Department: **UAMS Institutional Review Board**
Policy Number: **12.5**
Section: **Quality Assurances**
Effective Date: **March 5, 2008**
Revision Date: **January 24, 2011; February 15, 2016; July 6, 2020**

SUBJECT: Reports of Potential Non-Compliance and Potential UPIRTSOs

POLICY
The IRB shall receive and review reports of potential noncompliance or unanticipated problems involving risks to subjects or others (UPIRTSOs). This reporting and reviewing is intended to promote human subjects' rights, safety, and welfare, and to ensure research is conducted in accordance with applicable regulations, policies, and IRB determinations.

PROCEDURE
A. Reports of potential noncompliance/UPIRTSOs may be received in multiple formats, including but not limited to the following: audit reports/responses; deviation and violation reports; adverse event reports; publications; complaints; reportable new information form submissions.
B. Reports may originate from investigators; the research team; the Office of Research Compliance; study sponsors; OHRP; FDA; study participants; campus committees; or other third parties. Potential non-compliance or UPIRTSOs may also be found during regular IRB review.
C. IRB staff (including the chair or convened IRB reviewers, will review all reports of potential noncompliance/UPIRTSOs by the following methods, regardless of the source of the reports:
D. IRB staff shall review all reports of potential non-compliance or UPIRTSOs as follows:
    1. Review the initial report.
        a. If additional information is needed, contact the person or entity making the report.
        b. When the initial report was made through the IRB e-system, requests for additional information are to be recorded in the e-system.
    2. Consider the following questions:
        a. Does the report indicate a possible immediate risk to subjects or others, or a degree of noncompliance that puts the study's validity at risk?
            i. If so, contact the IRB Chair or IRB Director immediately to discuss whether immediate action is required.
            ii. Regardless of the chair's or director's determination, assign the report to a convened IRB agenda for consideration to determine the level of noncompliance, whether it meets the definition of a UPIRTO, and to consider remediation.
        b. Does the report represent an instance of potential noncompliance or a potential UPIRTSO as defined in IRB Policy 12.6, without requiring immediate director or chair notification?
            i. If so, refer to full board for consideration to determine the level of noncompliance and to consider remediation.
        c. If the answers to questions 2a AND 2b are both "no," then:
            i. If the report is in the form of an audit or an audit response, assign to IRB agenda as an audit report to be reviewed.
            ii. For all other reports, the report can be acknowledged in the e-system, or returned to the study team indicating it does not meet the criteria for immediate submission to the IRB. The study team may be asked to include the report with the next continuing review.
    3. If the IRB staff is unable to answer the questions at 2 above, the staff will consult the IRB director or Chair for guidance. The report may be referred to the convened IRB for review at the request of the director or chair.

REFERENCES
45 CFR 46.108(a)(4)
21 CFR 56.108(b)
AAHRPP Elements I.5.D, II.2.G, III.2.D
AAHRPP Tip Sheet 14, *Non-Compliance*
AAHRPP Tip Sheet 23, *Unanticipated Problems Involving Risks to Participants or Others*