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, IRB Director, Assistant IRB Director, Biomedical IRB Manager, or Social Behavioral 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 These reporting procedures are to be completed within 2 business days of approval of the IRB meeting minutes 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 is to take place within 30 days from the recognition 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.
5.3 Execute the “Finalize Documents” to stamp and accept all changes for attached documents.
5.4 Execute the “Prepare Letter” activity, and modify the letter as needed.
5.5 Execute the “Send Letter” activity.

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
7.2 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66