

Department: UAMS Institutional Review Board
Policy Number: 18.1
Section: Drugs and Devices
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SUBJECT: Review of Investigational New Drug (IND) Studies

POLICY

Research that involves the use of a drug, other than a marketed drug used in accordance with its labeling or in the course of medical practice, shall be evaluated to ensure it has an appropriate investigational new drug application (IND), as may be required. The IRB shall evaluate all studies which involve the use of an IND drug in accordance with applicable FDA regulations.

All local-investigator-initiated human research studies that may require an IND shall be evaluated by the Office of Research Regulatory Affairs before they are reviewed by the UAMS IRB. All projects requiring an IND are subject to UAMS Administrative Guide Policy 16.1.10.

PROCEDURE

A. Investigator Process

1. For local-investigator-initiated research, the study team shall consult with ORRA during the submission process to determine the need for an IND.
2. For studies conducted under a valid IND, the investigator must provide the IND number in the IRB e-system and submit documentation to confirm the IND's validity. Acceptable documentation is one of the following:
 - a. Industry-sponsored study protocol including the IND number
 - b. Written communication of the IND number from the sponsor
 - c. Written communication of the IND number from the FDA
3. For studies exempt from the IND requirements, investigators are to provide sufficient information to document the study meets one of the exemption categories described at 21 CFR 312.2(b), or is not subject to IND requirements under another relevant guidance such as the FDA Guidance titled *IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer*. Acceptable documentation is one of the following:
 - a. Industry-sponsored study protocol indicating the study is exempt from IND requirements.
 - b. Separate written communication from the sponsor indicating the study is exempt.
 - c. Written communication from the FDA indicating the study is exempt.

B. IRB Review Process

1. The IRB office, as part of its submission preview, shall confirm the appropriate regulatory consultation has occurred and that adequate documentation is present to support the determination of whether or not an IND is needed. If the appropriate regulatory consultation has not occurred, ORRA will be notified.
2. If an IND is required, the pre-reviewer shall confirm supporting documentation, such as a consent form addressing FDA requirements and the investigator's brochure or equivalent, are submitted.
3. The IRB office pre-reviewer will confirm that investigational product handling has been determined by the relevant institution(s)' pharmacy policy.
4. The IRB may proceed with a review of an investigator-initiated IND study while the IND submission is pending with FDA only if the study is expected to require an IND.
 - a. In these cases, the IRB will review the study under the assumption an IND will be required.
 - b. If the IRB grants its final approval before the IND is obtained, the approval letter shall include a note that the study may not begin until FDA approval is obtained and any FDA-required changes are submitted to the IRB as modifications and approved.
5. If it is unknown whether a study will require an IND, and it is submitted to the FDA primarily for a

determination of whether an IND is required, the IRB will not review the study until the FDA response is received.

REFERENCES

21 CFR 50

21 CFR 56

21 CFR 312

AAHRPP Elements I.7.A and I.7.B

AAHRPP Tip Sheet: Following the Guideline of the International Conference on Harmonisation – Good Clinical Practice (E6)

FDA Guidance titled *Guidance for IRBs, Clinical Investigators, and Sponsors IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed*