



## SOP: External Reporting Process

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-094	Executive Director, IRB Office Northwestern University	11/22/2018	Page 1 of 3

### 1 PURPOSE

- 1.1 This procedure establishes the process for the communication of 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 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 04/02/2018

### 3 POLICY

- 3.1 Northwestern University will notify 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 of IRB Approval or Termination of IRB Approval of that research.
  - 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.

### 4 RESPONSIBILITIES

- 4.1 The IRB Office Compliance staff carries out this procedure.

### 5 PROCEDURE

Reporting to applicable external agencies and institutional officials:

- 5.1 Within 5 business days of the 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 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
  - 5.1.3 If the study is NOT federally funded, regulated by the FDA, or supported by the USDOD, but involves a participant at Northwestern University or a Northwestern University Affiliate site, then it is only reportable to the University.
- 5.2 Prepare the letter for items that are reportable.



## SOP: External Reporting Process

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-094	Executive Director, IRB Office Northwestern University	11/22/2018	Page 2 of 3

- 5.2.1 If the study is subject to DHHS regulation (federal funding), address the letter to OHRP, using the letter template (HRP-719).
- 5.2.2 If the study is subject to FDA regulations (involving drugs, devices, and/or biologics), address the letter to FDA, using the letter template (HRP-719).
- 5.2.3 If the study is subject to both agencies, then use a single letter using letter template (HRP-719), but list both agencies.
- 5.2.4 If the study is supported by USDOD funding, then report to the USDOD, using the USDOD letter template (HRP-720).
  - 5.2.4.1 Submit a copy of the submission's meeting minutes with the reviewer name redacted in tandem with the USDOD external report letter.
- 5.2.5 If the study is reportable to an external department or agency that is not listed above, report to the appropriate agency using letter template (HRP-719), but refer to the appropriate agency and corresponding address.
- 5.2.6 If the study is reportable to the University only (per 5.1.3 above), inform the Principal Investigator's Department Chair or Division Chief by email using the letter template (HRP-719) as the email's text.
  - 5.2.6.1 Include the RNI acknowledgement letter with the correspondence.
- 5.2.7 If the study involves a Northwestern University affiliate site, then the appropriate institutional official must be copied on the letter.
- 5.2.8 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 in accordance with the signed Reliance Agreement.
- 5.3 Send draft letters to the Executive Director or designee for review.
- 5.4 Send final version to the applicable federal agencies within 30 business days of the IRB Panel meeting/determination date.
- 5.5 Provide follow-up information or IRB determinations to the applicable external agency (e.g., FDA, OHRP, USDOD) as needed.
- 5.6 Update the appropriate compliance tracking mechanism.
- 5.7 Save the correspondence and email notification in appropriate folder
- 5.8 Report the post review activity at the IRB Chairs' meeting.

Reporting to AAHRPP, if applicable:

- 5.9 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:
  - 5.9.1 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.
  - 5.9.2 Any litigation, arbitration, or settlements initiated related to human research protections that involve Northwestern University's HRPP.
  - 5.9.3 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 OHRP and FDA (HRP-719)
- 6.2 TEMPLATE: External Reporting Template for DOD (HRP-720)
- 6.3 SOP: Reportable New Information (HRP-024)
- 6.4 SOP: Post-Review (HRP-052)
- 6.5 GENERAL DOCUMENT: IRB External Reporting Flowchart

N	<b>SOP: External Reporting Process</b>			
	NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
	HRP-094	Executive Director, IRB Office Northwestern University	11/22/2018	Page 3 of 3

**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)