Department: **UAMS Institutional Review Board**
Policy Number: **12.1**
Section: **Quality Assurances**
Effective Date: **July 31, 2002**
Revision Date: **June 10, 2004**

SUBJECT: Educational Activities for IRB Reviewers

The IRB Office will provide information on its website for individuals who conduct or review human subject research related to pertinent items such as, *The Belmont Report*; the Federal Regulations at 45 CFR Part 46, guidelines/policies of federal regulations for agencies related to human subject research, and forms for providing information to the IRB. Additionally, the IRB or Office of Research Compliance (ORC) website will contain these documents in downloadable formats, and will also provide links to various agencies and resources for easy access to information (*e.g.*, National Institutes of Health, Food and Drug Administration, Office for Human Research Protections, National Bioethics Committee, *etc*.).

The IRB Office will provide information on its website for individuals who conduct or reviews human subject research where to review or obtain a handbook of UAMS. The handbook will include detailed information concerning:

1. Federal and institutional requirements for the protection of human research subjects

2. The IRB's roles and responsibilities

3. The requirements and procedures for initial and continuing IRB Committee review and approval of research

4. The rationale and procedures for proposing that the research may meet the criteria for expedited review

5. The requirements and procedures for verifying that research is exempt from IRB Committee review

6. The responsibilities of investigators during the review and conduct of research

7. Requirements and procedures for notifying the IRB Office of unanticipated problems or events involving risks to subjects, as well as any other expected or unexpected adverse events

8. An explanation of the distinction between FDA requirements for emergency use of test articles *versus* HHS regulations for the conduct of human subject research. Where appropriate, the IRB Office will provide written operating procedures to supplement its guidelines for investigators

All investigators or support staff performing human subject research will be required to participate in training to ensure the protection and rights of human subjects. The IRB will provide investigator training and monitor for adherence *via* two methods for the convenience of the investigators:

1. An on-line tutorial and certification examination with a passing score.

2. Participation in an Investigator Training Seminar, followed by the certification examination with a passing score.

Regularly scheduled training seminars will be provided on specific topics relating to the IRB process and federal guidelines. These topics may include, but are not limited to:

1. An Introduction to the IRB Process – A Workshop on Writing and Submitting an Application to the IRB (presented as needed)

2. Informed Consent Process/Capacity to Give Consent

3. How to Write a Consent Form which Subjects Will Understand

4. IRB Issues Related to Genetic Research

5. Sponsored Research, Grants and Contracts

6. Biosafety/Radiation Safety Issues and How They Relate to the IRB

7. Investigational New Drugs/Investigational Device Exemptions/Compassionate Use

8. How to Prepare for an Audit…Am I Compliant?

9. Final Approval – Then What? (An Update on Amendments, Adverse Events, and the Continuing Review Process and

10. An Update on the IRB