

**Department:** UAMS Institutional Review Board  
**Policy Number:** 7.9  
**Section:** Procedures for Study Review  
**Effective Date:** July 31, 2002  
**Revision Dates:** February 8, 2005; May 20, 2004

**SUBJECT:** Suspension or Termination of Approval for Cause

**DEFINITIONS:**

**Expired Studies:** Studies that expire due to lack of continuing review. Addressed in IRB Policy 7.6.

**Suspension for Cause:** An action taken by the IRB to stop temporarily some or all research procedures until the outlined requirements are met.

**Termination for Cause:** An action taken by the IRB to stop permanently some or all research procedures.

**POLICY:** The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB Policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects.

An example of suspensions or terminations *for cause* might include: inappropriate involvement of human subjects in research, serious or continuing noncompliance with federal regulations or IRB policies, new information regarding increased risk to human subjects, etc.

Any letter of suspension or termination of approval to an Investigator must include a statement of the reasons for the IRB's action.

If current participants must be withdrawn from the research, the IRB and Investigator will work together to notify the participants, address the procedures necessary to take into account their rights and welfare; and inform participants when follow-up for safety reasons is permitted.

Investigators must continue to report any adverse events or unanticipated problems involving risks to the participants or others as required by IRB Policy 10.2

In addition to the IRB, the Vice Chancellor of Academic Affairs and Research Administration (VCAA/RA) may suspend or terminate approval of research studies or privileges of individual investigators.

All suspensions or terminations of approval for cause will be reported in accordance with IRB Policy 2.6.