Department: **UAMS Human Research Advisory Committee**
Policy Number: **6.2**
Section: **Documentation**
Effective Date: **July 31, 2002**
Revision Date:

SUBJECT: Agenda

The HRAC has an agenda for each of its meetings. The agenda includes the full title of protocols associated with a numerical identifier for each project applications awaiting action by the HRAC. The HRAC Chair prepares the Agenda with the assistance of the HRAC Manager.

Assigning Studies

Behavioral Studies involving human subjects are assigned to the Behavioral HRAC. 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 one of the three Biomedical HRAC committees. 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).

Studies to be reviewed are assigned to a reviewer by the Chairpersons based on area of expertise, training, or diversity.

Locking the Agenda. The deadline for the behavioral committee agenda is the first Monday pri0r to the second Thursday meeting date. The deadline for including a project on the biomedical committee agenda is 4:30pm two weeks prior to a scheduled meeting. Chairpersons sign off to lock the agendas with items received and approved by the deadlines. Submissions not received in the HRAC office by the deadlines will be held over for the next meeting's agenda. Chairpersons may also hold submissions until the next meeting's agenda if the number of submissions is greater than what is feasible for the committee to review.

Distributing the Agenda. To assure quorum, members are expected to notify the HRAC 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 hand 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 packet also includes the minutes from the prior meeting.

Agenda Items

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 HRAC 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 or one or more of the expedited categories as authorized in 45 CFR. At the convened meeting, the HRAC 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 45 CFR46.101b or one or more of the expedited categories as authorized in 45 CFR46.110 (see HRAC 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 45CFR46.110cThe 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. This documentation must include a citation to the specific permissible category or categories justifying the expedited review.

c. Continuing Review

At the convened meeting, the HRAC 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)(8or9)] but excludes projects that either meet one or more of the exemption categories as authorized by 45 CFR. At the convened meeting, the HRAC 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)(8or9)] but excludes projects that either meet one or more of the exemption categories as authorized by 45 CFR46.101(b) (see HRAC policy 7.3).

d. Serious, Unexpected Adverse Events

At a convened meeting, the HRAC shall review serious unexpected adverse events (see HRAC policy 11). Factors that help determine the need for review at a convened meeting are:

1. The seriousness of the event;

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

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

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

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

f. Research Complaints

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

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

At the convened meeting, the HRAC 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 CFR. At the convened meeting, the HRAC 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 HRAC policy 8.1).

i. Compliance Issues

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

The results of any auditing or monitoring process by the HRAC will be reported to the Full HRAC Committee on the agenda of the next regularly scheduled meeting. 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 HRAC may suspend or terminate the research project prior to the next regularly scheduled HRAC meeting (see HRAC policy 12.2).

k. Emergency/Compassionate Use Acknowledgements

l. Closed Protocols