

Department: UAMS Institutional Review Board
Policy Number: 2.2
Section: Relationships
Effective Date: July 31, 2002
Revision Date: November 18, 2002; March 5, 2004; February 8, 2005; January 24, 2011;
August 6, 2015; February 15, 2016; June 5, 2020; July 29, 2020;
September 15, 2023, June 24, 2025; September 17, 2026

SUBJECT: IRB Relationship to Other University or Affiliated Committees/Departments

POLICY

The UAMS IRB functions independently of other committees and departments at UAMS. The IRB will work cooperatively with other university or institutional committees and departments. However, the IRB retains the authority to determine whether a research proposal adequately protects human subjects. The IRB is solely responsible for determining the criteria for approval are met, as described in IRB Policy 7.1; determining the appropriateness of consent processes and materials; making exemption determinations; and for ensuring Belmont Report principles are upheld in all research, including exempt research. Research may not begin until all required institutional and IRB approvals are obtained.

PROCEDURE

- A. The IRB office will review new submissions and any relevant modifications to ensure other committee/department reviews and approvals have been obtained or are in process.
- B. The other committees/departments that review research include, but may not be limited to:
 1. **Institutional Biosafety Committee (IBC)** or other appropriate safety committee:
 - a. Human research involving potentially hazardous agents or Human Gene Transfer requires review and approval by the appropriate safety committee in addition to review and approval by the IRB.
 - i. Potentially hazardous agents include, but are not limited to the following:
 - a. Recombinant or synthetic nucleic acid molecules
 - b. Microorganisms or infectious agents handled at BSL-2 or BSL-3
 - c. Biologically derived toxins; regulated toxins
 - d. Human blood, blood products, body fluids, tissue, cells/cell lines, or other potentially infectious material (OPIM)
 - e. Highly toxic or carcinogenic (known or suspected) compounds
 - ii. Human Gene Transfer is defined by the *NIH Guidelines* as the deliberate transfer into human research participants of either:
 - a. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
 - b. Synthetic nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules
 2. **Radiation Safety Committee (RSC):** Human research involving exposing subjects to radiation through x-rays or radionuclides to which the subject would otherwise not be exposed except for the research must receive approval from the appropriate RSC.
 3. **Tissue Use Committee (TUC):** The TUC reviews research studies proposing the use of biospecimens and data from biorepositories under the oversight of the Tissue Banking and Procurement Service. The committee assesses whether the proposed use is appropriate and whether adequate resources are available to fulfill the request.
 4. **Academic Conflict of Interest Committee (ACOIC) and Institutional Conflicts of Interest Committee (ICOIC):** Per UAMS Administrative Guide Policies related to Conflict of Interest ("COI"), Academic Staff Members and Institutional Officials are required to disclose Significant Interests to the UAMS Conflict of Interest Office. Once the appropriate COI Committee has determined a Conflict exists, the IRB is notified of the Committee's finding and provided a copy of the related COI management plan(s) when the conflicted research includes human subject research. In its review of research, the IRB shall determine if the conflict and its management as described in the management plan affect the criteria for approval of research. The IRB retains the authority to approve consent form language and to determine whether the conflict and the COI management plan allow the research to be approved by the IRB. If a related research interest is reported after IRB approval and results in a COI management plan, the IRB will re-review the

study and the management plan. The IRB may require additional measures beyond the bias mitigation techniques employed in a researcher's Conflict of Interest Management Plan. If an external IRB is the IRB of record for research affected by a management plan, the UAMS IRB, in its local context review, will remind the study team to notify the reviewing IRB of the management plan in accordance with the study's reliance agreement.

5. **Pharmacy Approval:** Pharmacy approval from the involved institution's pharmacy will be required prior to granting final IRB approval for research involving the pharmacy.
 6. **Office of Research Regulatory Affairs (ORRA):** UAMS-sponsored research involving investigational drugs, devices, or biologics shall be reviewed by ORRA to determine whether an IND or IDE is needed.
 7. **Legal Review:** Studies involving the transfer of or access to UAMS data, biological materials, UAMS proprietary information, the receiving of external funds, or the provision of UAMS funds (including Federal pass through funds) to an external entity, shall be reviewed by the Office of General Counsel to determine if a research or procurement contract is necessary. When a contract is necessary, the Study may not begin until the contract is in place.
 8. **Other Committees/Reviews:** Research projects may be subject to review and approval of other committees or ancillary reviews where the research is being conducted or for certain types of research (Examples: Translational Research Institute, Protocol Review and Monitoring Committee, Disease-Oriented Committees, Office of Research and Sponsored Programs, Laser Safety Committee, Artificial Intelligence Governance Committee (AIGC)). These committees may assess items such as a protocol's scientific or scholarly validity, availability of resources, whether the local site has a sufficient potential study population, and to ensure compliance with federal, state or institutional rules and regulations.
- C. When possible, other committee reviews will be completed before the IRB review occurs.
1. The IRB has the authority to hold its review until other committee reviews are complete, if the IRB determines those reviews relate to information the IRB needs to make required determinations.
 2. The IRB may review and approve a study before other reviews are complete if the IRB determines it has enough information to make its required determinations before the reviews are finalized. The approval letters for these reviews will include a notation that the study may not begin until
 - a. All relevant committee approvals are obtained AND
 - b. Any changes required by other committees will be submitted to and approved by the IRB before implementation.
- D. Investigators shall:
1. Seek approval from other committees/departments as required by the IRB or institutional requirements prior to commencing the research project.
 2. Ensure that all recommendations and requirements are incorporated and submitted to and approved by the IRB before implementation.

REFERENCES

45 CFR 46.111

21 CFR 56.111

UAMS IRB Policy 7.1, Criteria for IRB Approval of Research

UAMS IRB Policy 7.3, Exempt Categories of Research

AAHRPP Elements I.1.C, I.1.F, I.6.A, I.6.B, III.1.B, III.2.A

AAHRPP Tip Sheet, Financial Conflict of Interest for Researchers and Research Staff