

11. Reporting to Regulatory Agencies and Institutional Officials

11.1. Policy

Federal regulations require prompt reporting to appropriate Institutional Officials (IO) and the department or agency head of:

- Any Unanticipated Problem;
- Any Serious Non-Compliance or Continuing Non-Compliance or the requirements or determinations of the IRB; **and**
- Any suspension or termination of IRB approval.

The Research Compliance Office (RCO) will comply with this requirement and the following procedures describe how these reports are handled.

11.2. Procedures

IRB staff will initiate these procedures as soon as the IRB takes any of the following actions:

- Determines that an event may be considered an Unanticipated Problem
- Determines that Non-Compliance was Serious or Continuing
- Suspends or Terminates approval of research

The RCO Director (or designee) is responsible for preparing reports or letters which includes the following information:

- The nature of the event (Unanticipated Problem involving risks to subjects 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 research project 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 consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
- Plans, if any, to send a follow-up or final report to the appropriate institutional officials or department or agency head by the earlier of
 - A specific date or
 - When an investigation has been completed or a corrective action plan has been implemented

The IRB Chair, RCO Director, and the IO will review the letter and modify the letter/report as needed.

The IO is the signatory for all correspondence from the institution.

The Director (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 IO
- The following Federal agencies:
 - OHRP, if the study is subject to DHHS regulations or subject to a DHHS Federal-wide assurance
 - 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 agency as required by the agency
 - Principal investigator
 - Sponsor, if the study is sponsored
 - Contract research organization (“CRO”), if the study is overseen by a contract research organization
 - Department head or supervisor of the PI
 - Others as deemed appropriate by the IO

Note: 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.

The RCO Director ensures that all steps of this policy are completed within **an acceptable and appropriate timeframe** of the initiating action. For more serious actions, the Director will expedite reporting.

Approved by: Lawrence Dreyfus, PhD
Name of University Institutional Official


Signature of University Institutional Official

3/27/14
Date

