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; August 27, 2020**

SUBJECT: Review by Convened IRB

POLICY

The convened IRB shall review research that does not qualify for expedited or exempt status 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 section 3, Committee Membership.

Each agenda item under review by the convened IRB will be individually presented and discussed at the meeting. 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. Motions are approved by 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 the IRB's e-system will have access to the IRB letter. However, only the PI and other study staff designated to receive notifications will receive email notification that a new letter has arrived.

PROCEDURE

A. Agenda and Access to Studies under Review

1. Notice of the upcoming agenda will be sent to reviewers sufficiently in advance of the meeting to allow time for review.
2. All reviewers have access to the complete agenda and associated documents through the IRB e-system.

B. Reviewer Obligations Prior to Meeting

1. **Assigned Reviewers**. The chair will assign reviewers to each agenda item, taking into account individual reviewers' expertise, background, and number of agenda assignments.
   a. Assigned reviewers shall be prepare to present to the convened IRB an overview of the study, and to discuss 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.
   b. The reviewers shall have access to checklists through the IRB e-system to guide their reviews. These checklists address criteria for approval and determinations specific to certain populations.
   c. Reviewers are asked to add draft contingencies and notes for discussion to the IRB e-system prior to the meeting. These items will be discussed and finalized at the meeting.
2. **New Submissions**. For each new study assigned, the reviewer should conduct a thorough review of the entire submission, including all associated documents, to assess whether the convened IRB can determine the criteria for approval are met and whether any other required determinations can be made.
3. **Continuing Reviews**. For continuing reviews, the review should encompass the continuing review form, current consent form, previously approved modifications and any other reporting that may reflect a possible change in the criteria for approval or other required determinations.
4. **Modifications.** For modifications requiring full board review, the review shall encompass the Modification Form and associated documents to ensure the criteria for approval and any other required determinations continue to be met.
5. **Major Contingency Responses.** For responses to major contingencies, the reviewer shall access the previous outstanding contingencies and confirm that the submitted response meets each of the contingencies.

6. **All Other Agenda Items.** Other assigned items may include audit reports, reports of potential non-compliance or of potential unanticipated problems involving risk to subjects or others. Reviews of these items shall be done as described in IRB Policies 10.2, 12.5 and 12.6 as applicable.
7. **All Reviewers** should be prepared to participate in the discussion and vote on each item. All reviewers have access to the entire meeting agenda and associated documents. Reviewers should look at the following for each agenda item, including those items to which they are not assigned:
   a. **New Submissions:** Original submission form, proposed consent document and recruitment materials.
   b. **Continuing Reviews:** Continuing review form and reports of any adverse events or protocol deviations
   c. **Modifications:** Modification Form outlining requested changes and the associated documents.
   d. **Other forms**: The submission form and documents directly associated with that form
   e. Minutes: Reviewers should look over the minutes from the previous month's meeting and contact the Chair to correct if necessary or add necessary detail.
   f. Reported Items: Reviewers have access to the list of reported items. They can review and ask for clarification or more detail if necessary.

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 noticed 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 and that they understand the motion, including any contingencies, put forward.
2. **New Studies.** For studies undergoing Initial Review, the IRB shall also determine and document:
   a. Which protocols need review more often than annually (the approval period);
   b. The criteria for approval are met
   c. Any other required determinations are made. 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. The current approval period remains appropriate;
   c. Nothing pertaining to the criteria for approval or other required determinations has changed;
   d. Whether to seek verification from sources other than the study team that no material changes have occurred since the previous review.
   e. The following are examples of studies that may more frequent review or verification from other sources:
      i. Studies involving 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 adverse events or protocol violations
      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.

REFERENCES

45 CFR 46.108(3)(i)
21 CFR 56.109
AAHRPP Elements II.2.D and II.2.E
AAHRPP Tip Sheet 16, *Convened IRB Review*
IRB Policies cited above