

Guidance and Procedures Number: 60

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

Date of Last Revision: February 26, 2009

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 guidance 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

- A. The IRB is responsible for reporting to the appropriate institutional officials and federal department(s) or agency head(s) any unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with the regulations or the requirements and/or determinations of the IRB; and any suspension or termination of IRB approval.
 - 1. If upon review by the IRB, IRB Chair or Vice Chair the reported unanticipated problem does not meet the criteria, the event will be considered **not** to represent an unanticipated problem and therefore further reporting to federal department or agency head(s), institutional officials and other parties is not required.
 - 2. Reporting to federal department or agency head(s) is not required if notification has been made through other mechanisms, such as reporting by the external site, investigator or other organization.
 - 3. For multicenter studies, only the institution at which the unanticipated problem occurred must report to federal department or agency head(s). However, the institution and/or the study sponsors are also required to notify the other institutions involved in the study.
- B. The IRB shall distribute the reports to the institutional officials and external agencies as described in Section III below.

III. Procedures

- A. Unanticipated problems involving risks to subjects or others, any serious and/or continuing noncompliance, any suspension or termination of IRB approval, and the outcome of the IRB's actions will be reported to the appropriate institutional official(s) and to the appropriate federal department(s) or agency head(s) as follows:.
1. The Director, Operations Director or Assistant Directors of the Office of Protection of Research Subjects (OPRS) Human Research Protection Program will coordinate with the appropriate IRB Chair and IRB senior staff to prepare and forward correspondence. Unless unavailable, the correspondence will go out over the signature of the Director of OPRS; if the Director is not available, then the correspondence will go out over the signature of one of the OPRS HRPP Assistant Directors or the Operations Director.
 2. The correspondence will be prepared and forwarded within ten working days of the IRB's final determination.
 3. A copy of the correspondence to will be forwarded to the following parties in all cases:
 - a. Principal Investigator,,
 - b. Applicable IRB Chair(s),
 - c. Dean, Department Chair, and/or Unit Head , and
 - d. HRPP Institutional Official
 4. The correspondence will also be forwarded to the following individual or agencies as applicable as described below:
 - a. If the study is externally funded, the UCLA University contracting office—the contracting office is responsible for notifying the study sponsor, including any federal funding sponsors or agency;
 - b. Western Institutional Review Board, if the Western IRB is the IRB of record;
 - c. U.S. Department of Navy (DON) for DON supported research only.
 - d. Institutional Official and/or HRPP Director of any other site involved in the research for which the UCLA serves as the IRB;
 - e. Food and Drug Administration if the study involves an FDA-regulated product;
 - f. Office for Protection of Human Research if the study is federally funded;
 - g. Other Common Rule agencies if the research project is conducted under the oversight of these agencies, e.g., the Department of Energy, Department of Defense, Department of Homeland Security;
 - h. UCLA Office of Audit and Advisory Services;
 - i. UCLA Office of Administrative Policy and Compliance;
 - j. Other internal offices (such as the Institutional Biosafety Office or the Medical Radiation Safety Committee) or internal or external (i.e., Office of Biotechnology Activities) as required by the nature of the findings and the jurisdiction and expertise of the office.
 5. Written correspondence will include but is not limited to the following:

- a. Name of the institution;
- b. Title of the research project;
- c. Name of the principal investigator;
- d. IRB number, sponsor protocol number and/or number of applicable federal award, grant, contract or cooperative agreement, IND or IDE number (if FDA regulated);
- e. The type of determination made by the IRB (i.e., unanticipated problem, serious and/or continuing noncompliance, suspension or termination);
- f. Detailed description of the findings and the reason for the determination;
- g. Actions undertaken to address the problem; and
- h. Plans for continued investigation or action, if any.

B. Follow Up Reports

If any follow up reports are written, they will follow the same procedures described above.

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

OHRP, *Guidance on Written IRB Procedures*, January 15, 2007. <http://hhs.gov/ohrp/humansubjects/guidance/irbqd107.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>

AAHRPP Tip Sheet: *Reporting of Unanticipated Problems, Terminations, Suspensions, and Non-compliance* (May 24, 2007)