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

Subject: Non-compliance with Human Research Protection Program Requirements

Definitions:

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) that any other reasonable Investigator would have foreseen as compromising the rights and/or welfare of a subject.
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.
4. **Scientific Misconduct**: Fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results.

The UAMS IRB, UAMS Office of Research Compliance (ORC) and the UAMS Vice Chancellor for Academic Affairs (VCAA/RA) 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.

Procedure for Reporting potential non- compliance or research misconduct

All reports of alleged non-compliance or inappropriate involvement of humans in research will be investigated. Such reports may be received from any source by the UAMS IRB staff, chair or members, the ORC, or the VCAA/RA. The process will be:

Scientific Misconduct

- Reports regarding alleged scientific misconduct will be immediately directed to the VCAA/RA according to the requirements of university policy

Non-compliance

1. IRB Director will accept all reports of potential non-compliance from all sources
2. IRB Director will review the report with the appropriate IRB chair.

3. The IRB chair will review the information and determine if it is non-serious, serious, or continuing. The Office of Research Compliance may be asked to participate in this determination.
4. If the chair determines that the action is non-serious, the following action should promptly be taken and documented in the ARIA study file.
    a. Formulate a corrective action plan
    b. Forward this plan to the investigator
    c. Place the required plan on the IRB agenda as an information item
5. The IRB chair may determine that more information is required and request a directed review *via* e-mail from the ORC. A copy of this request will be placed in the ARIA study file and forwarded to the investigator. In the event that an affiliate institution is involved, the affiliate will also be notified of the problem and the IRB's request for a directed review at the same time. ORC will work cooperatively with affiliate compliance personnel to complete the directed review in a reasonable time frame.
6. ORC directed review reports will be available for IRB executive committee review. Summaries of the ORC directed reviews will be placed on an agenda of a convened IRB committee as directed by the IRB chair.
7. If the review by the IRB chair determines that the information potentially inhibits the rights or welfare of participants, the information will be forwarded to the full IRB for review and consideration of suspension or termination. A directed review by the ORC can occur simultaneously with the IRB committee review for consideration of suspension.
    a. If drugs or devices are involved in the study the IRB chair shall immediately determine if there are any potential safety risks to subjects and notify the appropriate pharmacy if such a risk is present. The Investigator and the appropriate Research Pharmacist at the institution will be informed of such decisions by e-mail.
8. 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 IRB 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 were no issues of non-compliance
    b. There is not enough information to make a determination and an initial or further request for investigation by ORC will be issued.
    c. The non-compliance was neither serious or continuing
    d. Serious and or continuing non-compliance has occurred and requires reporting to appropriate federal and institutional bodies and sponsors according to the FWA and IRB Policy 2.6.
    e. The IRB may issue sanctions or require additional protections from the investigator and also the institution.

9. 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. Terminate the study for cause

10. Additional protections the IRB may request include, but are not limited to:
    a. No further action
    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

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

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