Department: **UAMS Institutional Review Board**
Policy Number: **17.14**
Section: **Special Populations**
Effective Date: **January 20, 2022**
Revision Dates:

SUBJECT: Planned Emergency Research at UAMS

Policy:
Planned emergency research, also known as emergency research done under an Exception from Informed Consent (EFIC) requirements, may be carried out as long as doing so complies with relevant institutional policy and this policy.

Definitions:
Community in which the research will be conducted: The geographic area (hospital, city, or region) where the hospital or clinical investigator study site is located.
Community from which the subjects will be drawn: The group of patients sharing a particular medical or other characteristic that increases the likelihood they or a family member may be enrolled in the EFIC research.
Exception from informed consent requirements for emergency research, or EFIC research: Research meeting requirements described at 21 CFR 50.24 and/or the 1996 OHRP letter on EFIC research, as applicable, allowing research to proceed without the prior consent of participants or their legally authorized representative. The requirements are, in summary:

- The subjects are in a life-threatening situation and available treatments are unproven or unsatisfactory;
- Obtaining informed consent is not feasible;
- Participation in research holds out the prospect of direct benefit;
- The research could not be carried out without a waiver of informed consent;
- The investigator has a plan to attempt to reach a legally authorized representative for consent during the potential therapeutic window;
- The reviewing IRB has reviewed and approved informed consent procedures, and appropriate additional protections of subjects' rights and welfare are in place.

See the regulation/letter for the full requirements.

Planned emergency research: Same as EFIC above.
EFIC research conducted or supported by HHS – Research meeting the EFIC definition that, because of HHS involvement, is subject either solely to HHS regulations or, if it involves an FDA-regulated product, to both the FDA and HHS regulations pertaining to the protection of human subjects. EFIC research conducted or supported by HHS may not include prisoners or pregnant women.
Note: EFIC research is NOT the same as Emergency Use of a Test Article. See IRB Policy 18.3 for Emergency Use requirements.

Procedures:
I. Until further notice, only EFIC studies that do not originate at UAMS (i.e. are NOT UAMS-investigator initiated) and for which UAMS is not the lead site will be allowed to proceed at UAMS.

II. UAMS will not serve as the reviewing IRB for EFIC studies except to the extent described below. IRB review will be ceded to an external IRB (xIRB) as described in IRB policy 2.3, *Use of Central IRBs.*
III. The UAMS IRB's oversight role shall be limited to a local context review of the study's plans for community consultation and public disclosure and any other routine local context review issues, as applicable, such as consent form wording.In its review of the community consultation and public disclosure components, the UAMS IRB shall confirm the proposed community consultation plan:
    A. Informs the communities that informed consent will not be obtained for most (or all) research subjects, including an explanation as to why consent is not feasible.
    B. Informs the communities about all relevant aspects of the proposed study, including potential risks and expected benefits.
    C. Hears and responds to the perspective of the communities on the proposed research.
    D. Provides information about ways, if any, in which individuals wishing to be excluded from the research indicate this preference.
    E. Includes the people most likely to be affected by the research.
IV. The UAMS IRB shall retain the authority to require changes to the community consultation and public disclosure components.
V. Nothing in this policy shall prohibit any UAMS IRB member from observing or otherwise participating in community consultation and public disclosure process; such participation/observation is strongly encouraged.
VI. In its review related to local context and the xIRB reliance process, the UAMS IRB shall confirm, as necessary:
    A. The xIRB is duly constituted and ensures the relevant requirements at 21 CFR 50.24, 56.11, and Part 50, Subpart D are met and documented, including, but not necessarily limited to:
        1. The concurrence of a licensed physician who was a member or consultant to the IRB and otherwise not participating in the clinical trial was obtained
        2. The requirements at 21 CFR 50.24; 56.11; and Part 50, subpart D if the study will enroll minors, were met, if the research is subject to FDA oversight; and that the requirements in the October 31, 1996, OHRP/OPRR letter titled "Informed Consent Requirements in Emergency Research" requirements are met if the research is not subject to FDA oversight.
    B. Any other requirements related solely to the local context are met, e.g. appropriate language in any consent or recruitment materials.

REFERENCES

FDA Guidance titled *Exception from Informed Consent Requirements for Emergency Research*
1996 OPRR/OHRP letter titled *Informed Consent Requirements in Emergency Research*
UAMS IRB Policy 2.3, *Use of Central IRBs*
21 CFR 50.24; 21 CFR 50 Subpart D; 21 CFR 56.11