Department: **UAMS Institutional Review Board**
Policy Number: **2.2**
Section: **Relationships**
Effective Date: **July 31, 2002**
Revision Dates: **February 8, 2005; March 5, 2004; November 18, 2002**

SUBJECT: To Other University or Affiliated Committees/Departments

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, CAVHS, ACH and ACHRI. The IRBs will work in conjunction with other university or institutional committees; however, it will review research projects independently to ensure that human participants 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: Research involving the direct and deliberate transfer of biologically derived products listed below into human participants must receive approval from the appropriate Biosafety Committee before final IRB approval may be granted: The IRB may grant final approval pending approval of the Institution's Biosafety Committee. The IRB Chair or experienced IRB member designated by the Chair will review the approval of the Institution's Biosafety Committee. If the approval raises issues or questions that are directly relevant to the determinations required by the IRB, or request more than minor changes to the research approved by the IRB, the information or changes will be placed on the agenda of a convened IRB meeting for review. Otherwise, the IRB Chair or experienced IRB member designated by the Chair may grant final approval under expedited procedures.

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_{50} 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.

1.2 Radiation Safety Committee: Research involving exposing human subjects to radiation through x-rays or radionuclides for which the participant would otherwise not have been exposed except for the research must receive approval from the appropriate Radiation Safety committee before final IRB approval may be granted. The IRB may grant final approval pending approval of the radiation safety committee. The IRB Chair or experienced IRB member designated by the Chair will review the approval of the Radiation Safety Committee. If the approval raises issues or questions that are directly relevant to the determinations required by the IRB, or request more than minor changes to the research approved by the IRB, the information or changes will be placed on the agenda of a convened

IRB meeting for review. Otherwise, the IRB Chair or experienced IRB member designated by the Chair may grant final approval under expedited procedures.

1.3. Conflicts of Interest Committee: Research involving any actual or perceived conflicts of interest as *per* institutional policies. The IRB will not review research with a declared financial interest until the Conflicts of Interest Committee has completed its evaluation and any management. The written determination of the Conflicts of Interest Committee, and the reasons for those determinations will be provided to all IRB members for review at a convened meeting. ORSP maintains all the annual disclosures of conflicts of interest and the proposed management plan and will upon request provide the annual conflict of interest disclosure forms to the IRB Director, IRB Chair or their Designee. The IRB Director/Chair/Designee shall have access to conflict disclosures which may assist in forming the basis to ascertain the level of conflict or changes in conflict using the following criteria: If the financial conflict of interest management plan affects the IRB approval criteria, the IRB will not approve the project. The IRB may require the consent to reveal any conflict and management plan, even if the approval criteria are not affected.

1.4 Pharmacy Approval. Pharmacy approval from the involved institution's pharmacy will be required prior to granting final IRB approval. The IRB may grant final approval pending approval of the institution's pharmacy. The IRB Chair or experienced IRB member designated by the Chair will review the approval of the institution's pharmacy. If the approval raises issues or questions that are directly relevant to the determinations required by the IRB, or request more than minor changes to the research approved by the IRB, the information or changes will be placed on the agenda of a convened IRB meeting for review. Otherwise, the IRB Chair or experienced IRB member designated by the Chair may grant final approval under expedited procedures.

1.5. CAVHS R&D Committee. The IRB may grant final approval pending approval of R&D Committee. An approval letter from the R&D Committee stating that their approval is only contingent on IRB approval will be acceptable in order for final IRB approval to be granted. The IRB Chair or experienced IRB member designated by the Chair will review the approval of the R&D Committee. If the approval raises issues or questions that are directly relevant to the determinations required by the IRB, or request more than minor changes to the research approved by the IRB, the information or changes will be placed on the agenda of a convened IRB meeting for review. Otherwise, the IRB Chair or experienced IRB member designated by the Chair may grant final approval under expedited procedures.

1.6 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: GCRC, PRMC, grants and contracts office). Approval from such other committees will not be required prior to IRB final approval. 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 Institution requirements.

2.2 Ensure that all recommendations and requirements are incorporated and submitted to and approved by the IRB before implementation.