Department: UAMS Institutional Review Board
Policy Number: 3.8
Section: Committee Membership
Effective Date: July 31, 2002
Revision Dates: February 8, 2005; March 12, 2004; November 18, 2002

SUBJECT: IRB Reviewer Training Requirements

Definitions:

1. **UAMS Human Subject Protection Training – Biomedical:** This online course covers 8 essential areas in human subject protection for research studies that are biomedical in nature. Some of the subject areas include: reporting, investigator responsibilities, emergency use, and vulnerable populations. Anyone that is involved as a member of a biomedical research team must complete this training. Recertification in this training must occur every two years by UAMS Policy.

2. **Human Subject Protection Training – Behavioral:** This online course covers 8 essential areas in human subject protection for research studies that are behavioral in nature. Some of the subject areas include: reporting, investigator responsibilities, special considerations for behavioral studies, and vulnerable populations. Anyone that is involved as a member of a behavioral research team must complete this training. Recertification in this training must occur every two years by UAMS Policy.

3. **HIPAA for Research:** This is an online course that covers HIPAA's impact on the research environment, and what a research staff member should know to be compliant with HIPAA regulations. Anyone involved as a member of a research team must complete this course.

Policy:

All IRB Committee members must complete initial orientation and annual training in the review and conduct of human research protections. Assessment of quality of review and guidance may also be provided as deemed necessary by the Chair.

IRB Reviewer Orientation Training

All new Committee members are required to complete an initial orientation before being allowed to serve on the IRB Committee, which includes the following:

1. The UAMS Online course for Human Subjects Protection
2. The UAMS HIPAA online course
3. The three OHRP Training Modules for Assurances. This tutorial explains the responsibilities involved in an institutional program of human participant research, as well as the informed consent process from the perspective of the OHRP. The tutorials can be accessed at http://www.hhs.gov/ohrp/
4. One on one training in the use of ARIA
5. Committee Meeting Attendance and Observations. New IRB Committee members must attend and observe at least one IRB Committee meeting prior to functioning as a voting member.
6. Specific Reviewer Education – see procedure below.

7. Each new IRB Committee member will receive
    a. An electronic IRB Reference Library on cd and located on an IRB Website This manual will have current IRB Policies and Procedures, references to regulations, The Belmont Report, Helsinki Report, and the Nuremberg Report. Reviewer checklists, archived IRB tips and any other helpful references will be located at the site in a section entitled IRB Reviewer Resources.
    b. A laptop computer

First Assignments as Reviewer

1. Before a new Committee member is assigned as a Primary Reviewer, s/he must perform two consecutive agenda reviews as the secondary reviewer with either the Chair, or a senior member designated by the Chair, as the primary reviewer acting as a mentor.

Continuing Education Requirements and Opportunities

1. All IRB Committee members and alternate members are required to attend annual training conducted by the IRB and Office of Research Compliance staff. Those that do not complete the mandatory annual training may not be eligible to serve on the IRB Committee until this requirement is satisfied. All IRB Committee members are required to complete a self-evaluation tool assessing their knowledge, and identifying educational needs for the coming year at the annual training session.
2. Ongoing training sessions are also incorporated into scheduled IRB Committee meetings as pertinent topics are circulated or policies or procedures change.
3. "IRB TIPS" are short educational messages that will be sent to all committee members on a variety of topics as required.
4. IRB Committee members are required to participate in at least one additional continuing education opportunity each year. Committee members have an open invitation to attend or complete as many of the following sessions they would like; however, completion of one is mandatory to meet the continuing education requirement:
    a. Office of Research Compliance educational offerings
        i. Coordinator's Course
        ii. Seminars
        iii. Question and Answer Forums
    b. Any other local, regional or national educational opportunities on human research protections.
5. The IRB Chair and/or at least one Committee member from each Committee will be encouraged to attend a national or regional human research protections conference annually.

Procedure for Orientation Training

Each new reviewer will receive information and/or training in the following Categories in Sessions with the IRB staff, senior reviewers and the Office of Research Compliance

1. The UAMS Federalwide Assurance
2. The IRB Contact List
3. IRB Policies and Procedures
4. IRB Reviewer Responsibilities and Checklists;
5. The Investigator's Manual;

6. Template Language for Informed Consent Documents and Informed Consent Checklist;
7. Human Subject Protection & HIPAA Education Policy
8. INDs, IDEs and sponsor/investigator research
9. Special review issues related to vulnerable populations
10. Special review issues related to drugs and devices
11. Ethics of IRB review
12. Special requirements for review of VA related research

Procedure for Continuing Education

1. Each IRB reviewer will receive notice of continuing education opportunities *via* e-mail.
2. Verification of attendance through sign-in sheets, or certificates will be required.