



SOP: Post-Review

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1 PURPOSE

- 1.1 This procedure establishes the process for communications after an item 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 08/01/2024.

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 The IRB makes its findings and actions available to applicable federal agencies, where appropriate.
- 3.4 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 writing.
- 3.5 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.
- 3.6 When a modification (MOD), continuing review (CR), or modification/continuing review (ModCR) is reviewed to lift a suspension for a previous Suspension of IRB Approval, the state of the study will change from "Suspended" to "Approved" when the submission is approved.
- 3.7 If applicable, the IRB Executive Director or designee will report 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, to the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), 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 If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow HRP-031 - SOP - Non-Committee Review Preparation.
- 5.2 For initial reviews, continuing reviews, or modifications:
 - 5.2.1 If the communication is an IRB determination of Approved:
 - 5.2.1 For approval of initial reviews and continuing reviews, refer to the WORKSHEET: Approval Intervals (HRP-302) to calculate approval intervals (if applicable).
 - 5.2.1.1 For DHHS-regulated research involving prisoners, refer to the WORKSHEET: Communication of Review Results (HRP-303) to send applicable letters.
 - 5.2.1.1.1 If the CHECKLIST: Prisoners (HRP-415) reflects prisoners as a class or prisoners as controls, await OHRP approval before proceeding (if the checklist decision tree reflects this).



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- 5.2.2 If a study is closed to enrollment, the IRB Office staff will not stamp the consent form(s) at the time of continuing review unless it is determined to be necessary.
 - 5.2.2.1 Execute the "Finalize Documents" to stamp and accept all changes for attached documents.
 - 5.2.2.2 Execute the "Prepare Letter" activity and modify the letter as needed.
 - 5.2.2.3 Execute the "Send Letter" activity.
- 5.2.3 If the communication is an IRB determination other than Approved:
 - 5.2.3.1 Execute the "Prepare Letter" activity and modify the letter as needed.
 - 5.2.3.2 Execute the "Send Letter" activity.
- 5.3 For continuing reviews or modifications to studies where enrollment is suspended and the submission does not change the enrollment suspension status, execute the "Suspend" activity in the study workspace, and document that the enrollment to the study remains suspended.
- 5.4 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, or any combination of these:
 - 5.4.1 If the determination was Serious Non-Compliance; Continuing Non-Compliance; or Unanticipated Problem Involving Risks to Subjects or Others:
 - 5.4.1.1 Execute the "Prepare Letter" activity and modify the appropriate letter as needed.
 - 5.4.1.2 Execute the "Send Letter" activity.
 - 5.4.1.3 The IRB Office Compliance team will follow the procedures and timelines outlined in SOP: External Reporting Process (HRP-094).
 - 5.4.2 If the determination was Suspension or Termination of IRB Approval:
 - 5.4.2.1 The IRB Analyst or the IRB Lead Analyst will notify the IRB Compliance Team immediately of the suspension or termination issued by the IRB Panel.
 - 5.4.2.2 The IRB Office Compliance Team will follow the procedures outlined in SOP: Suspension or Termination of IRB Approval By Convened Panel (HRP-029).

6 MATERIALS

- 6.1 SOP: Non-Committee Review Preparation (HRP-031)
- 6.2 SOP: External Reporting Process (HRP-094)
- 6.3 SOP: Suspension or Termination of IRB Approval By Convened Panel (HRP-029)
- 6.4 WORKSHEET: Communication of Review Results (HRP-303)
- 6.5 WORKSHEET: Approval Intervals (HRP-302)
- 6.6 LETTER TEMPLATE: Review of Reportable New Information (HRP-717)
- 6.7 LETTER TEMPLATE: ModCR Approval (HRP-704)
- 6.8 LETTER TEMPLATE: Modification Approval (HRP-704)
- 6.9 LETTER TEMPLATE: Continuing Review Approval (HRP-703)
- 6.10 LETTER TEMPLATE: Deferral of Submission (HRP-712)
- 6.11 LETTER TEMPLATE: Modification Required to Secure Approved Determination (HRP-706)
- 6.12 LETTER TEMPLATE: IRB Waiver For Non-Emergency Individual Patient Expanded Access Use Of An Investigational Drug (HRP-575)
- 6.13 LETTER TEMPLATE: Compassionate Use Request for Device (HRP-1718)
- 6.14 LETTER TEMPLATE: Approval of Short Form Consent (HRP-730)
- 6.15 LETTER TEMPLATE: New Study Approval (HRP-701)
- 6.16 LETTER TEMPLATE: Exempt Determination (HRP-705)
- 6.17 LETTER TEMPLATE: Disapproval of Submission (HRP-714)



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- 6.18 LETTER TEMPLATE: Modification Required to Secure Not Human Research Determination (HRP-710)
- 6.19 LETTER TEMPLATE: Suspension of IRB Approval (HRP-715)
- 6.20 LETTER TEMPLATE: Termination of IRB Approval (HRP-716)
- 6.21 LETTER TEMPLATE: Study Closure (HRP-718)
- 6.22 LETTER TEMPLATE: Not Human Research Determination (HRP-709)
- 6.23 LETTER TEMPLATE: Human Research Not Engaged (HRP-707)
- 6.24 LETTER TEMPLATE: Modification Required to Secure Human Research Not Engaged Determination (HRP-708)
- 6.25 LETTER TEMPLATE: OHRP Notification of Emergency Waiver (HRP-724)
- 6.26 LETTER TEMPLATE: Review of Emergency Use – Criteria Met (HRP-572)
- 6.27 LETTER TEMPLATE: Review of Emergency Use – Criteria Not Met (HRP-573)
- 6.28 LETTER TEMPLATE: Failure to Submit Emergency Use Protocol (HRP-533)
- 6.29 LETTER TEMPLATE: NIH Genomic Data Sharing (GDS) Institutional Certification (HRP-563)
- 6.30 LETTER TEMPLATE: Pre-Review Emergency Use – Criteria Met (HRP-570)
- 6.31 LETTER TEMPLATE: Pre-Review Emergency Use – Criteria Not Met (HRP-571)
- 6.32 LETTER TEMPLATE: Failure to Submit Emergency Use Report (HRP-551)

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