Department: **UAMS Institutional Review Board**
Policy Number: **1.2**
Section: **Principles and Authority**
Effective Date: **July 31, 2002**
Revision Date: **March 5, 2004**

SUBJECT: Authority of the Committee

The IRB has the authority to:

1. Approve, disapprove, or require modifications of research activities (21CFR56.109(a); 38CFR16.109; 45CFR);

2. Require progress reports from the investigators and oversee the conduct of the studies [21CFR56.109(f); 45CFR];

3. Or suspend or terminate approval of an ongoing study. (21CFR56.113; 38CFR16.113; 45CFR)

4. Reopen terminated/closed protocols

In order to approve research, the IRB shall determine that all of the following requirements are satisfied [45CFR46.111; 38CFR111(a1-7)]:

1. **Risks to subjects are minimized:** (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. **Risks to subjects are reasonable in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. **Selection of subjects is equitable**. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged, and terminally ill persons.
4. **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §45CFR46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §45CFR46.117.
6. When appropriate, the research plan makes adequate provision for **monitoring the data collected** to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to **protect the privacy of subjects** and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons,

economically or educationally disadvantaged, and terminally ill persons, **additional safeguards have been included** in the study to protect the rights and welfare of these subjects.

In its review of human subject research, the IRB has jurisdiction over all aspects of the research including, but not limited to:

Methods of identifying potential subjects

Methods proposed for contacting potential subjects

Materials to recruit subjects and proposed compensation

Pilot studies

Proposals to use or provide stored blood, tissues, or confidential data

Surveys and questionnaires

The informed consent process and forms

The protocol and summary of the research

Evaluation of risks and benefits to subjects

Unanticipated problems involving risk to subjects

Proposed changes to the research

Continuing reviews

Use of investigational drugs and devices in emergencies

Humanitarian use of drugs and devices

Eligibility for exemption or expedited review