Department: **UAMS Institutional Review Board**
Policy Number: **9.1**
Section: **IRB Decisions**
Effective Date: **July 31, 2002**
Revision Date: **August 26, 2004**

SUBJECT: Range of IRB Decisions

The full IRB must review all protocols that involve more than minimal risk to human subjects– based on the federal regulation definition of minimal risk. Full IRB 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 IRB. The protocol will be discussed until there is a majority of votes for approval or revision. Committee members who are involved in the protocol being discussed are not allowed to vote on the protocol. Following each IRB meeting, the investigator will be informed by letter of the protocol status.

Protocol Approved: The project and its study tools, including the informed consent documents, are approved as submitted. Once the investigator receives the IRB 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 IRB can grant approval. Protocols with approval deferred for major deficiencies must be re-reviewed by the convened IRB before final approval is granted.

Protocol Tabled: Serious deficiencies in a newly submitted protocol with issues to be addressed by the investigator before the IRB can grant approval. The PI should be aware that the IRB upon receiving the responses to a tabled protocol may have additional requested revisions.

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 IRB. The protocol requires major revision of safety issues and a new protocol submission.