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

Subject: Non-compliance with Human Research Protection Program Requirements

Overview: The Vice Chancellor for Academic Affairs and Research Administration (VCAA/RA) or designees (hereafter VC) must review all reports of potential non compliance . The VC bears the responsibility of examining the report and deciding if reported information rises to the level of serious or continuing noncompliance, as defined below.

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 institution's purview. Institutions other than UAMS who use the UAMS IRB also have assurance requirements for compliance.

Definitions:

1. Minor 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. Non-compliance may be unintentional or willful.

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 or affects the rights and welfare of human participants or violates the basic principles of the Belmont report to which the institution has promised to adhere. This category may also include actions that could compromise the validity and integrity of the research data.

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 or affects or could affect the rights and welfare of human subjects or violate the basic principles of the Belmont report to which the institution has promised to adhere.

If during review the VC suspects Scientific Misconduct, which is Fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results, the VC shall follow its institutional scientific misconduct 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 which contain instances of Noncompliance
1. Reports of non-compliance, whether reported by the PI , one of the compliance Offices, or the IRB, will be submitted to the VC for review and determination under this policy. Determinations shall be documented by completing the "Assessment of Noncompliance" form at the end of this policy.

2. The VC may take immediate action prior to the convened IRB review if there is a finding of 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 VC may temporarily suspend the study, terminate the study, and require other immediate remediation or additional protections as described below in part 4 and 5 respectively. If a drug study, VC 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.

3. After the VC assigns the level of noncompliance, the decision is reported to the IRB. IRB members will have access to all the audit information at the convened meeting, but IRB Director and/or the Office of Research Compliance Director, or designee, will present a concise report of the findings, the classification, the remediation plan and/or the sanctions. At this meeting, the IRB will acknowledge the report and determine if the sanctions and remediation are adequate to protect the participants. The IRB shall notify the investigator and institutional officials of any additional requirements/decisions.

4. Sanctions the VC or IRB may consider and include in the notification to the Investigator but are not limited to the following:

a. Requiring additional information to make a determination.
b. Requiring additional investigator or study staff education.
b. Requirements for changes in study design or methodologies
d. 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
e. Suspension of the investigator's research privileges
f. Termination of the investigator's research privileges

g. Termination of the study for cause

5. Additional protections may 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 receives 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 CRC, PRMC, etc
6. Appropriate and timely communication to affiliate institutions involved will occur through the entire process.

12.4 Noncompliance Determination Form:

1. Did or could the event result in serious harm to subjects?
2. Did or could the event significantly impact the rights and welfare of human subjects?
3. Did or could the event significantly impact the research record or data integrity?
4. Was it an isolated event, first occurrence?
5. Was it part of a pattern of occurrences?
6. Was it reported by the investigator or by a third party?
7. Was it intentional?
8. Was it reckless?
9. Were laws, regulations or policies violated?