

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; April 5, 2007; March 5, 2008

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

The UAMS IRB and institutional officials are responsible for reporting under appropriate regulations, the terms of the Federal Wide Assurance, and IRB Policy. When required reporting includes an affiliate organization utilizing the UAMS IRB, the mechanisms will be outlined in an agreement with each affiliate. If an event meets the definitions of serious non-compliance as defined by 12.4, continuing non-compliance by 12.4, unanticipated problem involving risk to participants or others defined by 10.2, is placed on administrative hold as defined by 9.1, or is terminated or suspended according to policy 7.9; the following reporting procedure shall be followed:

Procedure for Classification (see policy 12.4)

At UAMS the institutional officials named in UAMS Policy 12.4 serve the role of classifying issues of potential noncompliance. **All compliance reports, reports of potential non-compliance, reports of potential continuing non-compliance, and unanticipated problems must be reported to Institutional Officials as outlined in IRB Policy 12.4 to determine appropriate classifications and remediation plans and subsequently to an IRB committee to determine if the rights and welfare of human subjects have been adequately protected.**

Activities that must be reported to the Office of Human Research Protections:

The IRB will assure the following issues are reported to appropriate agencies, institutional officials and the convened IRB promptly after the final determination of the convened committee by the end of a two week period following the receipt of the report :

1. Any unanticipated problems involving risk to participants or others (10.2).
2. Any event classified by the IRB as serious non-compliance (12.4)
3. Any even classified by the IRB as continuing non-compliance (12.4)
4. Any suspension or termination IRB approval by the convened committee (7.9).
5. Any administrative hold placed on a study (9.1)

Procedure for Reporting

1. Institutional officials defined in 12.4 will classify report to the IRB and Research Compliance any event classified under the five categories listed above.
2. The IRB will work with ORC to draft the report and assemble appropriate supporting documentation. The report will include:
 - a) A description of the event
 - b) Classification assigned by the IRB
 - c) Actions taken by the IRB and the reasons for these actions
 - d) Any administrative actions taken

- e) Any corrective action plans or plans for continued investigations
 - f) Outcomes and sanctions
3. If the report involves another institution, the IRB will work with the affiliate to draft the report.
4. Copies of the report will be sent to the OHRP If the IRB classified the event in any of the five activities above. It will also be sent to:
- a) The UAMS IRB
 - b) If the research is subject to any Common Rule agency, a copy is sent to that agency by the ORSP Director
 - c) FDA, if the research is regulated by FDA
 - d) IRB Chair,
 - e) Study file
 - f) Investigator
 - g) Investigator's Dept. Chair
 - h) VCAA/RA
 - i) ORC file
 - j) Institutional Officials at affiliate sites where UAMS IRB serves as the IRB of record, as applicable
 - k) UAMS Risk Management, if appropriate
 - l) Other indicated parties
5. The ORSP Director will forward a copy of the letter to the appropriate funding agencies or sponsors and to the Vice Chancellor for Institutional Compliance.
6. The IRB Chair will place the report on an IRB agenda as an information item.