1 PURPOSE

1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.

1.2 The process begins when the IRB receives an information item including, but not limited to, reports of noncompliance, problem report forms, or reports of suspension or termination of research.

1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Significant revisions for AAHRPP accreditation; replaces version 8/21/13

3 POLICY

3.1 The organization will promptly notify the federal department or agency funding the research of any for cause investigation of that research by another federal department or agency or national organization.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Review each item of information, answer the following questions and complete the “For IRB Use Only” section of “FORM: Reportable New Information”: (See attached flowchart for a diagram of the flow of this procedure.)

5.1.1 Is this an Allegation of Non-Compliance?

5.1.2 Is this a Finding of Non-Compliance?

5.1.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.4 Is this a Suspension or Termination of IRB Approval?

5.2 If you are unable to answer a question, consult the IRB chair.

5.3 If the IRB chair is unable to answer a question, follow “SOP: Investigations.”

5.4 If the answer is “no” to all questions, skip section 5.5 and continue with section 5.7.

5.5 If the answer is “yes” to one or more questions, then follow the corresponding sections below.

5.5.1 If the information represents an Allegation of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.5.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.5.1.2 If no, follow any other corresponding sections.

5.5.2 If the information represents a Finding of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.5.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.5.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.5.3 If the information represents Non-Serious/Non-Continuing Non-Compliance

5.5.3.1 Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.

5.5.3.2 If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.
5.5.4 If the information represents **Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others**

5.5.4.1 Complete Section 1 of "WORKSHEET: Review of Information Items"

5.5.4.2 Place on the agenda for the next available convened IRB meeting as an item of **Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others**.

5.6 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair to consider a **Suspension of IRB Approval** following the “SOP: Suspension or Termination of IRB Approval.”

5.7 If the notification involves a subject becoming a **Prisoner** in a study not approved by the IRB to involve **Prisoners**:

5.7.1 Confirm that the subject is currently a **Prisoner**.

5.7.1.1 If the subject is currently not a **Prisoner**, no other action is required.

5.7.2 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving **Prisoners** are met or until the subject is no longer a **Prisoner** would present risks to the subject.

5.7.2.1 If the subject’s involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.7.2.1.1 Keep the subject enrolled in the study and review the research for involvement of **Prisoners**. If the research is subject to DHHS oversight, notify OHRP.

5.7.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

5.7.2.2 If the subject’s involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving **Prisoners** are met or until the subject is no longer a **Prisoner**.

5.8 Take any additional actions required to resolve any concerns or complaints associated with the information in accordance with attached flowchart.

5.8.1 For determinations of **Suspension or Termination of IRB Approval** follow the “SOP: Suspension or Termination of IRB Approval”.

5.8.2 For determinations of **Serious Non-Compliance; Continuing Non-Compliance; or Unanticipated Problem Involving Risks to Subjects or Others**, IRB Chair notifies Organizational Official or designee who will send “TEMPLATE LETTER: External Report” along with the reasons for the decision within ten (10) working days of IRB determination if required under the OHRP and FDA regulations as well as the DoD Human Research Protection Officer (HRPO) for DoD-supported research.

5.9 Update the protocol history in “IRB Database”.

5.10 Follow “SOP: IRB Records.”

6 **MATERIALS**

6.1 IRB database

6.2 FORM: Reportable New Information

6.3 SOP: Investigations

6.4 SOP: IRB Records

6.5 SOP: Suspension or Termination of IRB Approval
6.6 TEMPLATE LETTER: Review of Information Item
6.7 TEMPLATE LETTER: External Report
6.8 WORKSHEET: Review of Information Items

7 REFERENCES
7.1 21 CFR §56.108(b)
7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
7.3 Flowchart

New Information

Ask all four questions

- Allegation of Non-compliance?
  - Yes: Is Non-compliance Serious or Continuing?
    - Yes: Consider Interim Actions
    - No: Manage Administratively
  - No: Does allegation have a basis in fact?
    - Yes: Review by convened IRB
    - No: Stop if ALL paths lead to “No” answers

- Finding of Non-compliance?
  - Yes: Review by convened IRB
  - No: Stop if ALL paths lead to “No” answers

- Unanticipated Problem Involving Risk to Subjects or Others?
  - Yes: Review by convened IRB
  - No: Stop if ALL paths lead to “No” answers

- Suspension or Termination of IRB Approval?
  - Yes: Review by convened IRB
  - No: Stop if ALL paths lead to “No” answers