

Policy Number: 53

Title: Reporting to the Appropriate Institutional Officials, and the Department or Agency Head(s)

Date of Last Revision: 08/10/05, 12/01/10, 01/24/11, 05/01/16

Policy:

It is the responsibility of the UCI IRB to assure compliance reporting occurs according to the Federal regulations, institutional policy and UCI IRB policy.

- I. The IRB will maintain written procedures for assuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of:
 - A. Any unanticipated problems involving risk to participants or others;
 - B. Any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and
 - C. Any suspension or termination of IRB approval for cause.
- II. Reporting will take place as soon as possible, but no more than 30 days between the IRB determination or recognition of a reportable event and fulfilling reporting requirements for unanticipated problems involving risk to participants and others. For more serious incidents, a preliminary written report will be provided within five business days with an estimated time for the final report.
- III. Any concerns regarding data integrity or research/scientific misconduct outside of the jurisdiction of the UCI IRB will be referred to the Vice Chancellor for Research for further consideration/action.
- IV. When human subject research involves the Department of Energy (DoE), the UCI IRB will follow DoE regulations and guidance that pertains to ensuring research compliance as per DoE O 443.1A. Specifically, researchers must promptly report the following to the human subject research program manager:
 - A. Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken
 - B. Any suspension or termination of IRB approval of research
 - C. Any significant non-compliance with HRPP procedures or other requirements
 - D. The time frame for "promptly" is defined as per HRP policy for unanticipated problems (See HRP Policy # 19).
 - E. Any compromise of personally identifiable information must be reported immediately
 - F. The time frame for "immediately" is defined as per HRP policy for unanticipated problems (See HRP Policy # 19).
- V. When human subject research involves the Department of Defense (DoD), specifically, issues relating to non-compliance, the matter will be referred to the next higher management echelon to take deliberate action for resolution. All findings of serious non-compliance shall be reported to the Director, Defense and Research Engineering.
- VI. The following shall be reported to the Department of Navy (DoN) Human Research Protection

Program (HRPP) Office, as it relates to research involving the DoN and matters of non-compliance:

- A. All suspensions and terminations of previously approved DoN research protocols.
 - B. The initiation and results of investigations of alleged non-compliance with human subject protections.
 - C. Unanticipated problems involving risks to subjects or others, or serious adverse events in DoN supported research.
 - D. All audits, investigations or inspections of DoN supported research protocols.
 - E. All audits, investigations or inspections of the institution's HRPP conducted by outside entities (e.g. FDA, OHRP)
 - F. Significant communication between institutions conducting research and other federal departments and agencies regarding compliance and oversight.
 - G. All restrictions, suspensions or terminations of institutions' assurances.
- VII. The Naval command or activity with responsibility for the research will review all allegations of non-compliance with human subject protections and take action, if appropriate. Report the initiation of all investigations and report results, regardless of the findings to the Navy Surgeon General (SG) and appropriate sponsors.
- VIII. Naval IRBs: The primary role of the IRB is to ensure safety and welfare of human research subjects. IRBs make recommendations to the approval authority for research protocols. Naval IRBs report to the Commander, Commanding Officer or Officer in Charge the following:
- 1. All suspensions or terminations of previously approved research protocols,
 - 2. The initiation of investigations of alleged non-compliance with human subject protections,
 - 3. Unanticipated problems involving risks to subjects or others, or serious adverse events,
 - 4. All audits, investigations or inspections of the institution's HRPP conducted by an outside entity (e.g., the FDA of OHRP),
 - 5. Significant communication between the institutions conducting research and other federal departments and agencies regarding compliance and oversight.

References:

45 CFR 46.103(b)(5)

21 CFR 56.108(b)

OHRP Guidance on Reporting Incidents to OHRP

DoE O 443.1A

DoD: DoDD 3216.2, para. 4.10

SECNAVINST 3900.39D, para 8d(2), para 8e(6), para 8g(6) and 6k

OHRP Guidance on Reporting Incidents to OHRP

Procedure Number: 53.A

Title: Procedure for Reporting to the Appropriate Institutional Officials, and the Department or Agency Head(s)

Procedure:

This procedure describes how compliance reporting occurs according to the Federal regulations, institutional policy and UCI IRB policy.

I. IRB Responsibilities

- A. The IRB Chair will report to the Executive Director of Research Protections or designee:
 - 1. Any event determined by the IRB to represent any unanticipated problems involving risk to participants or others;
 - 2. Any non-compliance determined by the IRB to be serious or continuing non-compliance; and
 - 3. Any action of the IRB to suspend or terminate its approval for cause.

II. HRP Administration Responsibilities

- A. The Executive Director of Research Protections or designee prepares a letter that outlines:
 - 1. The nature of the event;
 - 2. The findings of the organization and IRB;
 - 3. Actions taken by the organization or IRB;
 - 4. Reasons for the organization's or IRB's actions; and
 - 5. Plans for continued investigation or action.
- B. The letter is sent to the following people for review and approval:
 - 1. The Assistant Vice Chancellor for Research; and
 - 2. The IRB Chair of the Committee that made the determination.
- C. The letter is signed by the Institutional Official (Vice Chancellor for Research).
- D. The Executive Director of Research Protections or designee sends a copy of the letter to:
 - 1. IRB Members of the applicable Committee (as an information item in the agenda packet);
 - 2. OHRP when the study is covered by DHHS regulations.
 - 3. FDA, when the research is FDA-regulated;
 - 4. Other federal agencies when the research is overseen by those agencies, and they require prompt reporting separate from that to OHRP.
 - 5. Study sponsor, if the research is sponsored (this includes NIH, NSF, and industry sponsors);
 - 6. UCI Medical Center IDS pharmacist, if the protocol is suspended or terminated and the research involves investigational drugs;
 - 7. Sponsored Projects, if the research involves a grant or contract for all determinations involving faculty, staff, or students whose primary affiliation is with UC Irvine;
 - 8. The School Dean, Department Chair, Supervisor, and Faculty Sponsor of the Lead Researcher, if applicable;
 - 9. The Associate Vice Chancellor of Research
 - 10. The Associate Dean of Research (School of Medicine)
 - 11. Institutional officials at external sites where the research is conducted and UCI serves as their IRB of record;
 - 12. The appropriate HRP binder, if applicable;
 - 13. Legal Counsel, if appropriate; and/or
 - 14. Risk Management, if appropriate.