

Department: UAMS Institutional Review Board
Policy Number: 7.9
Section: Procedures for Study Review
Effective Date: July 31, 2002
Revision Date: May 20, 2004; February 8, 2005; January 24, 2011

SUBJECT: Suspension or Termination of Approval for Cause

I. POLICY

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

On an urgent basis, the Chair or Experienced IRB Reviewer may also suspend studies if a report under IRB Policy 10.2 indicates subjects or others are at immediate risk of harm. The suspension will be reported to the IRB in accordance with IRB Policy 10.2

The Vice Chancellor for Research may suspend or terminate approval of research studies or privileges of individual investigators. The Vice Chancellor will notify the IRB of these decisions.

II. DEFINITIONS

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

NOTE: When continuing review of a research project does not occur prior to the end of the approval period, the IRB approval expires automatically. While research activities must stop in most cases, this is not considered a suspension or termination of IRB approval.

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

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.

III. PROCESS

A. Notification to PI. If a study is suspended or terminated for cause, the notification letter to the Investigator will include reasons for the IRB's action.

B. Consideration for Subjects Currently Enrolled. If the study has currently enrolled subjects, the IRB will consider:

1. What actions are needed to protect those subjects;
2. The procedures for withdrawal of those subjects must take into account their rights and welfare. This may include such actions as making arrangements for care off study, transferring to another Investigator or continuing the research under independent monitoring.
3. Whether current subjects should be informed of the suspension or termination and the process for informing those subjects.

C. Investigator Reporting Obligations. Even if a study is suspended or terminated, Investigators must continue to meet the reporting requirements as required by IRB Policy 10.2

D. IRB Reporting Obligations. All suspensions or terminations for cause will be reported in accordance with IRB Policy 2.6.