



SOP: Reportable New Information

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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 and/or suspensions or terminations of the research by the sponsor, investigator, or institution are managed to protect the rights and welfare of participants.
- 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 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/29/2021.

3 POLICY

- 3.1 For research that is federally-funded and/or regulated by the FDA, the institution will notify the applicable federal agencies such as the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other applicable federal agencies within 30 business days of any IRB determinations that constitute Serious and/or Continuing Non-Compliance, Unanticipated Problems involving Risks to Subjects or Others (UPIRSO), Suspension or Termination of that research as outlined in "SOP: External Reporting Process (HRP-094)."
 - 3.1.1 For Department of Defense (USDOD) research, the report is sent to the DOD human research protection officer.
- 3.2 The institution will promptly notify the USDOD if the IRB of record changes.

4 RESPONSIBILITIES

- 4.1 IRB Office staff members carry out this procedure.

5 PROCEDURE

- 5.1 Review the information reported, request more information as needed and answer the following questions needed to complete the RNI Pre-Review Activity:
 - 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 the research by the sponsor, investigator, or institution?
- 5.2 If you are unable to answer a question, consult the IRB chair, IRB Executive Director, Biomedical IRB Manager, Social Behavioral IRB Manager, or IRB Compliance Manager.
- 5.3 If the answer is "no" to all questions and no additional review is required, skip ahead to section 5.7.
- 5.4 If the answer is "yes" to one or more questions, then follow the corresponding sections below.
 - 5.4.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.
 - 5.4.1.1 If yes, follow the procedures under Findings of Non-Compliance.
 - 5.4.1.2 If no, follow any other corresponding sections.
 - 5.4.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.
 - 5.4.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.
 - 5.4.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.
 - 5.4.3 Non-Serious/Non-Continuing Non-Compliance



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- 5.4.3.1 As applicable, require the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.
- 5.4.3.2 If the individual or group responsible for the Non-Compliance is unable or unwilling 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.
- 5.4.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension or termination of the research by the sponsor, investigator, or institution; or Unanticipated Problem Involving Risks to Subjects or Others
 - 5.4.4.1 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 or termination of the research by the sponsor, investigator, or institution or Unanticipated Problem Involving Risks to Subjects or Others.
 - 5.4.4.2 If the convened IRB Panel makes a determination of Serious Non-Compliance; Continuing Non-Compliance; Suspension or termination of the research by the sponsor, investigator, or institution or Unanticipated Problem Involving Risks to Subjects or Others a member of the Compliance team will review the minutes for potential external reporting following “SOP: External Reporting Process (HRP-094).”
 - 5.4.4.3 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.
- 5.4.5 Suspension or termination
 - 5.4.5.1 If in your opinion the rights and welfare of participants might be adversely affected before the convened IRB can review the information, contact the IRB chair or appropriate IRB manager to consider a Suspension of IRB Approval following the “SOP: Suspension or Termination Issued Outside of Convened IRB (HRP-026).”
 - 5.4.5.2 If the IRB votes for a Suspension or Termination of IRB Approval follow “SOP: Suspension or Termination of IRB Approval By Convened Panel (HRP-029).”
 - 5.4.5.2.1 A member of the Compliance team will review the minutes for potential external reporting following “SOP: External Reporting Process (HRP-094).”
- 5.5 If the notification involves a participant becoming a Prisoner in a federally-funded study not approved by the IRB to involve Prisoners:
 - 5.5.1 Confirm that the participant is currently a Prisoner.
 - 5.5.1.1 If the participant is currently not a Prisoner no other action is required.
 - 5.5.2 Consider whether it would present risks to the participant to discontinue all research interactions, research interventions, and collection of identifiable private information about the now-incarcerated participant until the regulatory requirements for research involving Prisoners are met or until the participant is no longer a Prisoner.
 - 5.5.2.1 If the participant’s involvement in the research cannot be stopped for health or safety reasons, do one of the following:
 - 5.5.2.1.1 Keep the participant enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify the Compliance Team to obtain Prisoner’s Certification from OHRP.
 - 5.5.2.1.2 Remove the participant from the study and provide the study intervention as clinical care or compassionate use.



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- 5.5.2.2 If the participant'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 participant must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the participant is no longer a Prisoner.
- 5.5.3 For Department of Defense (DOD) research, have the convened IRB promptly re-review the research protocol to ensure that the rights and well-being of the human subject, now a prisoner, are not in jeopardy.
- 5.5.3.1 For US Department of Defense (USDOD) research, promptly report all determinations to the US Department of Defense (USDOD).
- 5.5.3.2 The US Department of Defense (USDOD) must concur with the IRB before the participant can continue to participate while a prisoner.
- 5.6 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:
- 5.6.1 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.
- 5.6.2 Litigation, arbitration, or settlements initiated related to human research protections.
- 5.6.3 Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.
- 5.7 Take any additional actions required to resolve any concerns or complaints associated with the information.
- 5.8 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension or termination of the research by the sponsor, investigator, or institution; or Unanticipated Problem Involving Risks to Subjects or Others, complete review and prepare and send letter per SOP: Post-Review (HRP-052).
- 5.9 The Principal Investigator may choose to submit a written response to the RNI determination letter within 10 business days, by sending an email to the IRB analyst assigned to the RNI submission and irbcompliance@northwestern.edu. The IRB Compliance staff member will instruct the PI regarding next appropriate steps, which may include submission of another RNI in eIRB+, or other applicable action.

6 MATERIALS

- 6.1 FORM: Reportable New Information (HRP-214)
- 6.2 SOP: Directed Review Audits (HRP-025)
- 6.3 SOP: Suspension or Termination Issued Outside of Convened IRB (HRP-026)
- 6.4 SOP: Suspension or Termination of IRB Approval by Convened Panel (HRP-029)
- 6.5 SOP: Post-Review (HRP-052)
- 6.6 SOP: External Reporting Process (HRP-094)
- 6.7 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 32 CFR §219.103(b)(5), 32 CFR §219.113