Department: UAMS Institutional Review Board
Policy Number: 8.1
Section: Change in Protocol
Effective Date: July 31, 2002
Revision Date: June 1, 2005; February 1, 2005; March 5, 2008
SUBJECT: Changing Study Protocol/Modifications to previously approved research

POLICY: All major and minor amendments or revisions must be submitted to the IRB for approval. The IRB Chair or his or her designee shall be the only one to determine as to whether an amendment is major or minor, based on degree of risk involved in the change. This determination must be made using all criteria in Policy 7.1.

1. Investigator will:
1.1. Make all amendment or modification requests through ARIA. Each modification will include:
1.1.1. Description of the changes;
1.1.2. Reason for the change;
1.1.3. Investigator's opinion as to impact of change on study and on participants; and
1.1.4. Whether or not changes are needed to the consent form.
1.1.5. All documents, including but not limited to consents, protocols, recruitment materials, and Form 1572s, to be modified. If a sponsor or a granting agency has requested the amendment, a copy of the communication from the sponsor, as well as a copy of the amendment and/or the amended protocol should also be included. If the change affects the consent, provide both a tracked and a clean document.
Note: The IRB reserves the right to defer review if the changes are not highlighted or tracked on the document to be revised. If a document is received from a sponsor where tracking changes is not possible then an outline of the protocol changes must be provided.

1.2. Not implement any change until IRB approval, and as applicable Sponsor approval, is received. The only exception is a change necessary to eliminate apparent immediate hazards to the research participants. In such cases, the Investigator will promptly inform the IRB, and as applicable the Sponsor, of the implemented change.

2. IRB Chair or Committee Roles For Minor or Major:

The chair and the committee must always use the criteria in 7.1 to make a determination of whether approval can be granted. Upon notification of any new information or change which might affect the willingness of a participant to continue in the study or changes the risk-benefit balance for those already enrolled, the Investigator will be directed to notify participants. Depending upon the seriousness, the Investigator may be directed to contact the participants by letter, re consent at next opportunity, or phone participants to schedule a visit for immediate reconsent process.

In situations where changes are to address administrative type changes and do not

impact the participant or their ability to contact those associated with the study, the IRB typically will not required re-consenting of previously enrolled subjects.

A. Chair/Designee. Criteria in policy 7.1 must be followed when it affects any one of the criteria for review. Minor changes will be reviewed and approved by the Chair/Designee, reported to the Investigator, and reported to the Committee on a future agenda.

B. Committee. Proposed changes in research which increase risk or discomfort or decrease benefit will be considered major. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented, unless the change is necessary to eliminate immediate hazards to the research participants. In the case of a change implemented to eliminate immediate hazards to participants, the Committee will review the change to determine that it is consistent with ensuring the participants' continued welfare.

The Office Notes section of the Agenda will list what items have been submitted to be reviewed. All members will have access to the materials in order to follow along, discuss the protocol and participate in the vote. Using the criteria in policy 7.1 as a guide, all committee members will be expected to review all modified documents along with the two primary reviewers assigned to the modification. The primary and secondary reviewers will present the changes to the committee in enough detail to enable discussion and a vote. All approvals or requested revisions will be reported back to the Investigator in writing.