**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**

**SUBJECT: Reports of Potential Non-Compliance**

Reports of potential non-compliance may be in the form of, but not limited to, audit reports, deviations, violations, adverse event reports, publications and complaints, or events included on reportable new Information forms in the e-system..

These reports can come from investigators, members of the research team, research compliance, study sponsors, OHRP, FDA, participants, committees on campus and interested third-parties. Potential non- compliance may also be discovered during regular IRB review.

**Process**

IRB Staff (including the Chair or Reviewers) shall review all reports of potential non-compliance by the following methods:

1. Review report. If additional information is needed, contact the person who made the initial report and any other person involved to make sure all the facts are available.

2. Consider the following questions:

a) Does this information represent an action of potential non-compliance? If yes, refer to IRB Policy 12.6 regarding findings of noncompliance.

b) Is this information unanticipated AND does it indicate that participants or others are at increased risk of harm? If yes, place on IRB agenda and follow IRB Policy 10.2 and report as required by IRB Policy 2.6.

If the answer to both questions is no and the report is in the form of an audit, assign to IRB agenda as audit report to be reviewed.

For all other reports, process the report will be acknowledged and the study team may be asked to include the report with the next continuing review.

3. If IRB Staff is unable to answer the questions in step 2, IRB staff will consult with IRB Director or IRB Chair for determination. The report may be referred to the convened IRB for review at the request of the director or chair.