

18 Reporting to Regulatory Agencies and Organizational Officials

Federal regulations require prompt reporting to appropriate organizational officials and, as applicable, the federal department or agency head or the FDA, of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval. University of Virginia IRB complies with this requirement as follows.

18.1 Procedures

- 1) IRB staff will initiate these procedures as soon as the IRB takes any of the following actions:
 - a. Determines that an event may be considered an unanticipated problem involving risks to participants or others
 - b. Determines that non-compliance was serious or continuing
 - c. Suspends or terminates approval of research
- 2) The IRB Director or designee is responsible for preparing reports or letters which includes the following information: (
 - a. The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of IRB approval of research)
 - b. Name of the institution conducting the research
 - c. Title of the research project and/or grant proposal in which the problem occurred
 - d. Name of the investigator on the project
 - e. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
 - f. A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision
 - g. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol/research plan, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
 - h. Plans, if any, to send a follow-up or final report by the earlier of
 1. A specific date
 2. When an investigation has been completed or a corrective action plan has been implemented

- 3) The IRB Chair/vice chair will review the letter, make modification as needed and sign.
- 4) The IRB Director or designee sends a copy of the report to:
 - a. The IRB by including the letter in the next agenda packet as an information item
 - b. The Institutional Official
 - c. The following federal agencies:
 - OHRP, if the study is subject to DHHS regulations or subject to a DHHS FWA.
 - FDA, if the study is subject to FDA regulations.
 - If the study is conducted or funded by any Federal Agency other than DHHS that is subject to “The Common Rule”, the report is sent to OHRP or the head of the federal agency as required by the agency.
 - Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
 - d. Investigator
 - e. Sponsor, if the study is sponsored
 - f. [Chairman or supervisor of the investigator]
 - g. [The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from a covered entity]
 - h. [The Information Security Officer of an organization, if the event involved violations of information security requirements of that organization]
 - i. [Office of Risk Management, if appropriate]
 - j. Others as deemed appropriate by the Institutional Official

The IRB Director ensures that all steps of this policy are completed within 30 working days of the determination. For more serious actions, the Director will expedite reporting.