

SOP: Post-Review

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-052	06/15/2017	C.Gates	C. Kiel	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 notified the IRB staff; OR
 - 1.2.2 An IRB meeting has adjourned and the IRB chair or IRB director or designee 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 has been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised reporting timeline to allow for investigator request for reconsideration.

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 These reporting procedures are to be completed within 10-15 business days of the IRB meeting or receipt of the completed Non-Committee Review materials.
- 3.5 Reporting to regulatory agencies (e.g., OHRP, FDA, DOD, etc.) of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others is to take place within 30 business days from the date of the final determination.
- 3.6 When an analyst is logged into the electronic IRB system using a valid username and password, and uses the system to generate correspondence that communicates the results of IRB decisions, including approval determinations, the correspondence is considered to have been signed by the analyst under the authority of the IRB chair and the IRB director or designee.

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 Check the accuracy of “CHECKLIST: Pre-Review (HRP-401)” or equivalent and revise as needed.
- 5.3 Refer to “WORKSHEET: Approval Intervals (HRP-302)” to calculate approval intervals.
- 5.4 Affix all newly approved consent materials with the approval date.
- 5.5 Refer to “WORKSHEET: Communication of Review Results (HRP-303)” and send all applicable letters.
 - 5.5.1 Send the letter to the inside addresses and cc list as directed by the letter.
 - 5.5.2 If not available electronically, attach all dated consent materials.

6 MATERIALS

- 6.1 CHECKLIST: Pre-Review (HRP-401)
- 6.2 SOP: New Information (HRP-024)
- 6.3 SOP: Non-Committee Review Preparation (HRP-031)
- 6.4 WORKSHEET: Communication of Review Results (HRP-303)
- 6.5 WORKSHEET: Approval Intervals (HRP-302)

7 REFERENCES

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NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-052	06/15/2017	C.Gates	C. Kiel	2 of 2

- 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