



TITLE: Reportable Information Items that are Potentially Problematic
PURPOSE: Establish the process to manage potentially problematic information reported to the IRB
RESPONSIBILITIES: HSPP Staff

PROCEDURES:

Review each item of information for completeness. If information is missing, contact the investigator or alternate contact.

Answer the following questions based on the information provided. If unable to do so, contact the IRB Chair(s) and/or Director or designee for guidance. If unable to answer the question, follow SOP-015: Investigations.

1. Is this an Allegation of Non-Compliance?
2. Is this a Finding of Non-Compliance?
3. Is this an Unanticipated Problem Involving Risk to Subjects or Others?
4. Is this a Suspension or Termination of IRB Approval?

Allegation of Non-Compliance

If the Allegation of Non-Compliance has basis in fact, determine if it is a:

- Non-Serious/Non-Continuing Non-Compliance, or
- Serious Non-Compliance or Continuing Non-Compliance

Non-Serious/Non-Continuing Non-Compliance: Work with the individual or group to develop and implement a suitable corrective action. In situations where a correction action is unable to be developed and/or implemented, the non-compliance will be considered Continuing Non-Compliance and the procedures for Continuing Non-Compliance must be followed.

Serious Non-Compliance; Continuing Non-Compliance; Suspension or Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:

1. Notify the Director or designee
2. Complete Section 1 of W306-Review of Information Items
3. Place the item on the agenda for a convened IRB meeting in an IRB with the appropriate scope as an item of:
 - Serious Non-Compliance
 - Continuing Non-Compliance
 - Suspension of IRB Approval
 - Termination of IRB Approval
 - Unanticipated Problem Involving Risks to Subjects or Others.
4. Notify the Investigator of the date/time for review of the item by the convened IRB. Provide the investigator the opportunity to:



- a. Submit a written statement addressing the item for review by the convened IRB, or
 - b. Attend the IRB meeting either in person or via conference call to address the IRB, answer questions, and present any materials to support the investigator's opinion. If the investigator is present at the IRB meeting, they may present their case and then must leave during any deliberation and vote by the convened IRB.
5. An exception to the above process is when the IRB determines research must be suspended to eliminate an immediate risk to subjects. A project may be suspended for risk by a Chair until further review by the convened IRB is scheduled, or the convened IRB may suspend for risk.

Unanticipated Problem Involving Risk to Subjects or Others: If the rights and welfare of subjects might be adversely affected before a convened IRB can review the information, contact the IRB chair to consider a Suspension of IRB Approval following the *Operations Manual: Suspension or Termination of IRB Approval*.

Prisoners: If the notification involves a subject becoming a prisoner in a study not approved by the IRB to involve prisoners, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must stop until regulatory requirements for research involving prisoners are met. If the investigator asserts that it is in the best interests of the prisoner-subject to remain in the research study while incarcerated, the investigator must promptly submit a modification to the IRB to include prisoners in the study.

Privacy: Contact the UA Privacy Officer if the new information involves an issue involving privacy.

Department of the Navy: If the research is conducted or funded by the Department of the Navy (DON) and involves any of the following, report the information to the Undersecretary of the Navy:

- Allegations of Non-Compliance;
- The initiation and results of investigations of Allegations of Non-Compliance;
- Audits, investigations, or inspections;
- Audits, investigations, or inspections of the organization's human research protection program conducted by outside entities (e.g., FDA or OHRP);
- Significant communication between the organization and other federal departments or agencies regarding compliance and oversight; and
- All restrictions, suspensions, or terminations of the organization's Federalwide Assurance.

Administrative Follow-up

Issue an *HSPP Correspondence Form* outlining the event, the determination, any corrective action, approved management plans, and required follow-up.

Update the UAccess Research database if the protocol was "Suspended" or "Terminated."

Follow SOP-018: Post-Review and the Operations Manual: Post-Review



Follow SOP-070: IRB Records.

MATERIALS:

- SOP-014: Investigations
- SOP-070: IRB Records
- SOP-015: Suspension or Termination of IRB Approval
- SOP-013: Reportable Information Items that are Potentially Problematic
- W306 - Review of Information Items
- HSPP Correspondence Form

REFERENCES:

- 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
- 21 CFR §56.108(b)

REVIEW/REVISIONS:

From 2014/01 version: Added details regarding an Investigator's ability to address the IRB for serious and/or continuing non-compliance.

From 10/01/2010 version: Linked P&P-052: Post-review to complete the process.; Clarified in the policy that only reportable items as described in P&P-024 and the Investigator Manual should be received by the IRB; Added reference to P&P-024 for completeness; Indicated that the SAVAHCS R&D office is also responsible for carrying out this procedure; Added Related, Unanticipated, and Serious Events per VA policy; No longer require the Assistant Director, Process Improvement and Compliance to prepare an item for convened IRB review.

From 08/01/11 version: Removed reference to the VA; Removed reference to the Assistant Director, Process Improvement and Compliance.

From 01/2014 version: Renumbered from P&P-024; Materials updated to reflect the new numbering system: P&P-025 to SOP-014, P&P-070 to SOP-070, P&P-026 to SOP-015; P&P-024 to SOP-013.