Department: UAMS Institutional Review Board
Policy Number: 7.4
Section: Procedures for Study Review
Effective Date: July 31, 2002
Revision Dates: June 1, 2005; February 8, 2005; May 7, 2004; March 5, 2008
SUBJECT: Standard or Full Committee Review

Policy: The standard or full committee review category is used for research that does not qualify for expedited or exempt review. Substantive review of full committee protocols will take place at convened meetings where quorum is met and be individually presented and discussed. In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting. The chair and the IRB office will ensure that the committee is staffed with members who have expertise in the areas under review for a particular meeting, or invite outside individuals with the appropriate expertise in accordance with IRB policy 3.9.

Primary Reviewers. All reviewers will have access to all new materials submitted, as well as the history file. Two primary reviewers from among the Committee members will be assigned for each new standard review protocol. The primary and secondary reviewers should conduct an in-depth review of all pertinent documentation and present the protocol to the full Committee addressing each of the criteria for approval outlined in policy 7.1. Non-Scientist members are not restricted from being primary or secondary reviewers. The chair shall assign non-scientist members to be primary or secondary reviewers for any category of review for each meeting.

Other Committee Members: The other Committee members who are not assigned a specific protocol must review the Original Submission Form, the consent form and recruitment materials in light of policy 7.1 and must participate in the discussion and vote on each protocol. Other committee members have an obligation to raise issues encountered during their review of these documents. No IRB member should vote to approve a protocol unless they feel comfortable that the rights and welfare of the subjects are protected as much as possible.

Non-scientist members: Non-scientist members are no different from other committee members. Non-scientist members do not need to understand complex scientific or medical information or procedures in order to evaluate human subject protection issues which is the primary mission of an IRB member.

Investigators Responsibilities:
1) Submit new study in ARIA to the appropriate Committee, either Biomedical or Behavioral depending upon design of study. See IRB Policy 4.1.

2) Submit in ARIA the following new application materials:
1. Complete Original Submission Form through ARIA
2. Detailed Protocol or any standard operating procedures (SOPs) to be used in the research, addressing:
    a. Study background with scientific rationale and aims;
    b. Methods;

c. List of all experimental procedures;
d. Anticipated risks and benefits to subjects and procedures to minimize risks;
e. Provisions to protect participant privacy;
f. Provisions to maintain the confidentiality of data;
g. Recruitment or enrollment procedures;
h. Participant selection criteria;
i. Data analysis method;
j. Additional safeguards to protect vulnerable participants; and references.

3. If a DHHS approved protocol exists, provide it as well and justification for any substantial deviations.
4. Informed Consent Form or script, unless waiver requested.
5. If a DHHS approved sample consent exists, provide it as well and justification for any substantial deviations.
6. HIPAA Authorization, if applicable
7. Any relevant merit reviews or grant applications
8. Advertisements or subject information
9. Surveys or questionnaires to be used
10. Investigator's brochure (if applicable)
11. Approvals from any other required institutional committees
12. Letters of assurance from other research sites (if applicable)
13. A simplified CV or accurate completion of profile in ARIA providing same information.

IRB Responsibilities:
1) The IRB may only approve an application when its decision is based on consideration and discussion of the criteria for approval outlined in IRB Policy 7.1.
2) Determine a category of risk as defined in IRB Policy 16.1.
3) The IRB must determine which protocols require continuing review more often than annually, as appropriate to the degree of risk and as necessary to ensure the continued protection of the rights and welfare of research subjects. See Policy 16.1 for detailed risk-benefit analysis. Studies with a high risk and low probability for benefit may require approval periods of greater than just once a year.

The following are examples of studies that may need additional review:
a. Involvement of vulnerable populations;
b. Research conducted internationally;
c. The involvement of recombinant DNA or other types of gene transfer protocols;
d. The use of waiver of informed consent procedures, e.g. surrogate consent;
e. Classified research;
f. Research for which subjects would be exposed to additional risks, e.g. breach of confidentiality, continual non compliance with federal regulations, Phase 1 studies, disproportionate number or severity of SAEs;
g. Previous suspension of the researcher due to compliance, record-keeping or other concerns
f. Recommendations from other intra-institutional committees
g. The IRB will promptly convey the decisions and requirements for modifications by the IRB to investigators through ARIA. Decisions to decline a protocol will be

accompanied by reasons for the decision and an invitation for an opportunity for reply by the investigator, either in person or in writing.