-263(n);21 CFR56.102(j); 45 CFR].

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 HRAC 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.

Institutional procedures may require that the HRAC be notified prior to such use, however, this notification should not be construed as an HRAC approval. Notification should be used by the HRAC to initiate tracking to ensure that the investigator files a report within the five day time-frame required by 21 CFR56.104c; 45 CFR. The FDA regulations do not provide for expedited HRAC approval in emergency situations. Therefore, "interim," "compassionate," "temporary" or other terms for an expedited approval process are not authorized. An HRAC must both convene and give "full board" approval of the emergency use or, if the conditions of 21 CFR56.102d and 45 CFR are met and it is not possible to convene a quorum within the time available, the use may proceed without any HRAC approval.

Consent. Even for an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the requirements of exception for consent in emergency research detailed in section 15.2 of this manual.

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 the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The

investigator must notify the HRAC within 5 working days after the use of the test article [21 CFRIf, 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 the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the HRAC within 5 working days after the use of the test article [21 CFR50.23(c); 21 CFR56; 104(c).