

UCSD OFFICE OF IRB SERVICES			
Guidance	<b>Title:</b> Reporting Certain Determinations		
<b>Number:</b> 4.4	<b>Version Date:</b> 29 July 2019	<b>Author:</b> K. Allen	<b>Approver:</b> K. Kantelo

**1.0 Purpose:** To assure reporting occurs according to federal regulations and institutional policy.

**2.0 Policy:**

- 2.1 The IRB will maintain written procedures for assuring prompt reporting to appropriate institutional officials, sponsoring agencies, and the Department or Agency head(s) of:
  - 2.1.1 Any unanticipated problems involving risk to participants or others;
  - 2.1.2 Any serious or continuing non-compliance with applicable regulation or institutional policy for protection of human subjects or the requirements or determinations of the IRB; and
  - 2.1.3 Any suspension or termination of IRB approval.
- 2.2 This reporting will take place within 30 business days of the completion of an investigation and/or determination.
  - 2.2.1 If a situation remains unresolved (for example, if IRB approval is suspended as a precautionary measure while allegations of non-compliance are investigated), a preliminary report shall be made within this timeframe.
  - 2.2.2 Preliminary reports shall be followed by a follow-up report within 30 days of resolution of the situation and when otherwise requested by oversight agencies.
- 2.3 Any reportable determination made by an external IRB or institution shall be reported to UCSD for handling according to this procedure. Unless explicitly agreed to by UCSD in writing, external IRBs or institutions shall not report to external agencies on behalf of UCSD.
- 2.4 If allowable under the terms of the reliance agreement and with written notification to UCSD, an institution relying on UCSD IRB review may replace this procedure with its own procedure for reporting.

**3.0 Applicability:** UCSD Institutional Official, IRB Chairs, IRB Director, and IRB Analysts

**4.0 Administration:**

- 4.1 The Institutional Official or responsible IRB chair or analyst notifies director or designee of determination(s).
- 4.2 Director or designee prepares a letter that is addressed to the following as applicable:
  - 4.2.1 OHRP, when the research is federally-supported;
  - 4.2.2 OHRP-equivalent offices within the supporting federal department or agency (if not DHHS);
  - 4.2.3 FDA, when the research is FDA-regulated; or
  - 4.2.4 The Institutional Official (if research is neither federally-supported nor FDA-regulated).
- 4.3 The letter shall outline:
  - 4.3.1 The nature of the event;
  - 4.3.2 The findings of the organization and/or IRB to date;
  - 4.3.3 Actions taken by the organization and/or IRB to date;
  - 4.3.4 Reasons for the organization's and/or IRB's actions;
  - 4.3.5 Plans for continued investigation or action, if applicable; and,
  - 4.3.6 Plans for follow-up reporting, if applicable.
- 4.4 If letter is addressed to an external agency:
  - 4.4.1 Director or designee forwards draft to Institutional Official for review and/or further distribution for comment.
  - 4.4.2 Director or designee finalizes letter based on feedback.
  - 4.4.3 Institutional Official signs finalized letter and returns to director or designee.

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- 4.5 If letter is addressed to the Institutional Official:
  - 4.5.1 Director or designee finalizes and signs letter.
- 4.6 Director or designee distributes signed letter to the following as appropriate to the circumstances:
  - 4.6.1 The addressee(s);
  - 4.6.2 UCSD Vice Chancellor for Research;
  - 4.6.3 Directors of UCSD grants and contracting offices;
    - 4.6.3.1 By this copy, directors of those offices are responsible for notification to department or agency heads or other entities as required by regulation or by award or contract terms.
  - 4.6.4 Directors of applicable UCSD compliance, ethics or integrity offices;
  - 4.6.5 Responsible UCSD vice chancellor, dean, and department chair (or other supervisor) of the Principal Investigator;
  - 4.6.6 Other UCSD and/or UC offices (e.g., counsel, privacy, risk management);
  - 4.6.7 Institutional Official or designee of Rady Children’s Hospital San Diego;
  - 4.6.8 If required by agreement, the Institutional Official or designee of any:
    - 4.6.8.1 Institution providing IRB review services to UCSD
    - 4.6.8.2 Institution relying on UCSD IRB review;
  - 4.6.9 Chair of the reviewing IRB;
  - 4.6.10 Principal Investigator
    - 4.6.10.1 If the award is under a different PI than the human subjects protocol, both PIs shall be notified.

**5.0 References**

45 CFR 46.108(a)(4) and 21 CFR 56.108(b)  
 OHRP Guidance on Reporting Incidents to OHRP (2011)  
 Mandatory IRB Reporting: FDA Contacts (3/30/2018)

**6.0 Revision History**

29 July 2019: Replaces portions of UCSD IRB SOPP: Section 5.2 Communications, Sanctions, Appeals, and Disciplinary Actions - Version Date: 5/16/2017