

SOP: Post-Review				
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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 staff; OR
 - 1.2.2 An IRB meeting has adjourned, and the IRB chair or IRB manager has approved the minutes; OR
 - 1.2.3 An IRB 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 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The IRB reports its findings and actions to the investigator.
- 3.2 The IRB reports its findings and actions 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 Communication of review results to investigators are to be completed within 10 business days of the IRB meeting or receipt of the completed Non-Committee Review materials.
- 3.5 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.

4 RESPONSIBILITIES

- 4.1 IRB 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 "SOP: Non-Committee Review Preparation (HRP-031)."
- 5.2 Refer to "WORKSHEET: Approval Intervals (HRP-302)" to calculate approval intervals (if applicable).
- 5.3 Execute the "Finalize Documents" to stamp and accept all changes for attached documents.
 - 5.3.1 Execute the "Prepare Letter" activity, and modify the letter as needed.
 - 5.3.2 Execute the "Send Letter" activity.
- 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:
 - 5.4.1 Use "LETTER TEMPLATE: External Report (HRP-520)" to send to outside agencies within 30 business days from the determination of a reportable problem.
- 5.5

6 MATERIALS

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- 6.1 SOP: Non-Committee Review Preparation (HRP-031)
- 6.2 WORKSHEET: Communication of Review Results (HRP-303)
- 6.3 WORKSHEET: Approval Intervals (HRP-302)

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

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