



SOP: Reportable New Information

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-024	Executive Director, IRB Office Northwestern University	11/09/2023	Page 1 of 6

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. Any death of an NU/NU Affiliated participant must be reported to the IRB within 24-hours of knowledge or notification. All other reportable items must be submitted to the IRB within 5 business days.
- 1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or is referred to the convened IRB for review.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 05/30/2022.

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, 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?
 - 5.1.5 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.



SOP: Reportable New Information			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-024	Executive Director, IRB Office Northwestern University	11/09/2023	Page 2 of 6

- 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 or termination of the research by the sponsor, investigator, or institution; 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 or termination of the research by the sponsor, investigator, or institution; 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 or termination of the research by the sponsor, investigator, or institution 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 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 RNI with follow-up actions will be reviewed by the same IRB panel that reviewed the original RNI.
 - 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 without returning the RNI to the convened IRB.
- 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).”



SOP: Reportable New Information			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-024	Executive Director, IRB Office Northwestern University	11/09/2023	Page 3 of 6

- 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 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 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, and 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 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 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



SOP: Reportable New Information

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-024	Executive Director, IRB Office Northwestern University	11/09/2023	Page 4 of 6

irbcompliance@northwestern.edu. The IRB Compliance staff will instruct the 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 **Risk:** Information that indicates a new or increased risk, or a safety issue. This includes a chance that something bad could happen. For example:
 - 8.1.1 New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk.
 - 8.1.2 Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
 - 8.1.3 Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm.
 - 8.1.4 Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm.
 - 8.1.5 Any changes significantly affecting the conduct of the research.
- 8.2 **Harm:** Any harm experienced by an NU participant or other individual(s) that, in the opinion of the investigator, is unexpected and related or possibly related to the research procedures. Harms can include psychological, economic, legal, and other non-physical harms.
 - 8.2.1 A participant at the Northwestern site has experienced a severe and unexpected reaction to the study drug. The PI thinks this is possibly related to the study drug.
 - 8.2.2 An investigator finds out that the study involves a currently approved drug that may cause renal failure according to newly published literature. An interim analysis or safety monitoring report that indicates that frequency or magnitude of harms or benefits may be different than those initially presented to the IRB.
 - 8.2.3 Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
 - 8.2.4 An investigator realizes participants have accidentally been given study drug at a higher dose than was approved by the IRB. While no side effects were reported, the increase in dosage placed the participants at potential risk of harm.
 - 8.2.5 Four weeks into the study of a new asthma drug, a participant informs the research staff that she is pregnant although the pregnancy test done at screening was negative. Pregnancy is an exclusion factor in the study.



SOP: Reportable New Information			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-024	Executive Director, IRB Office Northwestern University	11/09/2023	Page 5 of 6

- 8.3 **(Reportable) Non-compliance:** Serious and/or continuing non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB that causes harm, increases the risk of harm, adversely affects the rights or welfare of participants, or undermines the scientific integrity of the data, or is an allegation of such non-compliance. Incidents of non-compliance on the part of research participants which do not involve risk need not be reported to the IRB (i.e., failure to turn in medication diary). Examples of Reportable Non-compliance include, but are not limited to, the following:
 - 8.3.1 Human subjects research conducted without IRB approval.
 - 8.3.2 Research personnel do not obtain written consent or assent for a study when the IRB has determined that consent or assent is required for a study that involves the collection of discarded tissue. While no harm occurred, failure to obtain consent/assent is a violation of the research participant's rights.
 - 8.3.3 Enrollment of participants before IRB approval has occurred and/or after IRB approval has lapsed.
 - 8.3.4 Continued treatment of participants after IRB approval has lapsed without first obtaining permission from the IRB.
 - 8.3.5 PI enrolls a participant that does not meet all of the inclusion/exclusion criteria. The criteria that were not met puts the participant at risk of harm.
 - 8.3.6 Enrollment of children, prisoners, pregnant women and fetuses, without prior IRB approval.
 - 8.3.7 Use of an unapproved consent form.
 - 8.3.8 Use of unauthorized study personnel to conduct study procedures, obtain informed consent, or have access to identifiable participant information.
 - 8.3.9 A required lab test is not done whose omission, in the opinion of the PI, poses risk of harm to participants.
 - 8.3.10 Assessment for any inclusion/exclusion criterion was not done prior to beginning if study procedures. The criteria that were not evaluated prior to study procedures puts the participant at risk of harm.
 - 8.3.11 A procedure, treatment, or visit specified in the protocol is conducted outside of the required time frame and has clinical consequence; poses risk of harm to participant or others; and/or is thought to be impactful to the scientific integrity of the study.
- 8.4 **Audit:** Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483). The information investigators should provide to the IRB after an FDA inspection is outlined on the [FDA Site Inspections Page](#).
- 8.5 **Report:** Only certain written reports of study monitors must be reported. Prompt reporting (within 5 days) is required for monitoring reports for which the industry sponsor determines the findings could affect the safety of participants or influence the conduct of the study.
- 8.6 **Researcher error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- 8.7 **Confidentiality:** Breach of confidentiality, data breach, or data incident. See Guidance on Evaluating Reports of Data Incidents (HRP-1908) to follow the steps outlined in the guidance. Include a summary of correspondence and any follow-up actions requested. For example:
 - 8.7.1 Sharing identifiable information with a study sponsor or non-IRB authorized personnel
 - 8.7.2 Sending communications to incorrect individuals (i.e., sending addressed recruitment letters to the wrong patient)
 - 8.7.3 Misplacement/lost fully executed consent forms containing participant name
- 8.8 **Unreviewed change:** To eliminate immediate hazard to participants For example, a participant at a non- Northwestern University/NU-Affiliated site, or a relying site, has experienced a severe and unexpected reaction to the study drug. The sponsor thinks this may be related to the study drug and instructs sites to promptly lower the drug dosage to eliminate an immediate hazard to participants. In this case, the PI should immediately implement the dosage change prior to IRB approval and then submit an RNI to notify the IRB.



SOP: Reportable New Information			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-024	Executive Director, IRB Office Northwestern University	11/09/2023	Page 6 of 6

- 8.9 **Incarceration:** Incarceration of a participant in a study not approved by the IRB to involve prisoners.
- 8.10 **Complaint:** Complaint of a participant that cannot be resolved by the research team.
- 8.11 **Suspension/Termination:** Premature suspension or termination of the research by the sponsor, investigator, institution, or external IRB.
- 8.12 **Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.
- 8.13 **Investigational pharmacy error:** An error involving the NMHC investigational pharmacy that puts participants' rights or welfare at risk or undermines the scientific integrity of the data. If selecting this option, please notify the Investigational Drug Services Pharmacy at nminvestigationaldrugservice@nm.org to get additional information for your RNI (e.g., Corrective and Preventive Action Plan).
- 8.14 **Short Form:** If using a translated short form from the IRB website and the English language consent document as the written summary, the short form consent process may take place prior to IRB review. An RNI should be submitted to the IRB within 10 days, to report the use of the short form consent process. Provide within the RNI Supporting Documents the required documents and confirmations as described on the [Short Forms Page](#).
- 8.15 **Death of a Research Participant:** Northwestern University investigators are required to report deaths of NU participants to the IRB office if the death was:
 - 8.15.1 Not anticipated, and
 - 8.15.2 Related or possibly related to participation in the study.
 - 8.15.3 NU participants include participants enrolled at NU's affiliate sites (Shirley Ryan Ability Lab and Northwestern Memorial Healthcare) or sites for which NU has agreed to serve as the IRB of Record through a reliance agreement.