Department: **UAMS Institutional Review Board**
Policy Number: **4.5**
Section: **Committee Operations**
Effective Date: **July 31, 2002**
Revision Date: **August 25, 2004**

SUBJECT: Functions of the IRB Committee

Each IRB shall follow written procedures for the following (21CFR56.108):

1. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
2. Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
3. Ensuring prompt reporting to the IRB of changes in research activity;
4. Ensuring that changes in approved research, during the period for which IRB approval has already been given may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.
5. Ensuring prompt reporting to the IRB, appropriate institutional officials, and the Office of Human Research Protections and as applicable the Food and Drug Administration of:

    a. Any unanticipated problems involving risks to human subjects or others;

    b. Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or

    c. Any suspension or termination of IRB approval.

Except when an expedited review procedure is used (21CFR56.110; 45CFR46.110), the IRB reviews proposed research at convened meetings at which a majority of the members of the IRB are present including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.