Department: **UAMS Institutional Review Board**
Policy Number: **6.1**
Section: **Documentation**
Effective Date: **July 31, 2002**
Revision Date: **May 7, 2004**

SUBJECT: Agenda

The IRB Office shall generate an agenda for each meeting. The agenda shall include the full title of protocols associated with a numerical identifier for each project application The IRB Chair or his/her designee prepares the Agenda with the assistance of the IRB staff.

Assigning Studies

Behavioral Studies involving human subjects are assigned to the Behavioral IRB. Behavioral research includes studies where data is generated by means of questionnaires, observation, studies of existing records, and experimental designs involving exposure to some type of stimulus or intervention.

Biomedical Studies involving human subjects are assigned to Biomedical IRB committee. Biomedical research includes studies designed to evaluate an intervention (*e.g.*, drugs, diet, exercise, surgical interventions, or medical devices), diagnostic procedures (*e.g.*, CaT scans or prenatal diagnosis through amniocentesis, chorionic villi testing, and fetoscopy), and preventive measures (*e.g.*, vaccines, diet, or fluoridated toothpaste).

Industry Sponsored Studies involving human subjects may be assigned to Industry Sponsored committee. Such research may be similar to that delineated by biomedical studies but typically the overall goal of the industry sponsored trial is to develop or test a new product, compound or device for eventual standardized use in humans.

Chairpersons or their designee assign studies to a reviewer based on area of expertise, training, or diversity.

Locking the Agenda. Deadlines for submission may vary depending on the committee to which the protocol is submitted. The IRB web-site lists the current deadline dates for each committee. Protocols submitted by the deadline date may be reassigned to a later committee meeting if the Chairperson signs off to lock the agendas because of undue volume of submissions. Submissions not received in the IRB office by the deadlines will be held over for the next meeting's agenda. The Chairperson may also add an item submitted after the published deadline when deemed to be appropriate in an extenuating circumstance.

Distributing the Agenda. To assure quorum, members are expected to notify the IRB office at least two weeks prior if they are unable to attend a scheduled meeting. The agenda is included at the beginning of the group of protocols to be reviewed and is delivered to all members and alternates at least a week before the meeting to provide time for review. For each protocol under review whether initial or continuing, all relevant

documentation is included with the agenda. The agenda also includes the minutes from the prior meeting which are accessible for review *via* the ARIA website.

Agenda Items may include the following but not necessarily in this order

1. Call to Order
2. Presence of Quorum Established
3. Announcements
4. Old Business
    a. Approval of Minutes from Previous Meeting
    b. Updates Requested by the Committee
    c. Previously Tabled Actions
5. New Business

a. New Submissions Requiring Full Committee Review

At the convened meeting, the IRB shall review all newly proposed human subjects research. This excludes those projects that either meet one or more of the exemption categories as authorized in 45CFR46.101b (see policy number 7.3) and those that either meet one or more of the expedited categories as authorized in 45 CFR46.110 (see IRB policy 7.5).

b. New Submissions Expedited by the Chair

The agenda will also include a section on "Notification of Approvals by the Chair" such as expedited approvals, exempt approvals, adverse events, and study closures. When a determination regarding a review conducted utilizing expedited review procedures has been made, this must be documented in the agenda provided to the full Committee for the next possible convened meeting as authorized in 45CFR46.110c. The approval letter will document the specific permissible category or categories justifying the expedited review.

c. Continuing Review

At the convened meeting, the IRB shall review all continuing human subjects research at intervals appropriate to the degree of risk, but not less than once per year. This includes continuing reviews on expedited studies, [45CFR46.101(b).

d. Serious Adverse Events

At a convened meeting, the IRB may review serious adverse events. A Safety Report, if such data has been submitted, appears in ARIA for each protocol on the agenda. In addition, committee members may access letter(s) written to the Principal Investigator either acknowledging receipt of safety issues or request for additional information concerning a given event. Factors that help determine the need for review at a convened meeting being placed on agenda are:

1. The seriousness of the event;

2. Was the event expected or unexpected?

3. Whether the event is described in the study protocol and informed consent document;

3. Whether the event occurred at a location for which the IRB is the IRB of record;

5. The PI's recommendations as to whether the adverse event was a direct result of a subject's participation in the research study.

6. Review by the Chairpersons and/or their designee determines that circumstances surrounding the reported serious adverse event warrants full committee input.

e. Data Safety Monitoring Board or other safety reports (those not considered with Continuing Review Report Form)

1. Review by the Chairpersons or their designee is conducted and presentation is made to the convened IRB as required.

f. Protocol violations or deviations (those not considered with Continuing Review Report Form).

1. Review by the Chairpersons or their designee is conducted and presentation is made to the convened IRB as required.

g. Research Complaints

1. Reviewed by Chairperson and IRB office staff followed by investigation requests to Compliance Office. Substantive findings are presented to a convened IRB as required.

2. Allegations of scientific misconduct or violations of other Institutional policies discovered in the investigation are referred to the Vice Chancellor for Academic Affairs.

h. Closure of a Study or Drug/Device Hold Status for Safety Concern

1. Chairperson may appoint a sub-committee to investigate any details not revealed in the initial report.

2. Chairperson instructs the Office of Compliance to submit appropriate report to OHRP.

i. Amendments, Modifications, or Revisions on Full Review Protocols

At the convened meeting, the IRB shall review any and all proposed changes to approved human subjects research. This excludes those projects that either meet one or more of the exemption categories as authorized in 45 CFR46.101b or one or more of the expedited categories as authorized in 45CFR.6.110 (see IRB policy 8.1).

h. Compliance Issues

The IRB Office will report promptly to the IRB Committee members any serious or continuing noncompliance with the regulations or requirements of the IRB by including an item on the next official IRB Committee meeting agenda.

1. Protocols automatically suspended for compliance problem

2. Protocols automatically terminated for compliance problem

3. Review by two reviewers or subcommittee report for compliance problem

j. Audits and Monitoring

A summary of the results of any audits performed by the UAMS ORC or external auditing bodies will be reported to the IRB chair who in turn will decide the manner of presentation to the Full IRB Committee. However, if information gained during the auditing or monitoring process indicates that human subjects of a research project are exposed to unexpected serious harm, the IRB Chair may suspend or terminate the research project prior to the next regularly scheduled IRB meeting (see IRB policy 12.2).

k. Emergency/Compassionate Use Acknowledgements

The Chair or designee may grant emergency/compassionate use of drugs, devices, or procedures to a Principal Investigator based upon circumstances where inaction might result in an adverse outcome for a subject. Granting of emergency/compassionate use is considered a limited event for a protocol. Repeat request of the Principal Investigator under the same protocol suggests that revisions are appropriate to accommodate future events.

I. Closed Protocols

Closure of a protocol is typically initiated by the Principal Investigator when approved accrual has been achieved and data reduction is complete. Upon written request, the IRB will close the protocol and requirement for subsequent review is ended. The IRB may also initiate closure of a protocol if review finds that an investigator has not conducted a study appropriately. In general, such findings will result in a termination of a protocol.