UAMS Institutional Review Board Department:

Policy Number:

4.6

Section:

Committee Operations

Effective Date:

July 31, 2002

Revision Dates:

February 8, 2005; March 12, 2004; November 18, 2002

SUBJECT: Duties of IRB Staff

1. Study Specific

- 1.1 Review materials for completeness before review by the IRB:
 - a. Full protocol
 - b. Informed consent form
 - c. Appropriate completion of Original Submission Form
 - d. Any relevant merit reviews or grant applications
 - e. Investigator's brochure
 - f. Advertisements or subject information
 - g. Subject surveys or questionnaires
 - h. Appropriate documentation of required investigator training certificates
 - i. Indemnity letter from sponsor, if appropriate
 - j. HIPAA Authorization, if appropriate
 - j. Data Safety Monitoring Plan
 - k. Appropriate completion of Continuing Review Forms
 - I. Appropriate completion of Modification Forms
- 1.2 Verify receipt of current consent form and/or protocols for study revisions and adverse event reports.
- 1.3 Contact researcher for additional materials or submission changes when appropriate.

2. Meeting specific

- 2.1 Coordinate the location and snacks for meeting.
- 2.2 Verify attendance at meetings to assure quorum, both prior to and during the meeting.
- 2.3 Prepare and disseminate agenda prior to the meetings.
- 2.4 Provide members with appropriate background and summary information on policies, rules, and regulations pertaining to issues relevant to protocol review.
- 2.5 Assist the Chair in taking notes at the IRB meeting.
- 2.6 Prepare correspondence for signature by the Chair.

2.7 Follow up as needed on all items marked as Pending, such as IND/IDE #s or other committee approvals.

3. General Duties

- 3.1 Ensure accuracy of data in database.
- 3.2 Disseminate and collect annual IRB questionnaires on COI and Affiliation.
- 3.3 Provide assistance to members and research staff with questions regarding regulations, policies, and ARIA and IRB procedures.