Department: **UAMS Human Research Advisory Committee**
Policy Number: **6.3**
Section: **Documentation**
Effective Date: **July 31, 2002**
Revision Date:

SUBJECT: Meeting Minutes

The HRAC office will prepare minutes of each meeting of the HRAC, during which research projects are being reviewed.

Distribution of Minutes. Minutes from the prior meeting are mailed with the next agenda for HRAC members and alternates to review. Any corrections/comments to the minutes are noted in the minutes of the next meeting. The minutes are considered final following these corrections. A copy of the final minutes is filed chronologically in the HRAC office, and sent to HRAC committee members, the VA R&D office, and the office of the Vice Chancellor for Academic Affairs and Sponsored Research at UAMS. The minutes shall be retained in the HRAC office for at least 3 years and accessible for inspection and copying by authorized representatives of the sponsoring Department or Agency at reasonable times and in a reasonable manner [45CFR46.115(b)].

The minutes of all HRAC Committee meetings must be in sufficient detail to show attendance at the meetings [45 CFR46.115(a)(2); 38 CFR16.115(a)(2)], including:

1. When there is a consultant or guest attending
2. Whether an alternate is voting
3. When a member leaves the room
4. When a member absents themselves during the vote due to a conflicting interest
5. Initial and continued presence of a majority of members, including at least one nonscientist member [45 CFR46.108(b)]

For each protocol discussed, the minutes document the following:

1. The HRAC protocol number and title
2. Actions taken by the HRAC Committee [45 CFR46.115(a)(2)]
    a. The vote on these actions including the number of members voting for, against, and abstaining [45 CFR46.115(a)(2)]
    b. In order to document the continued existence of a quorum, votes should be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1 (NAME)
3. When a protocol is approved, the minutes should reflect that the HRAC Committee determined:
    a. That the risks to subjects are minimized and reasonable in relation to the anticipated benefits [45 CFR46.111(a)(1,2)]

b. That the selection of subjects is equitable, with particular consideration for problems that may occur with vulnerable populations [45CFR46.111(a)(3)]

c. That informed consent is appropriately documented (see HRAC policy 15.1) [45CFR46.111(a)(4,5)]

4. That there are:

a. Provisions for safety monitoring of the data [45CFR46111(a)(6)]

b. Protections to ensure the privacy of subjects and confidentiality of data [45 CFR46111(a)(7)]

c. Appropriate safeguards for vulnerable populations [45CFR46.111b]

d. When protocol revisions are requested or a proposal is disapproved, the basis for doing so [45CFR46.115(a)(2)]

e. A written summary of the discussion of controverted issues and their resolution [45 CFR46.115(a)(2)]

f. A determination on the length of time between continuing reviews.

When a protocol is under continuing review, the minutes document the following:

a. The number of subjects accrued

b. A description of any adverse events or unanticipated problems involving risks to subjects or others; withdrawal of subjects from the research; or complaints about the research

c. A summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research

d. A copy of the current informed consent document

Specific Findings. When specific findings on the part of the HRAC Committee are required these findings should be fully documented in the HRAC Committee minutes and should include protocol-specific information justifying each HRAC finding. For example:

Alteration or Waiver of Informed Consent. When approving a procedure, which alters or waives the requirements for informed consent, the minutes must document that the Committee made the findings according to federal regulations (see HRAC policy 15.3) [45 CFR46.116(c,d].

Research Involving Prisoners. When approving research involving prisoners, the minutes must document that the Committee made the seven additional findings and the specific category which authorizes the research required (see HRAC policy 17.9) (45 CFR46.305-306). Additionally, the minutes must reference that either a majority of the HRAC Committee (exclusive of prisoner members) has no association with the prison(s) involved, apart from their membership on the HRAC [45 CFR46.304(a)]; or at least one member of the HRAC Committee is a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one HRAC only one HRAC need satisfy this requirement [45 CFR46.304(b)].

Research Involving Children. When approving research-involving children, the minutes must document that the Committee made the findings according to FDA regulations (see HRAC policy 17.1) (45CFR46.404-407). When reviewing research involving children who are wards of the state or any other agency, institution, or entity, the HRAC must find and document in the minutes that such research is: (1) related to their status as wards;

or (2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

Alternates. Meeting minutes must document when an alternate Committee member replaces the primary committee member.

Emergency Situations. When reviewing protocols that request exception for consent in emergency research, the HRAC Committee meeting minutes must specifically record the licensed physician member's affirmative vote (21 CFR50(b); 21 CFR50.2421 CFR50(b); 21 CFR50.24; 45 CFR).