1 PURPOSE
1.1 This procedure establishes the process for communicating findings of Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Suspension of IRB Approval or Termination of IRB Approval to applicable external agencies and institutional officials.
1.2 The process begins when a convened IRB panel determines that a reportable new information report meets the findings in 1.1.
1.3 The process ends when the applicable external agencies and institutional officials have been notified.
1.4 This procedure also establishes the process for reporting significant events or circumstances to the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

2 PREVIOUS VERSION
2.1 Revised from previous version dated 07/27/2021.

3 POLICY
3.1 Northwestern University will notify institutional officials and applicable federal agencies such as the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other federal agencies within 30 business days of any IRB determinations that constitute Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspension or Termination of a research study.
3.1.1 For US Department of Defense (USDOD) research, the report is sent to the USDOD human research protection officer.
3.2 The institution will promptly notify the USDOD if the IRB of record changes.
3.3 Voluntary holds are not considered suspensions or terminations and do not meet reporting requirements to OHRP, FDA, and other federal agencies.

4 RESPONSIBILITIES
4.1 The IRB Office Compliance staff carries out this procedure.

5 PROCEDURE
Reporting to applicable federal agencies and institutional officials:
5.1 Within 5 business days of the Northwestern IRB panel meeting, the Compliance Analyst will review the meeting determinations.
5.1.1 The Compliance Analyst will review the meeting determinations for:
5.1.1.1 Serious and/or Continuing Non-Compliance
5.1.1.2 Unanticipated Problems involving Risks to Subjects or Others
5.1.1.3 Suspension or Termination of a research study.
5.1.2 For studies that meet at least one of the determinations noted above, the Compliance Analyst will assess the following:
5.1.2.1 Whether the report originated from Northwestern University or involved a participant at Northwestern University, a Northwestern University Affiliate, or if Northwestern University serves as the IRB of record.
5.1.2.1.1 If no, then no further action is required.
5.1.2.1.2 If yes to any of the criteria noted in 5.1.2.1, then determine if the study is regulated by the FDA, federally funded, or supported by the USDOD or any other applicable federal agency.
5.1.3 If the study is NOT federally funded, regulated by the FDA, nor supported by the USDOD or any other applicable federal agency, but involves a participant at Northwestern University or a Northwestern University Affiliate site, then it is only reportable to institutional officials at the University. Proceed to 5.2.8 below.

5.2 Prepare the reports for the reportable items.

5.2.1 If the study is subject to DHHS regulation only (DHHS federal funding), prepare the draft report using the OHRP Report template (HRP-720).

5.2.2 If the study is subject to FDA regulations (involving drugs, devices, or biologics) or is subject to another agency, excluding DHHS, address the letter to the appropriate agencies, using the letter template (HRP-719).

5.2.3 If the study is USDOD funded, then report to the USDOD using the letter template (HRP-719).

5.2.3.1 Submit a copy of the submission’s meeting minutes with the reviewer’s name redacted in tandem with the USDOD external report letter.

5.2.4 If the study is subject to DHHS regulations and any other agency, prepare the draft report using the OHRP Report template HRP-720 and generate a letter using HRP-719 for all other agencies.

5.2.4.1 Initially generate one letter using HRP-719. Send the draft letter to the IRB Compliance Manager and IRB Executive Director or designee for review.

5.2.4.2 Add applicable contents of letter HRP-719 to the OHRP Report template HRP-720. The information regarding the event should be the same in both letters.

5.2.4.3 Complete the remainder of the OHRP Report template HRP-720. Send the OHRP Report template to the IRB Compliance manager for review.

5.2.4.4 Send the HRP-719 External Report to the non-OHRP agency per 5.5 below.

5.2.5 If the study is USDOD funded and reportable to another agency, excluding DHHS, then report to the USDOD and the other agency using the letter template (HRP-719), but save two versions of the report (one addressed to DoD and the other addressed to the other agency) and send by separate emails to the USDOD and the other agency.

5.2.5.1 Submit a copy of the submission’s meeting minutes with the reviewer’s name redacted in tandem with the external report letter sent to the USDOD only.

5.2.6 If the study is USDOD funded and subject to DHHS regulations (DHHS federal funding) and reportable to another agency, then report to the USDOD and the other agency using the letter template (HRP-719), but send by separate emails to the USDOD and other agency. Separately, prepare the DHHS draft report using the OHRP Report template (HRP-720). Refer to 5.2.4 above.

5.2.6.1 Submit a copy of the submission’s meeting minutes with the reviewer’s name redacted in tandem with the external report letter sent to the USDOD only.

5.2.7 If the study is reportable to an external department or agency that is not listed above, refer to the appropriate agency and corresponding address. Review WORKSHEET: Additional Federal Agency Criteria (HRP-318).

5.2.8 If the study is reportable to the University only (per 5.1.3 above), inform the Principal Investigator’s supervisor (such as Department Chair or Division Chief) by email using the letter template (HRP-1716) as the email’s text.

5.2.8.1 Include the RNI acknowledgment letter with the correspondence.

5.2.9 If the study involves a Northwestern University affiliate site, then the appropriate institutional official must be copied on the letter.
### SOP: External Reporting Process

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5.2.10 If the Northwestern IRB serves as the IRB of record for external participating sites, and the IRB determination impacts the participating site; then include the site(s) details in the letter, where appropriate, and copy the relevant site principal investigator(s), site reliance contact(s), and site Institutional Official (IO) or designee on the correspondence.

5.2.10.1 Serious Non-Compliance and Continuing Non-Compliance determinations specific to individual sites, including Northwestern, may only need to be reported to impacted sites.

5.2.10.2 Suspensions and Terminations of IRB approval must be reported to all sites.

5.2.10.3 Unanticipated Problems Involving Risks to Subjects or Others must be reported to all sites.

5.2.11 If the study relies on another IRB to serve as the IRB of record, then the executed IRB Authorization Agreement (i.e. Reliance Agreement) must be reviewed to assess the Northwestern University IRB responsibilities and reporting requirements. Proceed following the terms in the signed Reliance Agreement.

5.2.11.1 If an external IRB makes a reportable determination and provides the Northwestern IRB Office the draft letter for review, the IRB Compliance Analyst will:

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<td>5.2.11.1.1 Record the event in the appropriate compliance tracking mechanism.</td>
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<td>5.2.11.1.2 Save correspondence and the draft letter in the appropriate folder.</td>
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<td>5.2.11.1.3 Review the eIRB+ system to determine whether the Principal Investigator submitted a Reportable New Information Item that corresponds with the event.</td>
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<tr>
<td>5.2.11.1.3.1 If not, contact the Principal Investigator and instruct them to submit an RNI.</td>
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5.3 Send draft letters to the IRB Executive Director or designee for review.

5.3.1 In the case of a draft letter from an external IRB, send the IRB Compliance Manager and the IRB Office Executive Director the draft external report and the timeframe for review.

5.3.2 Return the draft letter to the external IRB with Northwestern IRB Office feedback and ensure the external IRB will copy the IRBCompliance@Northwestern.edu email on the federal agency notification email.

5.4 If the event occurred at a site relying on the Northwestern IRB, send the draft letters to the site reliance contact and site Institutional Official (IO) or designee for notification and consultation within 25 business days of the IRB Panel meeting/determination date.

5.4.1 When a report requires consultation with an external participating site official, send the final version to the applicable federal agencies within 45 business days of the IRB Panel meeting/determination date.

5.5 Send the final version to the applicable federal agencies within 30 business days of the IRB Panel meeting/determination date.

5.5.1 Report to OHRP by transferring the information from the OHRP Report template HRP-720 into OHRP's Incident Report Online Form. Once received, save each of OHRP's Incident Report Acknowledgment of Receipt emails as a .PDF. Send an email to the PI, submission preparer, and Institutional Officials with the .PDF version of the OHRP email containing the information submitted in the incident report attached, to inform them of the report.

5.5.2 In the case where an external IRB reports an event that occurred at Northwestern for a study under external IRB purview, the IRB Compliance Analyst will forward the
5.6 Provide follow-up information or IRB determinations to the applicable external agency (e.g., FDA, OHRP, USDOD) as needed.

5.7 Update the appropriate compliance tracking mechanism.

5.8 Save the correspondence and email notification(s) in the appropriate folder.

5.9 Report the post-review activity at the IRB Chairs’ meeting.

**Reporting to AAHRPP, if applicable:**

5.10 Within 2 business days or as soon as possible [after the IRB Office Compliance unit becomes aware], the IRB Compliance staff will prepare a notification letter to AAHRPP of:

5.10.1 Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA actions taken under non-US authorities related to human research protections, that involve Northwestern University's HRPP.

5.10.2 Any litigation, arbitration, or settlements initiated related to human research protections that involve Northwestern University’s HRPP.

5.10.3 Any negative press coverage (including, but not limited to, radio, TV, newspaper, online publications) regarding Northwestern University’s HRPP.

6 **MATERIALS**

6.1 TEMPLATE: External Reporting Template for federal agencies, excluding OHRP (HRP-719)

6.2 TEMPLATE: External Reporting Template for OHRP (HRP-720)

6.3 SOP: Reportable New Information (HRP-024)

6.4 SOP: Post-Review (HRP-052)

6.5 WORKSHEET: Additional Federal Agency Criteria (HRP-318)

6.6 GENERAL DOCUMENT: IRB External Reporting Flowchart

7 **REFERENCES**

7.1 45CFR46.103(b)(5), 45 CFR §46.108(a), 45CFR46.113,

7.2 21CFR56.113

7.3 32 CFR §219.103(b)(5), 32 CFR §219.113, 32 CFR §219.108(a)