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 None.

3 POLICY

3.1 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Organizational Official for further action.

3.2 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.

3.2.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.

3.3 The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Review each item of information and answer the following questions and complete the Submit RNI Pre-Review Activity: *(See attached flowchart for a diagram of the flow of this procedure.)*

5.2 Review each item of information and answer the following questions.

5.2.1 Is this an Allegation of Non-Compliance?

5.2.2 Is this a Finding of Non-Compliance?

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

5.2.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.3 If you are unable to answer a question, consult the IRB chair or IRB manager.

5.4 If the IRB chair and IRB manager are unable to answer a question, follow "SOP: Investigations (HRP-025)."

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 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 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 manager.

5.5.4.2 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 manager to consider a Suspension of IRB Approval following the "SOP: Suspension or Termination Issued Outside of Convened IRB (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 Consider whether stopping 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 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,

5.7.3 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 If the information involves any of the following, complete and send a "TEMPLATE LETTER: - AAHRPP Notice of Information Item (HRP-529)" to AAHRPP as soon as possible but generally within two days of the receipt of the information, in addition to other applicable procedures listed in this SOP:

5.8.1 Negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official

action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

5.8.2 Litigation, arbitration, or settlements initiated related to human research protections.

5.8.3 Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

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

5.10 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 review and prepare and send letter per SOP: Post-Review (HRP-052).

6 MATERIALS

6.1 FORM: Reportable New Information (HRP-214)
6.2 SOP: Investigations (HRP-025)
6.3 SOP: Suspension or Termination Issued Outside of Convened IRB (HRP-026)
6.4 SOP: Post-Review (HRP-052)
6.5 TEMPLATE LETTER: - AAHRPP Notice of Information Item (HRP-529)

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