INTRODUCTION

This procedure describes the federal Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations for reporting in three situations: (i) unanticipated problems involving risks to participants or others, (ii) serious or continuing noncompliance, and (iii) suspensions or terminations of IRB approval of research.

*Chapman has elected on its Federalwide Assurance (FWA) not to apply the Common Rule and subparts B, C, and D to research that is not federally conducted or supported. Chapman University therefore does not report unanticipated problems, serious or continuing non-compliance, or suspension or termination of IRB approval to Office for Human Research Protections (OHRP) when the research is not federally conducted or supported.*

Chapman University (Chapman) will promptly report to applicable institutional officials, funding sources, agency heads, and regulatory agencies all determinations by the IRB when an event represents:

- An unanticipated problem involving risks to subjects or others as determined by the IRB;
- A serious or continuing non-compliance with federal regulations or the requirements or determinations of the IRB; or
- A suspension or termination of IRB approval.

Chapman has reporting obligations for nonexempt human subject’s research when Chapman is engaged in the research, or the Chapman IRB is the IRB of record. The reporting requirements in this procedure are not necessarily applicable to administrative holds.
PROCEDURES

Report of IRB Determination

Chapman’s Director of Research Integrity (DRI) will draft a report following a determination by the IRB of a reportable unanticipated problem involving risks to subjects or others, serious or continuing non-compliance with federal regulations or the requirements or determinations of the IRB, or suspension or termination of IRB approval.

- Based on the materials provided, the DRI will evaluate the reporting requirements for the incident and, when verified, will prepare a letter that contains the following information:
  1. Name of the institution conducting the research;
  2. Title of the research project and/or grant proposal in which the incident occurred;
  3. Grant/contract number, if HHS-supported research;
  4. Name of test article and corresponding Investigational New Drug (IND) or Investigational Device Exemption (IDE) number, if applicable;
  5. Name of the PI on the protocol;
  6. Number assigned by the IRB for the research project and number of any applicable federal award(s);
  7. The findings of the IRB or organization and reasons for the findings;
  8. Detailed description of the unanticipated problem, noncompliance, suspension, or termination;
  9. Actions the institution is taking or plans to take to address the incident and reasons for the actions (e.g., revise protocol, suspend subject enrollment, revise informed consent);
  10. Plans for any further investigation or action (if applicable); and
  11. An indication of whether a follow-up or final report will be sent by the earlier of a specified date, completion of an investigation, or implementation of a corrective action plan.

Distribution of the Report

The final correspondence is distributed from the institutional official (IO) to the following:

1. IRB;
2. OHRP, when the research is covered by HHS regulations;
3. Sponsor, including grant management and program officers of HHS-supported research;
4. Other federal agencies when the research is overseen by those agencies and they require reporting separate from that to OHRP;
5. FDA, when research is FDA regulated;
6. Department of Defense (DoD) component Human Research Protections Officer (if DoD funded);
7. Principal Investigator (PI);
8. Other participating institutions, when the Chapman IRB is the IRB of record or has oversight for the research (e.g., Chapman is the lead site, coordinating center, or sponsor for the research)

Chapman will not report to federal agencies already made aware of an incident through reporting by the sponsor or another organization.

**Timeline for Reporting**

Reports to OHRP, FDA and other federal agencies will be made promptly. Unless otherwise authorized by the IO, the letter will be sent within 10 working days of the convened IRB’s determination. In the event a situation requires extended time to investigate or resolve, a preliminary report will be sent and followed by a final report.

**REFERENCES**

21 CFR 56.108(b)
45 CFR 46.103(b)(5)
AAHRPP Tip Sheet 15: Reporting Unanticipated Problems Involving Risks to Participants or Others, Terminations or Suspensions of IRB or EC Approval, and Serious or Continuing Non-compliance
OHRP, Guidance on Reporting Incidents to OHRP, May 27, 2005