1 PURPOSE

1.1 This SOP 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/HRPP staff; OR

1.2.2 An IRB meeting has adjourned and the IRB Chair or HRPP Director has approved the minutes; OR

1.2.3 An IRB/HRPP 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 Revised from version 5/30/2017

3 SOP Statement

3.1 The IRB reports its findings and actions to the investigator.

3.2 The IRB reports its findings and actions to the institution as required.

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 5-10 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 as applicable is to take place within 30 days from the determination of a reportable event.

3.6 When the IRB/HRPP staff analyst is logged into the electronic IRB system using a valid username and password and uses the system to generate and send correspondence that communicates the results of IRB decisions, including approval determinations, the correspondence is considered to have been signed under the authority of the IRB chair or designee.

3.7 Appeal of IRB Decisions

3.7.1 If an investigator disagrees with a decision of the IRB, the investigator may submit a written appeal to the IRB Chair or HRPP Director within 30 days of being notified of the decision.

3.7.1.1 The appeal should include information supporting any disagreement made in the appeal.

3.7.1.2 For appeals involving research conducted by designated review the appeal is reviewed by the designated reviewer, IRB Chair and HRPP Director.

3.7.1.3 For appeals involving research reviewed by the convened board, the appeal is reviewed by the convened board.

3.7.1.3.1 The investigator may request to address the board at the meeting to provide clarification or additional information to the IRB.

3.7.1.4 The investigator is notified in writing of the decision.

3.7.2 The Institutional Official may override the IRB's decision to approve research; however, the IO or institution may not approve the research if it has not been approved by the IRB or overrule other decisions made by the IRB.

4 RESPONSIBILITIES

4.1 IRB/HRPP staff members carry out post review administrative procedures. The IRB Chair and/or HRPP Director facilitate any appeal process.

5 PROCEDURE

5.1 Calculate the approval period for initial or continuing review of research. Refer to HRP-302 – WORKSHEET - Approval Intervals to calculated approval intervals.

5.1.1 Verify the calculated dates entered into the electronic system.

5.2 Finalize documents with the IRB stamp on all approved consent documents with the document approval date.
- 5.2.1 This is the beginning date that the consent document may be used.
- 5.2.2 The stamped consent may be used until a subsequent consent is IRB approved and stamped with a document approval date.

5.3 Finalize other documents as needed as part of the study records.
- 5.3.1 Generate the outcome letter using the appropriate template and modify the letter as needed. (See Table A for templates or use equivalent.)
- 5.3.2 Send Letter when complete.

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation

6.2 HRP-302 - WORKSHEET - Approval Intervals

6.3 HRP-303 - WORKSHEET - Communication of Review Results

7 REFERENCES

7.1 45 CFR §46.109(d) 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

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

7.3 AAHRPP II.2.E, II.2.F, II.2.G., II.2.H