

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

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

**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.**

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

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.

**All suspensions or terminations of approval for cause must be promptly reported** to the IRB Director, the IRB Chair, the Vice Chancellor for Academic Affairs and Sponsored Research (VCAA/RA), the office of Research Compliance, the Director of Pharmacy Services, and the Office of Research and Sponsored Programs.

In addition to the IRB, the Chief Research Officer (VCAA/RA) may suspend or terminate approval of research studies or privileges of individual investigators.

**Regulatory authorities** such as the OHRP, FDA, NIH or other federal sponsoring departments or agencies will also be promptly notified by Office of Research Compliance of any terminations for cause or suspensions for cause.