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 HRPO staff; OR
   1.2.2 An HRRC meeting has adjourned and the HRRC chair or HRRC Manager has approved the minutes; OR
   1.2.3 An HRRC chair, HRRC member or HRPO staff member, as appropriate, has verified that modifications required to secure approval have been made.
1.3 The process ends when all correspondence related to HRRC determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Correction of spelling and grammatical errors throughout SOP.
2.2 Replaced all references to “IRB” with “HRRC”
2.3 Updated procedures to reflect current process in electronic system.

3 POLICY
3.1 The HRRC reports its findings and actions to the investigator.
3.2 The HRRC reports its findings and actions to the institution.
3.3 When the HRRC 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 the HRRC meeting or receipt of the completed Non-Committee Review materials.
3.5 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of HRRC Approval; Termination of HRRC Approval; and Unanticipated Problem Involving Risks to Subjects or Others is to take place within 30 business days from the recognition of a reportable problem.

4 RESPONSIBILITIES
4.1 HRPO staff members carry out these procedures.

5 PROCEDURE
5.1 If the Non-Committee Review indicated a Conflict of Interest or a lack of expertise, follow “SOP: Non-Committee Review Preparation (HRP-031).”
5.2 Refer to “WORKSHEET: Approval Intervals (HRP-302)” to confirm calculated approval intervals.

5.3 Execute the “Finalize Documents” activity 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 to send communication of review results.

6 MATERIALS

6.1 SOP: Non-Committee Review Preparation (HRP-031)

6.2 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