SOP: Reportable New Information

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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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 reviewed to protect the rights and welfare of participants.

1.2 The process begins when the IRB receives a reportable new information (RNI) application. Any death of a Northwestern participant or a participant at a site where Northwestern is the IRB of record must be reported to the IRB within 24 hours of knowledge or notification if the death is unanticipated and related or possibly related. All other reportable items must be submitted to the IRB within 5 business days.

1.3 The process ends when the information is determined to represent an event that does not require IRB review, is reviewed administratively, or is referred to the convened IRB for review.

2 PREVIOUS VERSION

2.1 Revised from the previous version dated 11/01/2024.

3 POLICY

3.1 For research that is federally funded or federally regulated, 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 Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval, Unanticipated Problem Involving Risks to Subjects or Others, or any combination of the above, as outlined in "SOP: External Reporting Process (HRP-094)."

- 3.1.1 For Department of Defense (USDOD) research,
  - 3.1.1.1 The institution will send the report to the DOD human research protection officer.
  - 3.1.1.2 The institution will promptly notify the USDOD if the IRB of record changes.
  - 3.1.1.3 Substantiated allegations related to classified Department of Defense (DOD) Human Subjects Research must be reported immediately.

3.2 A modification (MOD), continuing review (CR), or modification/continuing review (MODCR) is required to lift a suspension of IRB approval and must be reviewed by the convened IRB to determine whether all corrective actions are met.

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 as 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?
- 5.1.5 Is Additional review required?

5.2 If 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 to section 5.7.

5.4 If the answer is "yes" to one or more questions, 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

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 of IRB Approval, Termination of IRB Approval; Unanticipated Problem Involving Risks to Subjects or Others; or Additional review required

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 of IRB Approval; Termination of IRB Approval; Unanticipated Problem Involving Risks to Subjects or Others; or Additional review required.

5.4.4.1.1 If the convened IRB Panel makes a determination of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others, the determination will be communicated to the responsible party via the RNI letter- Review of Reportable New Information (RNI) Report (HRP-717).

5.4.4.1.1.1 A member of the Compliance team will review the minutes for potential external reporting following “SOP: External Reporting Process (HRP-094).”

5.4.4.1.2 If the convened IRB Panel requires additional information before making a determination, then follow-up actions will be specified for the responsible party in the RNI letter- Review of Reportable New Information Report (HRP-717).

5.4.4.1.2.1 The same IRB panel that first reviewed the RNI will review the follow-up actions, unless that IRB panel directs otherwise.

5.4.4.1.3 In instances where the convened IRB Panel requires follow-up actions but does not require the outcome of the follow-up actions to return to the convened IRB Panel for review, this will be specified in the meeting minutes, and the minor follow-up actions will be processed by the responsible party as identified by the convened IRB panel without returning the RNI to the convened IRB.

5.4.5 Suspension or Termination of IRB Approval

5.4.5.1 If the IRB Office staff person carrying out this procedure determines the rights and welfare of participants might be adversely affected before the

convened IRB can review the information, contact the IRB chair, appropriate IRB review team manager, and IRB Compliance manager, to consider a Suspension or Termination of IRB Approval outside of convened IRB review 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 not currently 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 the 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.

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 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, and online publications) of a negative nature regarding the Organization's Human Research Protection Program (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 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 prepare and send the determination letter Review of Reportable New Information Report (HRP-717).

5.9 The Principal Investigator may submit a written response to the RNI determination letter within 10 business days, by emailing the IRB analyst assigned to the RNI submission and irbcompliance@northwestern.edu. A member of the Compliance Team, will instruct the Principal Investigator (PI) regarding the next appropriate steps, which may include the 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 WORKSHEET: Reportable New Information Items (HRP-321)
6.8 LETTER: Review of Reportable New Information (HRP-717)
6.9 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

8 APPENDIX – Reportable New Information Categories

8.1 See the IRB Office's Reportable New Information (RNI) Page for RNI Categories and examples.