

**Policy Number: 60**

**Title: Reporting Procedures For Unanticipated Problems, Noncompliance, Suspension, or Termination**

**Date of Last Revision: July 27, 2007**

## **I. General Overview**

The Department of Health and Human Services (DHHS) requires that institutions have “written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval” [45 CFR 46.103(b)(5)].

The Food and Drug Administration (FDA) requires that institutions follow “written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of: (1) any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval” [21 CFR 56.108(b)].

## **II. Policies**

Reports of an unanticipated problem involving risks to subjects or others, serious or continuing noncompliance with the regulations or the requirements/determinations of the IRB, and/or the suspension or termination of the approval to conduct research shall result in the notification of the appropriate federal agencies, institutional officials, and study sponsor as determined by the IRB.

Please refer to each of the following OPRS/IRB Policies for details:

1. [\*OPRS/IRB Policy 15: Biomedical Adverse Event Reporting\*](#),
2. [\*OPRS/IRB Policy 56: Incident Reporting\*](#),
3. [\*OPRS/IRB Policy 53: Noncompliance\*](#),
4. [\*OPRS/IRB Policy 59: Suspension and Termination of Research\*](#),
5. [\*OPRS/IRB Policy 57: Unanticipated Problems\*](#), and
6. [\*OPRS/IRB Policy 55: Protocol Violations\*](#).

### **III. Procedures**

- A. Upon determination by the IRB that a problem was an unanticipated problem involving risk to participants or others, noncompliance was serious or continuing, or if the IRB or organization suspends or terminates research approval, this procedure is followed for reporting to appropriate federal agencies, institutional officials and sponsors.
1. The written correspondence will be sent from the Director of the Office for Protection of Research Subjects (OPRS) to OHRP in all cases and to the FDA if the research is FDA-regulated.
  2. The IRB staff shall oversee/coordinate the written correspondence.
  3. The OPRS Director will review and approve the correspondence prior to agency notification.
- B. The written correspondence shall include but is not limited to the following:
1. Name of the institution.
  2. Title of the research project.
  3. Name of the investigator.
  4. IRB number and/or number of applicable federal awards.
  5. Detailed description of the reportable event, including the nature of the event.
  6. Action determinations made by the IRB to address the reportable event (i.e. explanation statement of the IRB's action, corrective action plan)
  7. Plans, if any, to send a follow-up or final report by the earlier of: a) a specific date, or b) when an investigation has been completed or a corrective action plan has been implemented.
- C. Copies of the correspondence shall be forwarded to the following:
1. Institutional officials (Executive Vice Chancellor, Vice Chancellor – Research)
  2. Principal Investigator
  3. Chair of the IRB that made the determination or took the action
  4. University departments and/or department head, if applicable and as determined by the IRB
  5. University Contracting office (The contracting office will be responsible for notifying the study sponsor, including any federal agencies sponsoring the research)

#### **Regulations:**

45 CFR 46.103(b)(5)  
21 CFR 56.108(b)

**References:**

OHRP, *Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance*, October 12, 2005. <http://hhs.gov/ohrp/compliance/findings.pdf>

OHRP, *Guidance on Reporting Incidents to OHRP*, May 27, 2005. [http://hhs.gov/ohrp/policy/procedures\\_for\\_reporting\\_052505.pdf](http://hhs.gov/ohrp/policy/procedures_for_reporting_052505.pdf)

OHRP, *Guidance on Written IRB Procedures*, January 15, 2007. <http://hhs.gov/ohrp/humansubjects/guidance/irbgd107.pdf>

OHRP, *Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events*, January 15, 2007. <http://hhs.gov/ohrp/policy/AdvEvtGuid.pdf>

FDA, *IRB Information Sheet- Continuing Review After Study Approval*, September 1998. <http://www.fda.gov/oc/ohrt/irbs/review.html>