Department: UAMS Institutional Review Board

Policy Number: 11.1

Section: Appeals and Reconsiderations

Effective Date: July 31, 2002 Revision Date: June 10, 2004

SUBJECT: Appeals and Reconsiderations

The purpose of an appeal is to give the researcher an opportunity to request reconsideration of the IRBs decisions under certain limited circumstances. Grounds for appeal are limited to:

- 1. New information not reasonably available during the review or investigation;
- 2. IRB failure to follow these policies and procedures; and
- 3. Documentation that the sanction exceeds the severity of the violations.

The Appeals Subcommittee will be comprised of three IRB members who were not involved in the previous review process and appointed by the chairman. The Appeals Subcommittee will review the written statement of appeal by the researcher and make a recommendation at to whether the IRB should reconsider any aspect of its decisions based on the ground(s) outlined above. In reaching this recommendation, the Appeals Subcommittee may seek a response from the IRB committee originally assigned to the protocol. The decision whether to forward a request for reconsideration should be made within 10 working days.

Upon reconsideration, the IRB determines whether to modify or uphold its original decision. This action is final. Consistent with the IRB's regulatory authority, no other entity within the University may override an IRBs decision which limits, imposes conditions or in any way restricts a researcher's privileges. The reconsideration phase is expected to be completed within 30 working days and the investigator will be notified of the decision in writing.