Department: **UAMS Human Research Advisory Committee**
Policy Number: **7.4**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
Revision Date:

SUBJECT: Standard or Full Committee Review

The HRAC has the authority to approve, require modification in, or disapprove, all research activities that fall within their jurisdiction (45CFR46.111).

The HRAC Office will promptly convey the decisions and requirements for modifications by the HRAC to investigators in writing. **Written notification** from the HRAC Office of decisions to disapprove a protocol will be accompanied by the HRAC reasons for the decision and an invitation for an opportunity for reply by the investigator, either in person or in writing.

The **standard or full committee review category** is used for research that does not qualify for expedited or exempt review. The standard review of protocols may occur only at convened meetings of the HRAC at which a quorum is present.

Substantive review of standard protocols must take place at convened meetings.

1. Applications undergoing review must be individually presented and discussed at a convened meeting of the HRAC.

2. **Primary Reviewer System**. Two primary reviewers from among the Committee members are assigned for each standard review protocol. The primary reviewers should conduct an in-depth review of all pertinent documentation and present the protocol to the full Committee.

3. In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting.

The HRAC may only approve an application when its decision is based on consideration of the following:

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 HRAC 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 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, 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, in accordance with, and to the extent required by federal regulation.

5. **Informed consent will be appropriately documented**, in accordance with, and to the extent required by federal regulation.

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.**

Review Interval. The HRAC must determine an appropriate review interval at which to conduct continuing review of all standard protocols. The review interval must be appropriate to the degree of risk, but not less than once per year. (See Policy II.D) The minutes of HRAC meeting should clearly reflect these determinations regarding risk and approval period (review interval). See HRAC policy 16.

Vulnerable Populations. 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, terminally ill persons, or economically or educationally disadvantaged persons, the HRAC must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects. For more specific information about vulnerable populations, see the HRAC policies below:

17.1	Children
17.2	Cognitively Impaired Persons
17.3	Economically and Educationally Disadvantaged Persons
17.4	Institutionalized Persons
17.5	International Research
17.6	Minorities
17.7	Non-English Speaking Persons
17.8	Pregnant Women, Fetus, Invitro Fertilization
17.9	Prisoners in Research
17.10	Students, Employees, Healthy Volunteers
17.11	Stored Data or Tissues
17.12	Terminally Ill Patients
17.13	Traumatized and Comatose Persons

Approval Deferred. When the HRAC Committee requests substantive clarifications, substantive protocol modification or substantive informed consent revisions, HRAC approval must be deferred, unless the Committee can specify revisions that require only concurrence by the Investigator, in which case, after satisfactory revisions by the Investigator, the HRAC Chairperson or designated reviewer may approve the research on behalf of the HRAC.

The HRAC may require that information in addition to that specifically mentioned in 21 CFR50.25 and 45 CFR (elements of informed consent), be given to the subjects when in the HRAC's judgment the information would meaningfully add to the protection of the rights and welfare of subjects (21 CFR56.109; 45 CFR).