Department: **UAMS Institutional Review Board**
Policy Number: **7.4**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
Revision Date: **May 7, 2004**

SUBJECT: Standard or Full Committee Review

The IRB has the authority to approve, require modification in, or disapprove, all research activities that fall within their jurisdiction (45 CFR 46.111).

The IRB Office will promptly convey the decisions and requirements for modifications by the IRB to investigators in writing. **Written notification** from the IRB Office of decisions to disapprove a protocol will be accompanied by the IRB 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 IRB 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 IRB.

2. **Primary Reviewer System**. Two primary reviewers from among the Committee members are assigned for each new 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 IRB may only approve an application when its decision is based on consideration of the items outlined in 7.1

Review Interval. The IRB 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. The minutes of IRB meetings should clearly reflect these determinations regarding risk and approval period (review interval). See IRB 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 IRB 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 IRB 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 IRB Committee requests substantive clarifications, substantive protocol modification or substantive informed consent revisions, IRB 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 IRB Chairperson or designated reviewer may approve the research on behalf of the IRB.

The IRB may require that information in addition to that specifically mentioned in 45 CFR (elements of informed consent); and 21 CFR 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects (45 CFR 46; 21 CFR 56.109).