

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

SUBJECT: Reporting to Appropriate Federal Oversight Bodies, Institutional Officials and Research Sponsors

DHHS and FDA regulations require reporting in three situations:

1. Unanticipated problems involving risks to subjects or others, defined in IRB Policy 10.2
2. Serious or continuing non-compliance, defined in IRB Policy 12.6
3. Suspensions or terminations of IRB approval, defined in IRB policy 7.9

When a determination is made that requires reporting under this policy, the IRB Director, or designee, will draft the report for review and signature by the IRB Director or Vice Chancellor for Research. The report will be completed within 30 days of institutional suspension or the IRB determination. In addition to IRB suspensions, suspensions may be imposed by either the UAMS Vice Chancellor for Research or the Arkansas Children's Research Institute President or Vice-President.

The Office of Research Compliance, General Counsel or affiliated institutions, such as Arkansas Children's Research Institute will be consulted as needed.

The report will include:

- a) A description of the event
- b) Classification assigned by the IRB
- c) Actions taken by the IRB and the reasons for these actions
- d) Any administrative actions taken
- e) Any corrective action plans or plans for continued investigations
- f) Outcomes and sanctions

All reports will be sent to OHRP. Copies of the report will also be sent to:

- a) FDA, if the research is regulated by FDA
- b) Other governmental agencies when the research is overseen by those agencies and they require reporting separate from that of OHRP
- c) Sponsors or funding agencies, as appropriate
- d) Affiliated institutions involved in the research
- e) IRB Office file
- f) Other institutional officials or committees at UAMS as appropriate