Department: **UAMS IRB**
Policy Number: **7.1**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
Revision Dates: **February 8, 2005; May 7, 2004**

SUBJECT: Criteria for IRB Approval of Research

The IRB shall determine that all of the following requirements are satisfied in order to approve research:

1. Risks to subjects are minimized:

a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

b. By using procedures already being performed on the subjects for diagnostic or treatment purposes, whenever appropriate.

2. Risks to subjects are reasonable in relation to:

a. Anticipated benefits, if any; and

b. 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 from therapies that 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, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

4. To the extent required, informed consent will be sought, as described in Policy 15.1.

5. To the extent required, informed consent will be documented, as described in Policy 15.1.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. See Policy 7.8

7. **When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

   The name of the HIPAA rule aside, privacy concerns people and confidentiality concerns data. In evaluating privacy interests, the IRB should consider how the Investigator will access information from or about participants. The use and disclosure of data is governed by Policy 13.3.

8. **When appropriate, additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence,** such as children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged.