HRP-024 | 02/01/2024 | Author: T. Bechert | Approver: S. Brooks

**SOP: New Information**

1. **PURPOSE**
   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.
   2. The process begins when the IRB receives an information item.
   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**
   1. Revised section 5.10 steps to post HRP-519 - Information Item; 10/2/23.
   2. Minor formatting correction; 2/1/24.
3. **POLICY**
   1. Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Institutional Official/Deputy Institutional Official (IO/DIO) for further action.
   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.
      1. For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.
   3. The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.
   4. Substantiated allegations related to classified Department of Defense (DOD) HSR must be reported immediately.
   5. For Veterans Administration (VA) research:
      1. The determination that Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance must be determined and documented by the convened IRB.
      2. The convened IRB must review notifications of apparent Unanticipated Problems Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, and external Suspension of IRB Approval, or Termination of IRB Approval within 30 calendar days after receiving the notification.
      3. The IRB Chair may take interim action on notifications of apparent Unanticipated Problems Involving Risks to Subjects or Others, Serious Non-Compliance or Continuing Non-Compliance as needed to eliminate apparent immediate hazards to subjects.
      4. For Unanticipated Problems Involving Risks to Subjects or Others that are local research deaths, they must be reported orally to the IRB immediately upon becoming aware of the information.
      5. An apparent unexpected Serious Adverse Event (SAE) that is related or possibly related to participation in human subjects research constitutes an apparent Unanticipated Problems Involving Risks to Subjects or Others.
      6. Except where remediation requires substantial renovation or fiscal expenditure, hiring, legal negotiations, or other extenuating circumstances, remedial actions must be completed within 180 calendar days after any determination of Non-Compliance.
   6. Requests to lift a suspension of IRB approval are reviewed by the convened IRB to determine whether all corrective actions are met.
4. **RESPONSIBILITIES**
   1. The IRB staff members carry out this procedure.
5. **PROCEDURE**
   1. Review each item of information and answer the following questions: (*See attached flowchart for a diagram of the flow of this procedure*.)
      1. Is this an Allegation of Non-Compliance?
      2. Is this a Finding of Non-Compliance?
      3. Is this an Unanticipated Problem Involving Risks to Subjects or Others?
      4. Is this a Suspension of IRB Approval or Termination of IRB Approval?
   2. If you are unable to answer a question, consult the IRB chair or IRB manager.
   3. If the IRB chair and IRB manager are unable to answer a question, follow HRP-025 - SOP - Investigations.
   4. If the answer is “yes” to one or more questions, then follow the corresponding sections below.
      1. Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.
         1. If yes, follow the procedures under Findings of Non-Compliance.
         2. If no, follow any other corresponding sections.
      2. Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.
         1. If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.
         2. If yes, follow the procedures under Serious or Continuing Non-Compliance.
      3. Non-Serious/Non-Continuing Non-Compliance
         1. Determine whether the individual or group responsible for the Non-Compliance has developed and implemented a suitable corrective action plan.
         2. If the individual or group responsible for the Non-Compliance is unwilling or unable 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.
      4. Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others
         1. If the notification involves enrollment of a Prisoner in a study not approved to enroll Prisoners, please see below for additional considerations to aid in decision-making.
         2. Confirm your decision with the IRB chair or IRB manager.
         3. 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. 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 HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB.
   6. If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:
      1. Confirm that the subject is currently a Prisoner.
         1. If the subject is currently not a Prisoner no other action is required.
      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.
         1. If the subject’s involvement in the research cannot be stopped for health or safety reasons, do one of the following:
            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.
            2. Remove the subject from the study and provide the study intervention as clinical care or compassionate use.
         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.
      3. For Department of Defense (DOD) research, have the convened IRB promptly (within 30 days) re-review the research protocol to ensure that the rights and well-being of the human subject, now a prisoner, are not in jeopardy.
         1. Promptly report all decisions to the Department of Defense (DOD).
         2. The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.
   7. If the information involves any of the following, complete and send HRP-529 - LETTER - AAHRPP Notice of Information Item 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:
      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.
      2. Litigation, arbitration, or settlements initiated related to human research protections.
      3. Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization’s HRPP.
   8. Take any additional actions required to resolve any concerns or complaints associated with the information.
   9. For Veterans Administration (VA) research:
      1. If the information represents an Unanticipated Problem Involving Risks to Subjects or Others that is a local research death:
         1. Within one (1) business day after receiving written notification of the death, the IRB Chair or Designated Reviewer must assess and document whether any actions are warranted to eliminate apparent immediate hazards to subjects and, if so, initiate those actions.
         2. Schedule the written notification, the immediate hazard assessment of the IRB Chair or Designated Reviewer, and the actions taken to date for the next convened IRB meeting, not to exceed 30 calendar days after the date of written notification. NOTE: This may require the IRB to convene an emergency session prior to its next scheduled meeting.
         3. The IRB must determine and document within 30 calendar days of the convened IRB’s initial review:
            1. Whether the death was both unexpected and related or possibly related to participation in the research; and
            2. What, if any, protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not investigators must notify or solicit renewed/revised consent from previously enrolled subjects; and if so, when such notification or consent must take place and how it must be documented.
      2. Within 5 business days of receipt of written notification of information that appears to represent an Unanticipated Problem Involving Risks to Subjects or Others, have the IRB Chair or a Designated Reviewer determine and document whether any actions are warranted to eliminate apparent immediate hazards to subjects (and if so, initiate those actions).
         1. Schedule the written notification, the immediate hazard assessment of the IRB Chair or Designated Reviewer, and the actions taken to date for the next convened IRB meeting, not to exceed 30 calendar days after the date of written notification (this may require the IRB to convene an emergency session prior to its next scheduled meeting).
            1. If the IRB determines that the problem or event is unexpected and related to or possibly related to participation in the research and indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized (i.e., whether the incident, experience or outcome constituted an actual Unanticipated Problem Involving Risks to Subjects or Others), the IRB must report in writing its determinations within 5 business days to:

VA Medical Facility Director.

ACOS/R&D.

The Research Compliance Officer (RCO).

* + 1. If the information appears to represent Serious Non-Compliance or Continuing Non-Compliance, schedule the information for the next IRB meeting to be reviewed by the convened IRB, not to exceed 30 calendar days after the date of written notification (this may require the IRB to convene an emergency session prior to its next scheduled meeting).
    2. If the IRB determines that the information constitutes Serious Non-Compliance or Continuing Non-Compliance, the IRB must report in writing its determinations within 5 business days to:
       1. VA Medical Facility Director.
       2. ACOS/R&D.
       3. The RCO.
  1. 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 complete review and acknowledge using “Finalize Review” activity and if a response is expected, prepare and send HRP-519 - LETTER - Information Item via the “Log Public Comment” activity.

1. **MATERIALS**
   1. HRP-025 - SOP – Investigations
   2. HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
   3. HRP-052 - SOP - Post-Review
   4. HRP-519 - LETTER - Information Item
   5. HRP-529 - LETTER - AAHRPP Notice of Information Item
2. **REFERENCES**
   1. 21 CFR §56.108(b)
   2. 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
   3. VHA Directive 1058.01 October 22, 2020
   4. AAHRPP elements I.5.A, I.5.D, I-9, II.2.D, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.4.A, III.2.D
   5. Flowchart

