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.
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 Added Section 3.2 with additional DOD reporting information.

3 POLICY
3.1 The Institution 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 Institution.
3.2 The institution will require corrective and preventive action plans when reports of non-compliance are received.
3.3 The institution will determine whether actions need to be taken to mitigate risks when unanticipated problems involving risks to subjects or others are reported.
3.4 The Institution will promptly notify the Department of Defense (DOD) human research protection officer:
3.4.1 When significant changes to the research protocol are approved by the IRB.
3.4.2 The results of the IRB continuing review.
3.4.3 If the IRB of record changes.
3.4.4 When the Institution is notified by any federal department, agency or national Institution that any part of the HRPP is under investigation for cause involving a DOD-supported research protocol.

4 RESPONSIBILITIES
4.1 The IRB staff members and IRB members carry out this procedure.

5 PROCEDURE
5.1 Review each item of information and answer the following questions and complete the “For IRB Use Only” section of “FORM: Reportable New Information (HRP-214)”: (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 or IRB director or designee.
5.3 If the IRB chair and IRB director or designee are unable to answer a question, follow “SOP: Investigations (HRP-025).”
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 Allegations 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 Findings 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 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 and preventive action plan (CAPA).

5.5.3.2 If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable CAPA, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

5.5.4 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 Confirm your decision with the IRB chair or IRB director or designee.

5.5.4.2 If the issue involves non-compliance, work with the investigator or research staff to develop and adequate corrective and preventive action plan,

5.5.4.3 If the issue involves an unanticipated problem involving risk to subjects or others, work with the PI to develop a plan to mitigate the risk to subjects or others.

5.5.4.4 Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope 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 or IRB director or designee to consider a Suspension of IRB Approval following the “SOP: Suspension or Termination of IRB Approval (HRP-026).”

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 Stop all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject 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 Submit a Reportable New Information (HRP-214) form for review by the IRB.

5.7.3 For Department of Defense (DOD) research promptly report all decisions to the Department of Defense (DOD).

5.7.4 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a prisoner.

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

5.9 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, complete and send a “TEMPLATE LETTER: Review of Information Item (HRP-519)” or equivalent to the person submitting the information.

5.10 If the Committee determines the event involves Serious or Continuing Non-Compliance, inform the Principal Investigator of the determination within three (3) business days by phone call or email. Include in the communication a statement that the investigator may address the Committee in writing or in person to request reconsideration and to provide additional information. Hold the TEMPLATE LETTER: Review of Information Item (HRP-519) until (1) three working days have lapsed and the PI does not request reconsideration: or (2) the Committee reconsiders the item and makes a determination.

6 MATERIALS
6.1 FORM: Reportable New Information (HRP-214)
6.2 SOP: Investigations (HRP-025)
6.3 SOP: Suspension or Termination of IRB Approval (HRP-026)
6.4 TEMPLATE LETTER: Review of Information Item (HRP-519)

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
  - Does allegation have a basis in fact?
    - Yes
    - Manage Administratively
    - Review by convened IRB
      - Report to regulatory agencies and appropriate institutional officials
    - No
      - Consider Interim Actions
      - Unable to achieve a collaborative outcome?
        - Yes
        - Review by convened IRB
    - No
  - No
    - Stop if ALL paths lead to “No” answers

- Finding of Non-compliance?
  - Yes
  - Is Non-compliance Serious or Continuing?
    - Yes
    - Manage Administratively
    - Review by convened IRB
      - Report to regulatory agencies and appropriate institutional officials
    - No
      - Consider Interim Actions
      - Unable to achieve a collaborative outcome?
        - Yes
        - Review by convened IRB
    - No
  - No
    - Stop if ALL paths lead to “No” answers

- Unanticipated Problem Involving Risk to Subjects or Others?
  - Yes
    - Manage Administratively
    - Review by convened IRB
      - Report to regulatory agencies and appropriate institutional officials
    - No
      - Consider Interim Actions
      - Unable to achieve a collaborative outcome?
        - Yes
        - Review by convened IRB
    - No
  - No
    - Stop if ALL paths lead to “No” answers

- Suspension or Termination of IRB Approval?
  - Yes
    - Manage Administratively
    - Review by convened IRB
      - Report to regulatory agencies and appropriate institutional officials
    - No
      - Consider Interim Actions
      - Unable to achieve a collaborative outcome?
        - Yes
        - Review by convened IRB
    - No
  - No
    - Stop if ALL paths lead to “No” answers