Department: **UAMS Institutional Review Board**
Policy Number: **10.1**
Section: **Principal Investigator Responsibilities**
Effective Date: **July 31, 2002**
Revision Date: **June 1, 2005**

SUBJECT: Principal Investigator Training

Investigator Training

UAMS has adopted a mandatory education program for all IRB members, Principal Investigators, and all key project staff (*e.g.* sub-investigators, study coordinators, study nurses, research technologists) having contact with human subjects, human subject data, or biological specimens. The program is described as follows:

PURPOSE

The purpose of this policy is to define the Human Subject Protection educational requirements for investigators and key personnel involved in human subject research overseen by the University of Arkansas for Medical Sciences Institutional Review Board (UAMS IRB).

POLICY

Recertification is required every two years after completion of the initial educational program requirement.

Accepted Educational Programs

Completion of one of the following educational programs will meet mandatory UAMS requirements for investigators and key personnel involved in human subject research.

1. Successful completion of one of the UAMS web-based tutorial programs on Human Subject Protection AND the HIPAA training course at http://www.uams.edu/orc/ . These two web-based courses are required of all researchers initially and may be repeated in subsequent years or other choices substituted as listed below. Researchers should complete one of the Human Subject Protection Training Programs appropriate to their research discipline:

    - Biomedical Course on Human Subject Protection Training

OR

    - Behavioral and Social Science Course on Human Subject Protection Training

    The Biomedical Course is appropriate for persons whose research involves drugs, devices, and surgical/ invasive procedures. The Behavioral and Social Science course is relevant to those disciplines and is not appropriate for investigators whose research involves drugs, devices or surgical/invasive procedures. Both courses integrate UAMS IRB requirements.

In addition, the on-line HIPAA for Research Training Course is required of all researchers. The HIPAA course is a short overview of the researcher and key research personnel responsibilities for confidentiality, use and disclosure of Protected Health Information obtained during research. UAMS, CAVHS and ACH each have additional policies and procedures to follow regarding HIPAA.

On-line courses are followed by exams and a record of successful completion is maintained by the Office of Research Compliance. The UAMS IRB will have access to these completion records. This course will be updated quarterly and, if regulatory changes dictate, more frequently by the Office of Research Compliance. The UAMS IRB may recommend or request that items be added or changed in the education model to reflect areas germane to the protocol review process.

2. Attendance and successful completion of the seminar "Conduct of Human Subjects Studies" sponsored by UAMS and/or ACH may also fulfill subsequent Human Subject Protections Training Requirement. This seminar is scheduled to be taught yearly and includes history, ethics, federal regulations, UAMS IRB procedures, and discussions pertinent to the group's interests. There is an exam and certificates of training are distributed to attendees if a successful score (80%) is achieved. If an attendee does not achieve an 80% on the initial attempt, the on-line course and test must be taken and passed.

3. On a case-by-case basis, the UAMS IRB Director and the Office of Research Compliance Director will consider other programs with equivalent or better content to meet this requirement.

Persons should save a copy of printed certificates of completion upon finishing any course other than the UAMS on-line courses.

Who Must Comply With This Policy:

The requirement of mandatory completion of the Human Subject Protection Training applies to the following individuals:

1. Investigators (including faculty, residents, and students) submitting a human subjects protocol to the IRB for review and approval.

2. Investigators and persons participating in human subject research, including faculty, residents, and students.

3. Faculty Supervisor of investigator submitting a human subject's protocol to the IRB for review and approval (if the investigator is a student).

4. Persons responsible for, but not limited to, day-to-day protocol decision-making related to the study conduct; subject recruitment, selection and eligibility; clarification of the complexities of the protocol to the subject and others; collecting subject information; and entering data.

5. Research Coordinators, Research Nurses, and Research Assistants/Associates.

6. Members of the UAMS IRB.

Deadline for Compliance

Effective January 31, 2004, all persons to whom this policy applies must have documentation of one of the acceptable courses listed above for Human Subject Protection. Mandatory HIPAA training for researchers was due April 14, 2003. Persons without appropriate training may not submit protocols for human research or conduct such research after these deadlines.

Continuing Education

Recertification will be required every two years through one of the methods below:

- Re-completion of the web-based tutorial programs at http://www.uams.edu/orc/.
- Re-attendance of the seminar "Conduct of Human Subject Studies"
- Other programs (e.g. Association of Clinical Research Professionals Seminar in Investigator Training) may be an acceptable alternative to the above courses. Please contact the Office of Research Compliance if this is chosen as an option prior to taking this course.

Affiliate Institutions Requirements

Arkansas Children's Hospital

ACH and ACHRI consider this policy as the mandatory base requirements for Human Subject Protection and HIPAA Training on its campus. ACHRI will work with the Office of Research Compliance Educator to enhance the on-line training courses to assure the protection of children in research. Additional courses required by ACH/ACHRI will be announced.

In addition to the UAMS IRB requirements listed above, researchers at Central Arkansas Veteran Hospital (CAVHS may have additional educational requirements. The VA R & D Office should be consulted for these requirements.

For More Information

Questions concerning this policy should be directed to the UAMS Office of Research Compliance at (501) 526-6876.

Other Contact Numbers:	ACHRI:	501-364-3571
	VA R & D:	501-257-4816
	UAMS IRB Director:	501-686-8845