Department: UAMS Institutional Review Board
Policy Number: 7.4
Section: Procedures for Study Review
Effective Date: July 31, 2002
Revision Date: May 7, 2004; February 8, 2005; June 1, 2005; March 5, 2008; January 24, 2011

SUBJECT: Review by Convened IRB

I. Policy

The convened IRB will review research that does not qualify for expedited or exempt review. The Chair will ensure that the reviewers have expertise in the areas under review for a particular meeting, or invite outside individuals with the appropriate expertise in accordance with IRB policy 3.9.

Each agenda item under review by the convened IRB will be individually presented and discussed. The IRB approval criteria outlined in IRB Policy 7.1 will be used for all reviews of research, including initial and continuing review and modifications to previously reviewed studies. In order for the item to be approved, it must receive the approval of a majority of those members present at the meeting.

All actions taken by the IRB will be reported to the study team in writing. This includes motions to approve, disapprove, table, or require major or minor contingencies. Should a study be tabled or disapproved, the IRB's letter will include the reasons for the decision. All study personnel listed in ARIA will have access to the IRB letter. However, only the Investigator and Study Contact will receive email notification that a new letter has arrived.

II. Reviewer Obligations and Process

A. Agenda and Access to Studies under Review

At least one week prior to each Committee meeting, the Agenda, Agenda Key, Approval Criteria Checklist and Minutes from the Committee's last meeting will be sent to the reviewers. All reviewers have access to the complete study submission in ARIA. Refer to the agenda category or office notes section of the agenda to identify the specific items to be acted upon under this Agenda.

B. Reviewer Obligations Prior to Meeting

1. Assigned Reviewers. Reviewers will be assigned in accordance with IRB Policy 4.4. The review and presentation to the convened IRB should address each of the approval criteria outlined in IRB Policy 7.1, plus any additional approval requirements specific to the type of research or agenda category. Contingencies should be added to ARIA prior to the meeting.

a. New Studies. For each new study assigned, the reviewer should conduct an in-depth review of the entire submission, including all associated documents.

b. Continuing Reviews. For continuing reviews, the review should encompass the protocol, current consent form, previously approved modifications and any other reporting that may reflect a possible change in the risk/benefit ratio in conjunction with the Continuing Review Form.

c. Updates by Two Reviewers. For modifications that could not be expedited, the review should encompass the Modification Form and associated documents.

d. Major Revisions. For responses to major contingencies, the reviewer will need to access the previous IRB letter and confirm that the submitted response meets each of the contingencies.

e. All **Other Agenda Items.** Other assigned items may include audit reports, reports of non-compliance or reports of unanticipated problems involving risk to subjects or

others. Reviews of these items should be in conjunction with IRB Policies 10.2, 12.5 and 12.6 as applicable.

2. Other Reviewers. Committee reviewers who are not assigned a specific protocol should be able to participate in the discussion and vote on each protocol. All reviewers have access to the entire study file. At a minimum, the following documents should be reviewed:

a. **New Studies:** Original submission form, proposed consent document and recruitment materials.

b. Continuing Reviews: Original submission form (or most recent modification form), currently approved and any newly proposed consent documents and the continuing review form.

c. Updates by Two Reviewers. Modification Form outlining what changes are requested and the documents associated.

C. Reviewer Obligations during Meeting for:

1. All Agenda Items

a. Determine whether the research, proposed modification, or contingency response meets the regulatory criteria for approval. Every reviewer has an obligation to raise issues encountered during review/discussion.

b. IRB Policy 9.1 identifies the range of IRB motions that are allowed.

c. If any review reveals significant new findings that may relate to a subject's willingness to continue participation, the IRB must determine the process to provide that information to the subjects.

d. No IRB reviewer should vote to approve a protocol unless they feel comfortable the rights and welfare of the subjects are protected to the fullest extent and that they understand the motion, including any contingencies, that is being put forward.

2. New Studies. For studies undergoing Initial Review, the IRB must also determine:

a. Which protocols need review more often than annually (the approval period); and

b. The risk category as defined in IRB Policy 16.1.

3. Continuing Reviews – Based upon information presented, the IRB must also determine whether:

a. The current consent form(s) is still accurate and complete;

b. Continuing review should occur at an interval less than one year; and

c. To seek verification from sources other than the study team that no material changes have occurred since previous review.

The following are examples of studies that may more frequent review or verification from other sources:

i. Involvement of vulnerable populations
ii. The involvement of recombinant DNA or other types of gene transfer protocols
iii. Classified research
iv. Phase 1 studies

v. Disproportionate number or severity of SAEs
vi. Findings of serious or continuing non-compliance or previous suspension of the researcher
vii. Recommendations from other intra-institutional committees
viii. The information provided is internally inconsistent and the inconsistency cannot be resolved through discussion with the investigator.