Department: UAMS Institutional Review Board

Policy Number: 1.6

Section: Principles and Authority

Effective Date: February 8, 2005

Revision Dates: NA

SUBJECT: Access to General Counsel

Purpose:

The purpose of this policy and procedure is to facilitate IRB access to General Counsel.

Policy:

All legal matters pertaining to the University are the responsibility of the Office of General Counsel. Assistance of the General Counsel must be requested for all contractual matters not otherwise delegated to the Office of Research and Sponsored Programs; existing or potential lawsuits; threats of violence; official inquiries, audits, and compliance visits from regulatory agencies or quasigovernmental organizations such as accrediting bodies; or other situations which may have legal consequence. In addition, the General Counsel, either through the University department designated to handle the specific matter or through direct contact, should be consulted in situations which by their nature give rise to legal concerns such as employee termination, charges of discrimination, crimes, tenure and promotion denial complaints, OCR and OHRP complaints. Employees are to request advice and assistance of the General Counsel before talking to attorneys, giving depositions, releasing University records, or giving orally relative to any pending or threatened lawsuit information regarding/involving the University or employees in the course and scope of employment.

In the research context, privacy issues, exculpatory language, or local and State laws with regard to consent or guardians are among the items in which an opinion may be requested from the Office of General Counsel.

Normally Investigators or IRB Chairs will work with the Director to request assistance from the Office of General Counsel.

Procedure:

- 1. Normally Research Study Personnel, IRB Chairs, Reviewers or IRB Staff Members requiring the assistance of the Office of General Counsel should:
 - 1.1 Contact the IRB Director.
- 2. IRB Director will:
 - 2.1 Gather necessary information regarding the question/situation at hand.
 - 2.2 Provide guidance/instructions to respond to questions if possible.
 - 2.3 Where legal guidance is needed, will work with the appropriate attorney from the Office of General Counsel.
 - 2.4 Track unresolved issues and follow up as needed to obtain a resolution.
- 3. Office of General Counsel will:

- 3.1 Research the issue and applicable law and provide a timely response.3.2 Take actions as may be appropriate.