**Department:** **UAMS Institutional Review Board**
**Policy Number:** **2.6**
**Section:** **Relationships**
**Effective Date:** **July 31, 2002**
**Revision Dates:** **February 8, 2005; March 5, 2004; November 18, 2002**

**Subject: Reporting to Appropriate Federal Oversight Bodies, Institutional Officials and Research Sponsors**

**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.
5. **Federal Oversight Body**: Any agency that is a signatory to the Common Rule.
6. **Sponsor**: The industry or government sponsor and/or grant holder for a study. Examples are National Institutes of Health, pharmaceutical companies, private foundations.
7. **Termination for Cause**: An action initiated by the IRB to permanently stop some or all research activities or procedures.
8. **Suspension for Cause**: An action initiated by the IRB to temporarily stop some or all research activities or procedures.
9. **Serious:** An event is "serious" if it involves considerable detriment to one or more persons (who may or may not be subjects), or required intervention to prevent one or more persons from experiencing considerable detriment or harm.
10. **Related**: An event is "related: if it is likely to have been caused by the research activity.
11. **Unexpected**: An event is "unexpected" when its specificity, nature, severity or incidence are not accurately reflected in the information previously reviewed and approved by the IRB.
12. **Unanticipated**: An event is "unanticipated" when it was unforeseeable at the time it occurred. Unanticipated is not a synonym for unexpected. A researcher can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.
13. **Unanticipated Problem Involving Risks to Participants or Others:** Any event that was serious, unanticipated and related to the research.

It is the responsibility of the UAMS IRB to assure that reporting required under appropriate regulations, the terms of the Federal Wide Assurance, and IRB Policy is accomplished. When required reporting includes an affiliate organization utilizing the UAMS IRB, the mechanisms will be outlined in an agreement with each affiliate.

The IRB will assure the following issues are reported to appropriate agencies, institutional officials and the convened IRB within 45 days of the final determination of the convened committee:

1. Any unanticipated problems involving risk to participants or others.
2. Any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB.
3. Any suspension or termination IRB approval by the convened committee.

**Procedure for Reporting**

1. The IRB Chair, ORC Director or IRB Director will report to the IRB Executive Committee any required reporting under the four categories listed above.
2. The executive committee will confirm the need to report
3. The IRB will delegate the task to ORC of drafting the report and assembling appropriate supporting documentation. The report will include:
    a. A description of the event
    b. Actions taken by the IRB and the reasons for these actions
    c. Any administrative actions taken
    d. Any corrective action plans or plans for continued investigations
    e. Outcomes and sanctions
4. If the report involves another institution, ORC will work with the affiliate to draft the report.
5. The report will be circulated through the members of the executive committee for final review and approval
6. Copies of the report will be sent to the
    a. OHRP (in all cases)
    b. If the research is subject to any Common Rule agency, a copy is sent to that agency.
        i. Specifically, if the research is VA Research, a copy will be sent to the VA Research and Development Committee and to the regional VA Office of Research Oversight
    c. FDA, if the research is regulated by FDA
    d. IRB Chair,
    e. Study file
    f. Investigator
    g. ORSP Director
    h. Investigator's Chair
    i. Investigator's Dean
    j. VCAA/RA
    k. ORC file
    l. Institutional Officials at affiliate sites where UAMS IRB serves as the IRB of record, as applicable
    m. Legal Counsel if appropriate
    n. UAMS Risk Management, if appropriate
    o. Other indicated parties
7. The ORSP Director will forward a copy of the letter to the appropriate funding agencies or sponsors.
8. The IRB Chair will place the report on an IRB agenda as an information item.