



SOP: Post-Review

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-052	Executive Director, IRB Office Northwestern University	02/01/2023	Page 1 of 2

1 PURPOSE

- 1.1 This procedure establishes the process for communications after a protocol is reviewed.
- 1.2 The process begins when:
 - 1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB Office staff; or
 - 1.2.2 An IRB meeting has adjourned and the IRB chair, vice chair or designee has approved the issues to be included in the letters; or
 - 1.2.3 An IRB Office staff member has verified that modifications required to secure approval have been made.
- 1.3 The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 10/25/2021.

3 POLICY

- 3.1 The IRB provides its findings and actions to the investigator.
- 3.2 The IRB makes its findings and actions available to the institution.
- 3.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.
- 3.4 These procedures are to be completed within 10 business days of approval of the IRB meeting issues or receipt of the completed Non-Committee Review materials.
- 3.5 If applicable, the IRB Executive Director or designee will report the Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval, or Unanticipated Problem Involving Risks to Subjects or Others to the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), and other applicable agencies as outlined in SOP: External Reporting Process (HRP-094).

4 RESPONSIBILITIES

- 4.1 IRB Office staff members carry out these procedures.

5 PROCEDURE

- 5.1 For initial reviews, continuing reviews or modifications:
- 5.2 Refer to "WORKSHEET: Approval Intervals (HRP-302)" to calculate approval intervals (if applicable).
- 5.3 Execute the "Finalize Documents" function in the electronic IRB system (eIRB+) to stamp and accept all changes for attached documents.
 - 5.3.1 If a study is closed to enrollment, the consent form will not be stamped at the time of continuing review unless determined by the IRB Analyst that it is necessary.
- 5.4 Execute the "Prepare Letter" activity, and modify the letter as needed.
- 5.5 Execute the "Send Letter" activity.
- 5.6 For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:
 - 5.6.1 Use "LETTER TEMPLATE: External Report (HRP-719)" or "LETTER TEMPLATE: External Report to OHRP (HRP-720)" as appropriate to send to outside agencies following the timeline outlined in SOP: External Reporting Process (HRP-094). If there



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NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-052	Executive Director, IRB Office Northwestern University	02/01/2023	Page 2 of 2

are no outside agencies to report the determination, use “LETTER TEMPLATE: University Only Reports (HRP-1716)” to report internally.

- 5.7 If reporting to an external agency is required:
 - 5.7.1 Follow SOP: External Reporting Process (HRP-094) to send to outside agencies within the defined reporting timeline.
 - 5.7.2 When sending to DHHS only, complete the OHRP Incident Report Online Form¹ using HRP-720 as a guide.
 - 5.7.2.1 If reporting to both DHHS and any other outside agency concurrently, utilize the OHRP Incident Report Form and HRP-094.

6 MATERIALS

- 6.1 SOP: Non-Committee Review Preparation (HRP-031)
- 6.2 SOP: External Reporting Process (HRP-094)
- 6.3 WORKSHEET: Communication of Review Results (HRP-303)
- 6.4 WORKSHEET: Approval Intervals (HRP-302)
- 6.5 LETTER TEMPLATE: External Report (HRP-719)
- 6.6 LETTER TEMPLATE: External Report to OHRP (HRP-720)
- 6.7 LETTER TEMPLATE: University Only Reports (HRP-1716)

7 REFERENCES

- 7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407, 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)
- 7.2 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

¹ See: <https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html>