SOP: Post-Review			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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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 Office staff; or

1.2.2 An IRB meeting has adjourned and the IRB chair, vice chair or designee has approved the minutes; 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 01/08/2019.

3 POLICY

3.1 The IRB reports 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 reporting procedures are to be completed within 10 business days of approval of the IRB meeting minutes or receipt of the completed Non-Committee Review materials.

3.5 The IRB reports to the IRB Office Executive Director or designee within 10 business days from the recognition of a reportable problem Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval, or Unanticipated Problem Involving Risks to Subjects or Others.

3.6 If applicable, the IRB Executive Director or designee will report the items listed in Item 3.5 to the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), and other applicable agencies within 30 business days from the determination of a reported problem.

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” to stamp and accept all changes for attached documents. 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)” to send to outside agencies within 30 business days from the determination of a reportable problem.

6 MATERIALS

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