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** **April 5, 2007** **March 5, 2008**

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. All contingencies and revisions must be approved by the IRB before an action of "approved" can be assigned to a project.

Approved with Major Contingencies: The project is not approved until the IRB convenes to discuss the requested 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. Major revisions are broad and unspecific such as "The IRB needs more information about why ARM 2 of the study is needed" or "The IRB is concerned that the PI has not done enough to reduce risks to human subjects. Please revise or explain" or "The consent form was written in a very scientific manner. Please revise so that it is understandable" or "the IRB is concerned that there are not enough resources to complete this project, please explain"

Approved with Minor Contingencies: The project is not approved until the chair or designee approves the specific requirements of approval that the IRB requires. 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. Minor revisions are very specific and direct so the Chair can verify them. Some examples are "Please revise consent form page 4 to add the study procedures described in your protocol on page 2" or "Please add the PIs name to the consent form page one in accordance with UAMS IRB policy" or "Remove ARM 2 of the study to reduce the risk of heart attack" or "Please remove the second sentence from your recruitment advertisement as it is coercive"

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 so the project can be revised in a new submission.

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. This action is a suspension of IRB approval and must be reported in accordance with UAMS policy 2.6.

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. This action is a suspension of IRB approval must be reported in accordance with UAMS IRB Policy 2.6.

Administrative Hold: The Convened IRB or the IRB Chair or designee can place an administrative hold on a project if the IRB lacks enough information to make a decision. Administrative holds are suspensions of IRB approval and will be reported in accordance with IRB Policy 2.6. The hold will be lifted after the PI responds and a new classification will be selected from the above list.