



Guidance and Procedure: IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension, or Termination

(last updated June 9, 2016)

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General Overview

The Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) 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\(b\)\(5\)\]](#) and [\[21 CFR 56.108\(b\)\]](#).

Policies

- 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.
 - 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.
 - Reporting to the appropriate federal department or agency head is based upon which department/agency regulates the research (i.e. DHHS/OHRP, FDA).
 - Reporting to federal department or agency head(s) is not required if notification has been made through other mechanisms (i.e. an external site).
 - 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.

- The IRB shall distribute the reports to the institutional officials and external agencies as described in Section below.

Procedures

- 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 convened 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:
 - The Director or an Assistant Director of the Office of the Human Research Protection Program (OHRPP) will in consultation with the IRB Chair prepare the report.
 - The report will be forwarded within 30 days of the convened IRB's final determination assuming full resolution has been achieved. If full resolution has not been achieved, a preliminary report will be forwarded within 30 days, and the final report within 30 days of final resolution.
 - A copy of the report will be forwarded to the following parties in all cases:
 - ▶ DHHS/Office for Human Research Protections (OHRP) if the study is federally funded,
 - ▶ Food and Drug Administration if the study involves an FDA regulated product,
 - ▶ OHRPP Institutional Official
 - ▶ Principal Investigator,
 - ▶ Applicable IRB Chair(s),
 - ▶ Dean, Department Chair, and/or Unit Head , and
 - ▶ University contracting office if the study is externally funded. The contracting office is responsible for notifying the study sponsor, including any federal funding sponsors or agency, industry sponsor, or contract research organization
 - The report will also be forwarded to the following as applicable:
 - ▶ Other University internal offices (i.e. Institutional Biosafety Committee, Medical Radiation Safety Committee, General Counsel) or external (i.e. Office of Biotechnology Activities) as required by the nature of the findings and the jurisdiction/expertise of the office;
 - ▶ Institutional Official and/or HRPP Director of any other site involved in the research for which the UCLA serves as the IRB;
 - ▶ 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, Department of Education, Department of Justice
 - Written correspondence will include but is not limited to the following:
 - ▶ Name of the institution;
 - ▶ Title of the research project;
 - ▶ Name of the principal investigator;
 - ▶ IRB number, sponsor protocol number and/or number of applicable federal award, grant, contract or cooperative agreement, IND or IDE number (if FDA regulated);

- ▶ The type of determination made by the IRB (i.e., unanticipated problem, serious and/or continuing noncompliance, suspension or termination);
 - ▶ Detailed description of the findings and the reason for the determination;
 - ▶ Actions undertaken to address the problem; and
 - ▶ Plans for continued investigation or action, if any.
- Follow Up Reports

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

References and Regulations

DHHS Regulations

- [45 CFR 46.103\(b\)\(5\)](#)

FDA Regulations

- [21 CFR 56.108\(b\)](#)

OHRP, [Compliance Oversight Activities: Determinations of Noncompliance](#), February 2, 2009.

OHRP, [Guidance on Reporting Incidents to OHRP](#), 2011.

[OHRP, Guidance on Written IRB Procedures, 2011.](#)

[OHRP, Unanticipated Problems Involving Risks and Adverse Events Guidance, 2007.](#)

[FDA Guidance – IRB Continuing Review After Clinical Investigation Approval, February 2012.](#)

Change history:

6/9/2016: Updates to links and references