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

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

POLICY
The UAMS IRB functions independently of other committees and departments at UAMS. The IRBs 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, and for determining the appropriateness of consent processes and materials.

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):** Human Research involving the collection of biological samples from human subjects or the direct and deliberate transfer of biologically derived products listed below into human subjects must receive approval from the appropriate IBC before final IRB approval may be granted:

    a. Experimentation using BL2 or BL3 infectious microorganisms.
    b. Experimentation or manipulation of samples, cells, or tissues from humans
    c. Experimentation using highly toxic or carcinogenic (known or suspected) compounds.
    d. Recombinant DNA, if BL2 or BL3 organisms are involved or if genetic modification might increase pathogenicity, transmissibility, host range or antibiotic resistance of a
    e. pathogen, or transfer toxin gene(s) lethal for vertebrates at dose of <100 ng/kg
    f. Human gene therapy even if the recombinant DNA is produced elsewhere.

2. **Radiation Safety Committee (RSC) :** Human Research involving exposing human subjects to radiation through x-rays or radionuclides for which the subject would otherwise not have been exposed except for the research must receive approval from the appropriate RSC.

3. **Academic Conflict of Interest Committee (ACOIC) and Institutional Conflicts of Interest Committee (ICOIC):** Actual or perceived conflicts of interest as per institutional policies must be reported to the COIC or ICOIC as appropriate. If either committee determines a conflict exists and that a management plan will be required, the management plan will be provided to the IRB. If any research related to the conflict subject to the management plan is not yet approved, the IRB shall determine if the conflict affects the IRB approval criteria. If the IRB is notified of the management plan after IRB approval, the study may be re-reviewed regardless of any previous IRB approval to ensure that any human subject protection concerns affected by the management plan are addressed. The IRB has the final authority to determine whether the conflict and the management plan as written allow the research to be approved. While the committees may provide suggested language to be used to disclose the conflict in the consent form, the IRB retains the authority to require changes to the suggested language.

4. **Pharmacy Approval**: Pharmacy approval from the involved institution's pharmacy will be required prior to granting final IRB approval for research involving the pharmacy.

5. **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.

6. **Other Committees.** Research projects may be subject to review and approval of other committees 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). These committees may assess items such as a protocol's scientific or scholarly validity, availability of resources, and whether the local site has a sufficient potential study population.

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 in cannot review the study before those reviews are finalized.
   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 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

UAMS IRB Policy 7.1, Criteria for IRB Approval of Research
45 CFR 46.111
21 CFR 56.111
AAHRPP Elements I.1.F, I.6.A, I.6.B, III.1.B, III.2.A,
AAHRPP Tip Sheet 20, Sufficient Information to Determine Whether the Criteria for Approval Are Met