Department: **UAMS Human Research Advisory Committee**
Policy Number: **12.1**
Section: **Quality Assurances**
Effective Date: **July 31, 2002**
Revision Date:

SUBJECT: HRAC Educational Activities

The HRAC Office will provide information to each individual who conducts or reviews human subjects research where he/she may review or obtain a copy of *The Belmont Report*; the Federal Regulations at 45 CFR Part 46, guidelines/policies of federal regulations or agencies related to human subject research, and user-friendly forms for providing information to the HRAC. Additionally, the HRAC 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 HRAC Office will provide information to each individual who conducts or reviews human subject's research where he/she may review or obtain a handbook of HRAC guidelines for research investigators in printed format, as well as in downloadable formats from the HRAC website. The handbook will include detailed information concerning:

1. Federal and institutional requirements for the protection of human research subjects
2. The HRAC's roles and responsibilities
3. The requirements and procedures for initial and continuing HRAC 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 HRAC Committee review
6. The responsibilities of investigators during the review and conduct of research
7. Requirements and procedures for notifying the HRAC 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 subjects research. Where appropriate, the HRAC Office will provide written operating procedures to supplement its guidelines for investigators

Principal Investigators will be required to participate in training to ensure the protection and rights of human subjects. The HRAC will provide investigator training via two methods for the convenience of the investigators:

1. An on-line tutorial and certification examination (examinations will be graded by an HRAC representative, and principal investigators must achieve a score of 86% or higher for certification); and

2. Participation in an Investigator Training Seminar, followed by the certification examination. Principal Investigators are responsible for ensuring that appropriate support staff associated with human subject research is adequately trained on the protection of the rights and safety of human subjects.

Monthly Training Seminars will be provided on specific topics relating to the HRAC process and federal guidelines. These topics may include, but are not limited to:

1. An Introduction to the HRAC Process – A Workshop on Writing and Submitting an Application to the HRAC (presented monthly as needed)
2. Informed Consent Process/Capacity to Give Consent
3. How to Write a Consent Form that Subjects Will Understand
4. HRAC Issues Related to Genetic Research
5. Sponsored Research, Grants and Contracts
6. Biosafety/Radiation Safety Issues and How they Relate to the HRAC
7. Investigational New Drugs/Investigational Device Exemptions
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 HRAC

The HRAC Reference Library houses information on assorted topics related to issues and regulations on human subjects research. These tools are available for checkout upon request.

The HRAC website will provide a “Frequently Asked Questions” and/or “Facts You Should Know” page, with the added feature of visitors being able to submit questions and/or ask for regulation clarification via email. This web page will be dynamic in nature and will be updated in a timely fashion to globally share information based on the questions received.