Department: UAMS Institutional Review Board
Policy Number: 12.5
Section: Quality Assurances
Effective Date: March 5, 2008
Revision Date:

Subject: Reports of potential non-compliance

Formal audit reports will be handled in accordance with IRB Policy 12.4. However, other reports of potential non-compliance can come from investigators, members of the research team, study sponsors, OHRP, FDA, participants, committees on campus, interested third-parties and most of all during regular IRB review. These reports may be in the form of, but not limited to, deviations, violations, adverse event reports, publications, package insert changes, and complaints.

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

1. Compile information. 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. Ask the following questions:
   a) Does this information represent an action of 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, acknowledge the report.
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.