Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: II.D
Section: HRPP Compliance
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Reporting to the Appropriate Institutional Officials, and the Department or Agency Heads(s)

Definitions:
1. Non-compliance: Failure to comply with Federal regulations, HRPP Policy, or the determinations or requirements of the IRB.
2. Serious Non-compliance: An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and welfare of a participant.
3. Continuing Non-compliance: A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with federal regulations, HRPP Policy, or determinations or requirements of the IRB.
4. Termination for Cause: An action initiated by the IRB to stop permanently some or all research procedures.
5. Suspension for Cause: An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB.
6. Serious: An event is “serious” if it involved a serious harm to one or more persons (who may or may not be participants), or required intervention to prevent one or more persons from experiencing serious harm.
7. Related: An event is “related” if it is likely to have been caused by the research procedures.
8. Unexpected: An event is “unexpected” when its specificity, nature, severity or incidence are not accurately reflected in the information previously reviewed and approved by the IRB.
9. Unanticipated: An event is “unanticipated” when it was unforeseeable at the time of its occurrence. The word unanticipated, is not a synonym for unexpected. A research protocol can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.
10. Unanticipated Problem Involving Risks to Participants or Others: Any event that was (1) unanticipated, (2) serious, and (3) related.

Policy:
It is the responsibility of the HRPP to assure reporting occurs according to the federal regulations, institutional policy and HRPP policy.

I. The HRPP will maintain written procedures for assuring prompt reporting to the IRB, appropriate institutional officials, sponsoring agencies, 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.
      1. This reporting will take place within 30 days of the completion of an investigation and/or determination.
II. Responses and other communications between Investigators and federal agencies (e.g., OHRP, FDA, etc.) occurring as a result of research study audits are reviewed by the HRPP Administration, the Office of General Counsel, the Associate Vice Chancellor for Research and the Vice Provost for Research, when applicable. All official communication to these agencies will be signed by the Institutional Official and the Principal Investigator, when applicable.