Department: UAMS Human Research Advisory Committee
Policy Number: 7.1
Section: Procedures for Study Review
Effective Date: July 31, 2002
Revision Date:

SUBJECT: Criteria for HRAC Approval of Research

In order to approve research covered by federal regulations the HRAC shall determine that all of the following requirements are satisfied (46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991):

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. 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 be expected to result. In evaluating risks and benefits, the HRAC should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits therapies that subjects would receive even if not participating in the research). The HRAC 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 HRAC 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. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, as described in section 15.1 of the HRAC manual.

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

6. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.