

Department: UAMS Institutional Review Board
Policy Number: 12.6
Section: Quality Assurances
Effective Date: March 5, 2008
Revision Date: January 24, 2011

SUBJECT: Findings of Non-Compliance under IRB Policy 12.5

I. Policy

When IRB Staff, Chair or Reviewers determine that information reported and reviewed under IRB Policy 12.5 rises to the level of noncompliance, these findings of noncompliance shall be classified using the federal regulation criteria for classification of noncompliance events.

II. Process

The IRB Staff (including the Chair) shall use the following format for each issue of noncompliance:

Classify – Report – Remediate - Follow Up Reports

Classify:

1. Minor Non-compliance: Unintentional or willful 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 that does not meet the definition of serious or continuing non-compliance.

2. Serious Non-compliance: An action or omission 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 that indicate 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 Scientific Misconduct is suspected, which is fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results, report the preliminary findings to the VC for Academic Affairs.

Report:

Report any incident of Serious or Continuing Non-Compliance to the IRB Chair immediately because subjects may be at risk. The IRB office must follow UAMS IRB Policy 2.6 for reporting all incidents classified as Serious or Continuing Non-Compliance.

Add report to next available IRB agenda as an "Update to be Reviewed by Two Reviewers" to allow the IRB to deliberate concerning remediation of the problem. All reviewers will have access to all available information.

Remediate:

While not limited to the following, IRB determinations may include:

- Requiring additional information to make a determination.
- Requiring additional investigator or study staff education.
- Requiring changes in study design or methodologies
- Suspension of any or all of the following study activities:

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- 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
- h. No further action may be needed if the investigator has presented an adequate corrective action plan.

Additional protections may include, but are not limited to:

- a. Revision or modification of the protocol, consent or other study processes
- b. Verification that subject selection is appropriate
- c. Direct observation of the informed consent process by the ORC or individual IRB members
- d. Require that current subjects be re-consented to participation
- e. 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.
- f. Request an off-cycle data and safety monitor or board review
- g. Request further directed reviews by ORC of targeted areas of concern
- h. Require the investigator to issue a status report after each subject receives an intervention
- i. Modify the continuing review cycle
- j. Require the Investigator, and his or her staff, to receive focused education relevant to the area of non-compliance
- k. Notify current subjects, if the information about the non-compliance might affect their willingness to continue participation
- l. Notification of other groups such as the CCTR, PRMC, *etc*

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

Follow Up Reports

Because reporting under IRB Policy 2.6 requires very prompt turn-around, a preliminary report is often sent. After the IRB reviews non-compliance issues and decides on further remediation, a follow up report may be required in accordance with IRB Policy 2.6