Department: **UAMS Institutional Review Board**
Policy Number: **6.2**
Section: **Documentation**
Effective Date: **July 31, 2002**
Revision Date: **May 7, 2004**

SUBJECT: Written Procedures Governing the Committee

A. Initial Review (See IRB policy 7.4)

1. **Requirement for Review of Research by the IRB at Convened Meetings.** In accordance with HHS regulations at 45 CFR 46.108(b), initial and continuing reviews of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas, except where expedited or exempt review is appropriate [45 CFR 46.110]. Approval of research is by a majority vote of this quorum (see IRB policy 3.2). Should the quorum fail during a meeting (*e.g.*, loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored. The chair counts toward quorum, but only votes in the case of a tie.

2. **Research Review Materials**

   Initial Review Materials. HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting the initial review of proposed research, the IRB must obtain information in sufficient detail to make the determinations required under the regulations. Materials should include the full protocol, a proposed informed consent document, any relevant grant application(s), the investigator's brochure (if one exists), and any recruitment materials, including advertisements intended to be seen or heard by potential subjects.

   The primary reviewer(s) will perform an in-depth review of all pertinent documentation (see previous paragraph). All other IRB members will have available to them, electronic files containing all the information utilized by the primary reviewer(s) to make the determinations required under HHS regulations 45 CFR 46.111. This will include the proposed informed consent document and any recruitment materials, including advertisements intended to be seen or heard by potential subjects.

B. Continuing Review (See IRB policy 7.6)

1. IRB members will have available electronic version(s) of the continuing review form submitted for evaluation. This will include, but not be limited

to the following: (i) the number of subjects accrued; (ii) a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review; (iii) a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review; (iv) any relevant multi-center trial reports; (v) any other relevant information, especially information about risks associated with the research; and (vi) a copy of the current informed consent document and any newly proposed consent document.

2. At least one member of the IRB (*i.e.*, a primary reviewer) will have reviewed a copy of the complete protocol including any modifications previously approved by the IRB. Any other IRB member~~s~~ would also have access to the complete IRB protocol file and relevant IRB minutes prior to and during the convened IRB meeting using the electronic system (ARIA).

3. When conducting Continuing Review research under an expedited or exempt review procedure, the IRB Chair (or designated IRB member(s)) will review all of the above-referenced documentation, including the complete protocol.

C. Expedited Review. (See IRB policy 7.5)

The Chair or designee may review information submitted by the Principal Investigator that is requested to have an expedited review or has previously been expedited. Such review will be in accordance with principles set forth above and may at the discretion of the Chair be deferred for full IRB committee review as part of an agenda.

D. IRB Review in Emergency Situations. (See IRB policy 18.3, 18.4, 18.5)

Human subject research activities can not be started, even in an emergency, without prior IRB review and approval. When emergency medical care *using an investigational drug or device* is initiated without prior IRB review and approval, the patient may not be considered a research subject under 45 CFR Part 46. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a prospectively conceived research activity. When emergency care involves investigational drugs, devices, or biologics, U.S. Food and Drug Administration (FDA) requirements must be satisfied. (21 CFR 312.54 §50.24). The Chair or designee may provide such emergency review and approval. Such action is subsequently reported to the IRB committee.

E. Approvals Deferred With Major Revisions Required~~.~~

When the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under HHS

regulations at 45 CFR 46.111, IRB approval of the proposed research should be "***approved with major revisions"*** pending subsequent review by the convened IRB of responsive material.

Approvals Deferred With Minor Revisions Required

Only when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB Chair or another IRB member designated by the Chair subsequently approve the revised research protocol on behalf of the IRB under an expedited review procedure (45 CFR 46 (b)(2).)

F. Conflicting Interest. (See IRB policy 3.3)

HHS regulations at 45 CFR 46.107(e) stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. OHRP recommends that except when requested by the IRB to be present to provide information, IRB members absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such should be noted in the IRB meeting minutes.

G. Records and Documentation

1. Minutes of IRB Meetings (See IRB policy 6.3)

2. Documentation of Informed Consent Requirements**.**

   - **Elements of Informed Consent**

     Informed Consent Checklist - Basic Elements

     - A statement that the study involves research.
     - An explanation of the purposes of the research.
     - The expected duration of the subject's participation.
     - A description of the procedures to be followed.
     - Identification of any procedures which are experimental.
     - A description of any reasonably foreseeable risks or discomforts to the subject.
     - A description of any benefits to the subject or to others which may reasonably be expected from the research.
     - A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
     - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

Informed Consent Checklist - Additional Elements, As Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
- The number of subjects involved in the study.

- **Waiver of Written Informed Consent**

  HHS regulations at 45 CFR 46.116(d) require that the IRB make and document findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. OHRP recommends that when approving such a waiver for research reviewed by the convened IRB, these findings be documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

- **Informed Consent and Vulnerable Populations**

Similarly, where HHS regulations require specific findings on the part of the IRB, such as:
(a) approving a procedure which waives the requirement for obtaining a signed consent form;
(b) approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.201-207);
(c) approving research involving prisoners (see 45 CFR 46.303-306); or
(d) approving research involving children (see 45 CFR 46.401, 407).

The IRB should document such findings. OHRP recommends that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

- **Informed Consent Reviewed Under Expedited Procedure**

  For research reviewed under an expedited review procedure, these findings should be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB record.

3. **Documentation of Risk and Approval Period.** The IRB must determine which protocols require continuing review more often than annually, as appropriate to the degree of risk [see IRB policy 16.1 and 45 CFR 46.103(b)(4) and 46.109(e). The minutes of IRB meetings should clearly reflect these determinations regarding risk and approval period (review interval) for each protocol.

4. Documentation of Committee action on study-approval, approval deferred minor revisions, *etc.*

5. **Retention of IRB Records.** HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (see IRB policy 5.1).

H. Review of Protocol Modifications

1. **Review of Proposed Protocol Changes by the IRB at Convened Meetings.** In accordance with HHS regulations at 45 CFR 46.108(b), review of proposed protocol changes must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas, except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(2).

2. **Expedited Review of Minor Changes.** Minor changes in previously approved research which can be approved under an expedited review procedure in accordance with HHS regulations at 45 CFR 46.110(b)(2). See also IRB Policy 7.5. At UAMS, when requesting changes to a submission, IRB committee members decide in a meeting what constitutes major or minor changes.

3. **Protocol Revisions.** Each revision to a research protocol should be incorporated into the written protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This procedure is consistent with the procedure used for revised and approved informed consent documents which then supersede the previous one.