Department: **UAMS IRB**
Policy Number: **7.1**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
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SUBJECT: Criteria for IRB Approval of Research

The IRB shall determine that all or the following requirements are satisfied in order to approve research covered by federal regulations as applicable (45 CFR 46; 21 CFR Parts 50, 56, 312, and 813; 38 CFR 16):

1. The investigator has demonstrated in writing that 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. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. The investigator has demonstrated in writing that risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may 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. The investigator's 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. Where applicable, the investigator will obtain informed consent and the informed consent design is readable and contains all the elements as described in section 15.1 of the IRB manual.

5. Where appropriate, the investigator's research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

6. Where appropriate, the investigator has provided adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7. Additional safeguards to protect rights and welfare of subjects when some or all subjects may be vulnerable to coercion or have limited autonomy, such as children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged.