11.0 Reporting to Regulatory Agencies and Institutional Officials

11.1 Policy

Federal regulations require prompt reporting to appropriate institutional officials and the department or agency head of any unanticipated problem involving risks to subjects or others, any serious non-compliance or continuing non-compliance with the HRPP or institutional policies or the requirements or determinations of the IRB; and any suspension or termination of IRB approval.

The Federalwide Assurance (FWA) of the institution is designated to apply to federally supported or conducted human-subjects research. In general, the same criteria and process for the conduct and oversight of human-subjects research, for determinations about reportable events, and for actions taken in response to such events will apply to all human-subjects research in which institution is engaged, regardless of funding source.

In addition to the reporting requirements to institutional officials and regulatory agencies, the IRB is responsible for reporting any major event to the Association for the Accreditation of Human Research Protection Programs (AAHRPP) to comply with AAHRPP's reporting requirements for accredited organizations.

The IRB 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 IRB staff 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 informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
  - Plans, if any, to send a follow-up or final report:
    - With a specific date defined
    - When an investigation has been completed or a corrective action plan has been implemented

- The IRB Chair and the institutional official will review the letter and modify the letter/report as needed.
- The institutional official is the signatory for all correspondence from the facility to the regulatory agencies.
- The IRB staff sends a copy of the report to:
  - The IRB by including the letter in the next agenda packet as an informational item
  - The Institutional Official
  - Report to the Research Integrity Officer, if a finding of non-compliance was serious or continuing
  - 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.
    - DOD, if the study is subject to Department of Defense 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

      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.
  - Principal investigator
  - Sponsor, if the study is sponsored

- Contract research organization (CRO), if the study is overseen by a contract research organization
- Other sites involved in the research when appropriate
- Others as deemed appropriate by the institutional official

The IRB Chair ensures that all steps of this policy are completed within 15 working days of the initiating action. For more serious actions, the IRB Chair will expedite reporting.