

Policies and Procedures for Reporting to Regulatory Agencies and Institutional Officials

Purpose/Scope

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure to ensure prompt reporting to the IRB, appropriate institutional officials, sponsor, coordinating center, if any, and the appropriate regulatory agency heads of events determined to be unanticipated problems involving risks to participants or others (UPIRTSO), non-compliance determined to be serious or continuing, and suspensions and terminations of approved research by the IRB.

Policy

The IRB's policy is to comply with all applicable local, state, and federal regulations in the conduct of research studies. Once the IRB has taken any of the following actions, additional reporting to the IRB, appropriate institutions officials, and agency heads may be warranted:

- Determined that an event represents an unanticipated problem involving risks to participants or others.
- Determined that non-compliance was serious or continuing.
- Suspended or terminated approval of research.

Written procedures are required for preparing and sending these reports.

Procedure

The Director, Office of Research Compliance, or designee will initiate these procedures as soon as the IRB takes any of the following actions:

- Determines that an event represents an unanticipated problem involving risks to participants or others.
- Determines that non-compliance was serious or continuing.
- Suspends or terminates approval of research.

The Director, Office of Research Compliance, or designee prepares a letter that contains the following information:

- The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research)
- Name of the institution conducting the research
- Title of the research project and/or grant proposal in which the problem occurred
- Name of the principal investigator on the protocol
- Number of the protocol assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
- A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision

- Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subject, etc.)
- Plans, if any, to send a follow-up or final report by a specific date

When an investigation has been completed or a corrective action plan has been implemented:

- The IRB Chair reviews the letter and modifies the letter as needed.
- The Director of Research Compliance or the IRB Chair signs the letter.
- The Director of Research Compliance or designee sends a copy of the report to:
 - The IRB by including the letter in the next agenda packet as an information item
 - The Institutional Official.
 - General Counsel/Vice President for Legal Affairs should be notified promptly of any findings of Non-compliance that is serious or continuing and any situations where the IRB approves suspensions or termination of approved research.
 - The following agencies:
 - OHRP, if the study is subject to DHHS regulations or subject to a DHHS Federalwide Assurance
 - FDA, if the study is subject to FDA regulations.
 - For VA research:
 - The Chair of the VA Research and Development Committee
 - The Regional VA Office of Research Oversight
 - VA Office of Research and Development, for VA-funded research
 - VA Central Office when there is an unanticipated problem involving risks to participants or others that is an adverse event
 - 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 and the head of the agency (or designee), 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.
 - Principal Investigator
 - Sponsor, if the study is sponsored
 - Contract research organization, if the study is overseen by a contract research organization
 - Chairman or supervisor of the principal investigator
 - The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity
 - The Information Security Office of an organization if the event involved violations of information security requirements of that organization
 - The Director of Research Compliance can provide copies to others as deemed appropriate

The Director of Research Compliance will ensure that all required notifications will be completed within 15 working days of the final IRB decision, except for unanticipated problems involving risks to subjects or others, for which required notifications are specified in

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Document 203. For more serious actions, the Director will expedite reporting. In cases where it is considered in the best interests of the subjects, the Director may use phone notification.