

**Department:** UAMS Institutional Review Board  
**Policy Number:** 12.6  
**Section:** Quality Assurances  
**Effective Date:** March 5, 2008  
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October 15, 2024; June 24, 2025

**SUBJECT: IRB Determinations of Non-Compliance and UPIRTSOs**

**POLICY**

When the IRB staff determine that information reported and reviewed under IRB Policy 12.5 rises to the level of potential noncompliance or a potential unanticipated problem involving risk to subjects or others (UPIRTSO), these reports shall be forwarded to the convened IRB for review. The convened IRB shall make the final determination regarding whether a report meets the definition of a UPIRTSO as described in IRB policy 10.2, or noncompliance. If the latter, the IRB will determine which level of noncompliance, as defined below, applies.

**DEFINITIONS**

**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, when such failure to comply does not meet the definition of serious or continuing non-compliance.

**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.

**Continuing Non-Compliance:** A pattern of repeated actions or omissions 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 violates the basic principles of the Belmont report to which the institution has promised to adhere.

**Scientific Misconduct:** Fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results.

**Unanticipated problem involving risks to subjects or others (UPIRTSO):** An incidence that is unanticipated or unexpected; related to the research, and involves new or increased risks to subjects or others.

**PROCEDURE**

- A. Classify -- The IRB shall determine whether the report falls into one of the above categories, and if so, which one.
  - 1. The IRB may also determine the report represents none of the above categories.
  - 2. The IRB may find it needs additional information to make a determination, and send back a letter deferring final consideration until such information is received.
- B. Remediate - The IRB shall consider any proposed remediation to determine its adequacy and to assess whether additional actions should be taken.
  - 1. If previous action had been taken on the report due to its having been thought to put subjects or the study's validity at risk, the convened IRB shall determine whether it concurs with that action.

2. Possible remediations include, but are not limited to:
  - a. Requiring additional investigator or study staff education.
  - b. Requiring changes in study design or methodologies
  - c. Reassignment of study personnel to different roles in the research
  - d. Suspension of any or all of the following study activities:
    - i. Subject recruitment
    - ii. Screening and enrollment activities
    - iii. Research interventions and interactions
    - 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.
3. The IRB may require additional changes to ensure compliance and/or support subjects' rights, safety, and welfare. See examples in IRB Policy 10.2.
4. Appropriate and timely communication to affiliate institutions involved will occur through the entire process.
5. If the UAMS IRB is the IRB of record for a multisite study, and a determination of noncompliance or UPIRTSO is made, the IRB shall work with the lead study site and the relying site(s) relevant to the determination to ensure the determination is reported to relying institutions and federal agencies as may be required.
- C. Reporting to the relevant agencies, funders, and/or institutional offices shall be done in accordance with UAMS IRB Policy 2.6.
- D. Preliminary reports may be made to notify federal agencies or others about the event within the timeframe described in IRB Policy 2.6. Follow-up reports may be submitted later after final determinations are made about the event and any remediation.
- E. If Scientific Misconduct is suspected at any time during the review, the preliminary findings shall be reported to the Vice Chancellor for Research and Innovation and/or the Vice Chancellor for Compliance and/or Managing Associate General Counsel.

## REFERENCES

45 CFR 46.108(a)(4)  
 21 CFR 56.108(b)  
 IRB Policy 2.6, *Reporting*  
 IRB Policy 10.2, *Events that Must Be Reported*  
 IRB Policy 7.13, *DoD-Conducted and -Supported Research*  
 AAHRPP Elements 1.5.D, II.2.G  
 OHRP Guidance *Unanticipated Problems Involving Risks & Adverse Events Guidance*