

Department: UAMS Human Research Advisory Committee
Policy Number: 9.1
Section: HRAC Decisions
Effective Date: July 31, 2002

Revision Date:

SUBJECT: Range of HRAC Decisions

When protocols involve more than minimal risk to human subjects - meaning a greater risk than that found in ordinary daily life - the full HRAC must review them. A review of the HRAC is defined as a regular meeting of a quorum of the Board members. The details of the discussion surrounding a full board review are not available outside the HRAC. The protocol will be discussed until there is a majority of votes for approval or revision. Committee members attending the meeting who are involved in the protocol being discussed are not included in the final vote. Following each HRAC meeting, the investigator will be informed by memo of the protocol status [21 CFR 56.109(a)].

Protocol Approved: The project and its study tools, including the informed consent documents, are approved as submitted. Once the investigator receives the HRAC approval letter, the study may begin.

Protocol Approval Deferred (Major or Minor): The project requires revisions. Minor revisions may be reviewed through the expedited process. Major revisions in the project as submitted must be addressed before the HRAC can grant approval. Protocols with approval deferred for major deficiencies must be re-reviewed by the convened HRAC before final approval is granted.

Protocol Tabled: Serious deficiencies in a newly submitted protocol with issues to be addressed by the investigator before the HRAC can grant approval. Protocols that are tabled must be resubmitted to the HRAC as if submitting the protocol for an initial application (35 sets of all revised materials).

Protocol Disapproved: The project has serious deficiencies affecting the safety and welfare of the projected subject population. Protocols that are disapproved may not be resubmitted to the HRAC. The protocol requires major revision of safety issues and a new protocol submission.