

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

SUBJECT: To Other University or Affiliated Committees/Departments

I. Purpose

The purpose of this policy and procedure is to explain how the IRB coordinates its review with other committees from UAMS or affiliated institutional committees or departments.

Policy: The UAMS IRBs function independently of (but coordinates its activities with) other committees and departments at UAMS. The IRBs will work in conjunction with other university or institutional committees; however, it will review research projects independently to ensure that human subjects will be adequately protected.

1. As appropriate to the type of research proposed and therefore the other committee approvals required, the IRB will grant its approval as follows:

1.1 Institutional Biosafety Committee (IBC): Human Research involving 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:

- 1.1.1 Experimentation using BL2 or BL3 infectious microorganisms.
- 1.1.2 Experimentation using carcinogenic (known or suspected) or highly toxic compounds.
- 1.1.3 Recombinant DNA, if BL2 or BL3 organisms are involved or if genetic modification might increase pathogenicity, transmissibility, host range or antibiotic resistance of a pathogen. The transfer of toxin genes lethal for vertebrates at an LD of <100 ng/kg
- 1.1.4 Modification of the germline genes of animals (transgenic).
- 1.1.5 Human gene therapy even if the recombinant DNA is produced elsewhere.

The IRB may grant final approval pending approval of the IBC. The PI must submit a modification to the IRB if the IBC requires any changes to the study.

1.2 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 before final IRB approval may be granted. The IRB may grant final approval pending approval of the radiation safety committee. The PI must submit a modification to the IRB if the RSC requires any changes to the study.

1.3. Conflicts of Interest Committee (COIC) and Institutional Conflicts of Interest Committee (ICOIC):

Research involving any actual or perceived conflicts of interest as *per* institutional policies must receive approval from 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 the research 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 review, 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.

1.4 Pharmacy Approval. Pharmacy approval from the involved institution's pharmacy will be required prior to granting final IRB approval.

1.5 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, Office of Research and Sponsored Programs, Office of Research and Regulatory Affairs) Approval from such other committees may not be required prior to IRB final approval, however, the research should not begin until those approvals are obtained.

2. Investigators will, as applicable:

- 2.1** Seek approval from other committees as required by the IRB or institutional requirements prior to commencing the research project.
- 2.2** Ensure that all recommendations and requirements are incorporated and submitted to and approved by the IRB before implementation.