Department: **UAMS Institutional Review Board**
Policy Number: **12.4**
Section: **Quality Assurances**
Effective Date: **February 04, 2005**
Revision Date: **June 1, 2005**
April 5, 2007

Subject: Non-compliance with Human Research Protection Program Requirements

Overview: The IRB assesses potential non-compliance events and assigns them to categories described by institutional and federal policy. Some categories require that the event be reported to one or more federal oversight agencies. However, not all non-compliance events require such reporting. The following policy assists the IRB with appropriate assessment and reporting.

The UAMS IRB, UAMS Office of Research Compliance (ORC) and the UAMS Vice Chancellor for Institutional Compliance (VCIC) work cooperatively to assure compliance of all studies under the IRB's review. Institutions other than UAMS who use the UAMS IRB also have assurance requirements for compliance.
The Vice Chancellor for Academic Affairs/Research Administration (VCAA/RA) may also be involved in compliance issues.

Classifications:

1. **Non-compliance:** Failure to comply with applicable Federal Regulations, UAMS IRB policies and procedures, UAMS and/or other institutional policies and procedures, or the determinations of the UAMS IRB.
2. **Serious Non-compliance**: An action or omission taken by an Investigator (or study personnel) which places, or could place, a subject at risk of significant harm.
3. **Continuing Non-Compliance:** A pattern of repeated actions or omissions taken by an Investigator (or study personnel) that indicates a deficiency in the ability or willingness to comply with Federal Regulations, UAMS and/or other institutional policies and procedures, or the determinations of the UAMS IRB.

If during its review the IRB suspects Scientific Misconduct, which is Fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results, the IRB shall immediately submit its findings to the VCAA/RA according to the requirements of university policy.

Reporting potential non- compliance

All reports of alleged non-compliance or inappropriate involvement of humans in research will be investigated and acted upon as necessary. Such reports may be received from any source by the UAMS IRB staff, Chair or members, the ORC, the VCIC, or the

VCAA/RA. Items may be reported to the IRB directly by the PI, as part of a routine audit or as a result of a directed audit.

Procedure for reviewing reports to the IRB which contain instances of Non-compliance

1. Reports of non-compliance, whether reported by the PI or one of the compliance offices, will be submitted to the IRB.

2. The IRB chair may take immediate action prior to the convened IRB review if there are any imminent safety risks to subjects or possible significant deficiencies in the ability or willingness to comply with Federal Regulations, UAMS and/or other institutional policies and procedures, or the determinations of the UAMS IRB. The IRB Chair may temporarily suspend the study or require other immediate remediation. If a drug study, the IRB Chair will notify the appropriate pharmacy of any suspension. The Investigator and the appropriate Research Pharmacist at the institution will be informed of such decisions by e-mail.

2. The IRB Chair will assign 2 or more reviewers to review all available information regarding the non-compliance and as applicable any summary directed review results for presentation at a convened IRB meeting. All IRBCR members will have access to this information, but only the assigned reviewers will be responsible for complete review and presentation for vote. At this meeting, the IRB will determine one of the following and notify the Investigator that:
    a. There is not enough information to make a determination. A request for more information or for an investigation by ORC may be requested.
    b. The non-compliance did not rise to the level of serious or continuing non-compliance as defined herein.
    c. Serious and/or continuing non-compliance has occurred, therefore, reporting to appropriate federal and institutional bodies and sponsors according to the FWA and IRB Policy 2.6 will be required.
    d. The IRB may issue sanctions or require additional protections from the investigator and also the institution.

3. Sanctions the IRB may consider and include in the notification to the Investigator are:
    a. Requiring additional investigator or study staff education
    b. Requirements for changes in study design or methodologies
    c. Suspension of any or all of the following study activities:
        i. Recruitment of subjects
        ii. Screening and enrollment activities
        iii. Research interventions and interactions or
        iv. Follow up activities
    d. Suspension of the investigator's research privileges with the IRB
    e. Termination of the investigator's research privileges with the IRB
    f. Termination of the study for cause

4. Additional protections the IRB may request include, but are not limited to:
    a. No further action may be needed if the Investigator has presented an adequate corrective action plan
    b. Revision or modification of the protocol, consent or other study processes
    c. Verification that subject selection is appropriate
    d. Direct observation of the informed consent process by the ORC or individual IRB members
    e. Require that current subjects be re-consented to participation
    f. Enhanced monitoring of the research activity through such mechanisms as: the employment of data safety monitors or a data safety monitoring board, or continued evaluation by the ORC.
    g. Request an off-cycle data and safety monitor or board review
    h. Request further directed reviews by ORC of targeted areas of concern
    i. Require the investigator to issue a status report after each subject receives an intervention
    j. Modify the continuing review cycle
    k. Require the Investigator and his or her staff receive focused education relevant to the area of non-compliance
    l. Notify current subjects, if the information about the non-compliance might affect their willingness to continue participation
    m. Notification of other groups such as the GCRC, PRMC, etc

5. Notifications to the Investigator regarding compliance determinations by the IRB will be copied to the appropriate department chair, college dean, VCIC, VCAA and ORC. In certain cases, the Corporate Compliance Office and the Hospital Risk management will be copied on such determinations.

6. Appropriate and timely communication to affiliate institutions involved will occur through the entire process.