Department: **UAMS Institutional Review Board**
Policy Number: **2.4**
Section: **Relationships**
Effective Date: **July 31, 2002**
Revision Date: **March 5, 2004**

SUBJECT: To the UAMS Office of Research Compliance

The UAMS Research Compliance Office (ORC) coordinates implementation and oversight of a comprehensive research compliance program for the UAMS IRB. The ORC demonstrates UAMS' commitment to the protection of human subjects through oversight and education that promotes research accountability and integrity, and minimizes the likelihood of noncompliance. As part of its role, the ORC investigates allegations of noncompliance, and addresses misconduct when it is substantiated. The ORC also advises the IRB regarding regulatory issues. ORC reports directly to the Vice Chancellor for Academic Affairs and Research Administration (VCAA/RA) and works cooperatively with, but is independent of the UAMS IRB.

The research compliance program applies to all research approved by the UAMS IRB and conducted by its faculty, staff, students, residents and other affiliated agents, including volunteer faculty who utilize university resources or personnel. ORC will coordinate compliance efforts on behalf of the UAMS IRB at Arkansas Children's Hospital Research Institute and Central Arkansas Veterans Healthcare System and other affiliated and non-affiliated institutions.

Audits of research studies will be conducted by ORC auditing staff. These are quality assurance and safety activities for the institution. Arkansas provides a broad network of statutes dealing with the reviewing and evaluating the quality of information used in the course of medical studies for the purpose of reducing morbidity and mortality. All audit proceedings, audit reports, memoranda or other data is strictly confidential and absolutely privileged. Audit reports will be filed in the ORC office. Auditing activities may be requested by the convened IRB committee, the IRB Chairperson, or IRB Director. In addition audits may be requested by the VCAA/RA. Audits may also be initiated after a written complaint is received in the ORC office, or through other programs of auditing approved by the VCAA/RA.

Monitoring activities including but not limited to human research, the informed consent process, and safety data, will be coordinated through the ORC office. Information collected from such activities will be submitted to the IRB for their review. The IRB may request the ORC provide additional information on research activity or monitor the informed consent process. Training is an important part of ORC activities and is a responsibility shared with the IRB.

Complaints received by subjects regarding their participation in a research program are forwarded to the ORC when the IRB deems an investigation is necessary. Reports on subject complaints are sent to the IRB, the VCAA/RA and others as appropriate to the protection of human research subjects.

The ORC also provides consultation on administrative issues related to regulatory processes within the IRB Administrative Offices and serves as a liaison with federal

regulatory agencies ensuring that IRB actions or events requiring notification are delivered as required by the Code of Federal Regulations.

The UAMS ORC Director is listed as a non-voting member on the IRB membership of each committee and provides guidance on regulatory issues during convened meetings. Individual staff members serve as alternates for the Director.