

Department: UAMS Human Research Advisory Committee
Policy Number: 7.9
Section: Procedures for Study Review
Effective Date: July 31, 2002
Revision Date:

SUBJECT: Suspension or Termination of Approval for Cause

The HRAC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the HRAC 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 HRAC'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 HRAC policies, new information regarding increased risk to human subjects, etc.

All suspensions or terminations of approval for cause must be promptly reported to the Director of the HRAC Office and the HRAC Medical Director. They will notify the Associate Vice Chancellor for Research, the Associate Provost for Research, the Department Head, the Dean of the Investigator's School, and the Chairperson of the HRAC Committee responsible for the review of the research. When applicable, notification will also be forwarded to the Office of Sponsored Research, the Faculty Advisor, and appropriate institutional officials.

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