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

POLICY

While the IRB should be notified of intended emergency use of a test article before use, prior IRB approval is not required under certain circumstances. Other reporting requirements apply, regardless of whether prior IRB approval was obtained.

DEFINITIONS

A. **Emergency Use:** The use of a test article on a patient in a life-threatening situation in which no standard acceptable treatment is available.
B. **Test Article:** 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:** Includes the scope of both life threatening and severely debilitating, as defined below.
    1. Life threatening are diseases or conditions where the likelihood 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.
    2. Severe debilitation 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.

PROCEDURE

A. The IRB strongly encourages, but does not require, prior notification of emergency use of a test article when possible, using the emergency use notification/follow-up report form in the IRB e-system. However, time constraints may make this prior notification impossible. In these instances, FDA requirements for emergency use must be met before the use may proceed.
B. If a prior notification is submitted, the documents should include:
    1. A patient history and treatment plan
    2. Intended route, dose, frequency, and duration of treatment.
    3. Criteria for discontinuation of treatment and planned dose modifications for adverse events

4. A description of the intended consent process to be used, if any.
5. A copy of the informed consent form to be used, if any, ensuring it includes information required under 21 CFR.50.25, the FDA regulation pertaining to informed consent. Note the consent form must be adapted throughout to clarify that this is a treatment program and not a research study.
6. Information about the test article, such as an investigator's brochure or device manual, if available.

C. If it is not possible to notify the IRB prior to use, the use must be reported to the IRB within 5 working days of the use of the test article, using the emergency use follow-up notification form in the IRB esystem.

D. A 5-day follow-up report, using the follow-up report form, shall also be required if the IRB was notified prior to use.

E. The 5-day follow-up report shall include
1. Name of test article used and date of I RB acknowledgement, if applicable
2. Date, time and location of use
3. Patient's diagnosis and outcome if known
4. Any adverse events or unanticipated problems
5. Unsigned copy of any informed consent form used in a consent process and an attestation that consent was obtained. The form should be unsigned to promote patient privacy. If written consent was not obtained, provide the assurance letters from the Investigator and the independent physician as outlined in section J below.

F. If the IRB is notified prior to use, the report must be reviewed by the convened IRB, UNLESS the physician/investigator provides documentation that the FDA has authorized alternative IRB review procedures. The documentation can be either:
1. A copy of the completed FDA Form 3926, Individual Patient Expanded Access lnvestigational New Drug Application, with box 10b checked.
2. A copy of any correspondence with the FDA indicating such authorization, including an email sent by the treating physician to the FDA confirming a phone discussion or other communication.

G. For an emergency use involving an investigational drug or biologic, the investigator must comply with institutional policies regarding receipt, storage, and dispensing of the test article.

H. ACH Use: Please contact the Arkansas Children's Research Institute Pharmacy at (501) 364-2596 and ask to speak with a Research Pharmacist. If a situation arises after normal business hours or on weekends and must be addressed immediately before the next business day, call the ACH Inpatient Pharmacy at (501) 364-4822 and ask to speak to a pharmacist. Please explain the situation, provide contact information, and request that a Research Pharmacist be notified.

I. UAMS Use: Please contact the UAMS Medical Center Research Pharmacy at (501} 6866246 and ask to speak with a Research Pharmacist. If a situation arises after normal business hours or on weekends and must be addressed immediately before the next business day, call the UAMS Medical Center Inpatient Pharmacy at (501) 686-6221 and ask to speak to a pharmacist. Please explain the situation, provide contact information, and request that a Research Pharmacist be notified.

J. Even for an emergency use, the informed consent of the subject or of the subject's legally authorized representative is to be obtained unless both the investigator/treating physician and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:
    1. The subject is confronted by a life-threatening situation necessitating the use of the test article
    2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
    3. Time is not sufficient to obtain consent from the subject's LAR
    4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

H. Informed consent shall meet the requirements described at 21 CFR 50.25. The IRB retains the authority to determine whether these requirements are met or if written certification as described above will be required.

I. Any subsequent use of the test article in a new patient will require IRB review and approval prior to use. However, the IRB acknowledges is would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB does not have sufficient time to review the subsequent use.

J. Under FDA regulations, emergency use of a test article 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.

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

L. Emergency use of a HUD not covered under a separate HUD submission, and/or a proposed emergency use outside the HUD's approved indication(s), shall be subject to the requirements of this policy.

M. Nothing in this policy shall require a manufacturer to make a test article available for emergency use. Physicians/investigators should seek the manufacturer's approval for this use prior to beginning the IRB submission process.

REFERENCES

21 CFR 50.23
21 CFR 312 Subpart I
FDA Information Sheet: *Emergency Use of an Investigational Drug or Biologic* (January 1998)
FDA Guidance: *Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors. Frequently Asked Questions About Medical Devices* (January 2006)
FDA Guidance: *Humanitarian Device Exemption Program* (September 2019)
FDA Webpage: *Expanded Access for Medical Devices*
FDA Guidance: *Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products. Guidance for IRBs and Clinical Investigators* (September 2023)