Department: **UAMS Institutional Review Board**
Policy Number: **2.6**
Section: **Relationships**
Effective Date: **July 31, 2002**
Revision Date: **November 18, 2002; March 5, 2004; February 8, 2005; April 5, 2007; March 5, 2008; January 24, 2011; August 6, 2015, February 15, 2016; June 20, 2016; July 6, 2020; August 15, 2020; September 15, 2023**

SUBJECT: **Reporting to Federal Agencies, Research Sponsors/Funders, the Institutional Official, and Human Research Protection Program Accrediting Bodies**

POLICY

The UAMS Institutional Review Board will follow the relevant federal regulations and accrediting body requirements for the required reporting of reportable determinations and events.

PROCEDURE

A. Reporting Requirements
   1. Federal regulations require reporting to federal agencies of the following events on human subject research conducted, supported, or otherwise regulated by any federal agency that has adopted the Common Rule or that has taken action to apply the Common Rule or that is subject to FDA oversight:
      a. Unanticipated problems involving risks to subjects or others, defined in IRB Policy 10.2
      b. Serious or continuing non-compliance, defined in IRB Policy 12.6
      c. Suspensions or terminations of IRB approval, defined in IRB policy 7.9
   2. The Association for the Accreditation of Human Research Protection Programs (AAHRPP), requires human research protections programs (HRPP) to report the following items to AAHRPP as soon as possible (generally within 48 hours) after the organization or any researcher (if the researcher is notified rather than the organization) of any of the following:
      a. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters; FDA Warning Letters; FDA 483 Inspection Reports with official action indicated; FDA Restrictions placed on IRBs or investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
      b. Any litigation, arbitration, or settlements initiated related to human research protections
      c. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the institution's HRPP.
   3. A decision by an investigator to suspend or terminate some or all study activities or a directive by any non-IRB entity (e.g. the institutional official, sponsors, cooperative groups, or funding agency) is not immediately reportable. Only if this action is reported to the IRB and the IRB makes a subsequent reportable determination is this type of suspension/termination reportable.
   4. Reports to sponsors or funding agencies will be made as required by individual sponsors/funders. The IRB will work in conjunction with study teams or other campus offices to ensure any relevant reporting requirements are met.
   5. The Vice Chancellor for Research and Innovation may be made aware of determinations or events not otherwise reportable under this policy.

B. When reporting under this policy, the IRB Director, or designee, will draft a report for review and signature by the IRB Director or Vice Chancellor for Research and Innovation. The report shall include any required supporting material e.g., copies of material or publications being reported to AAHRPP. The report, other than those sent to AAHRPP, will be completed within 30 calendar days of the IRB determination. Reports to AAHRPP shall be sent as soon as possible after becoming aware of the reportable information, generally within 48 hours.

1. The Office of Research Compliance, General Counsel or affiliated institutions, such as Arkansas Children's Research Institute, will be consulted as needed to prepare and finalize the report. The report will include:

    a. Name of the institution conducting the research
    b. Title of the research project in which the problem occurred
    c. Principal investigator's name
    d. IRB number and the number of any applicable federal awards
    e. Description of the problem
    f. Classification assigned by the IRB
    g. Actions taken by the IRB or the administration
    h. Reasons for the IRB's or administration's actions.
    i. Any corrective action plans or plans for continued investigation
    j. Outcomes and sanctions

2. If necessary, e.g. final outcomes have not been determined, an initial report may be sent within the 30-day deadline, with a follow-up report sent later.

3. All reports will be sent and copied to the appropriate recipients as required by regulation and this policy. Potential recipients include:
    a. OHRP
    b. The UAMS Institutional Official
    c. FDA, if the research is regulated by FDA
    d. Other governmental agencies when the research is overseen by those agencies and they require reporting separate from that of OHRP
    e. Sponsors or funding agencies, as appropriate and after consultation with the study team. The IRB may direct the study team to report the determination to the sponsor/funder.
    f. Affiliated institutions involved in the research
    g. AAHRPP
    h. IRB Office file
    i. Other institutional officials or committees at UAMS as appropriate

REFERENCES

45 CFR 46.108(a)(4)
21 CFR 56.108(b)(2)
AAHRPP Elements I.5.D; II.2.G; II.2.H
AAHRPP Tip Sheet 15 *Reporting Unanticipated Problems Involving Risks to Participants or Others, Terminations or Suspensions of IRB or EC Approval, and Serious or Continuing Noncompliance*
OHRP *Guidance on Reporting Incidents to OHRP* dated 2011
OHRP 2014 presentation *Guidance on Reporting Incidents to OHRP* https://videocast.nih.gov/pdf/ohrp072414.pdf