

Department: UAMS Institutional Review Board
Policy Number: 9.1
Section: IRB Decisions
Effective Date: July 31, 2002
Revision Date: June 1, 2005; August 26, 2004

SUBJECT: Range of IRB Decisions

Acknowledged: An action taken by the IRB or Chair/Designee to acknowledge documents submitted when approval is not required.

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. The exception is any VA investigator who must also obtain approval of the VA Research and Development Committee prior to starting.

Approved with Major Revisions: The project requires major revisions, which the IRB can list as part of the motion. These must be addressed and re-reviewed by the convened IRB before the IRB can grant approval. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond. The response will be reviewed by the convened IRB.

Approved with Minor Revisions: A vote such as this incorporates all the noted contingencies. The project requires minor revisions which must be addressed before final approval can be granted. Minor revisions may be reviewed and approved through the expedited process.

Tabled: The project has serious deficiencies in the submitted protocol. These must be addressed and re-reviewed by the convened IRB before the IRB can grant approval. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond. The response will be reviewed by the convened IRB. PIs should be aware that the IRB upon receiving the responses to a tabled motion may have additional requested revisions.

Declined: The project has serious deficiencies in submitted protocol affecting the safety and welfare of the projected subject population. These must be addressed in a new protocol and be reviewed by the convened IRB before the IRB can grant approval. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond. The response will be reviewed by the convened IRB.

Suspended for Cause: An action taken by the IRB to stop temporarily some or all research procedures until the outlined requirements are met. The IRB can, at its discretion, make a range of motions regarding the conduct of a given protocol in order to better secure the protection of participants.

Terminated for Cause: An action taken by the IRB to stop permanently some or all research procedures. The IRB can, at its discretion, make a range of motions

regarding the conduct of a given protocol in order to better secure the protection of participants.