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 The investigator has resubmitted to a prior Non-Committee Review or full-board (convened) IRB review requiring a modification to secure an approval.

A Designated Reviewer had already completed a Non-Committee Review and provided completed materials to the IRB staff; OR

1.2.2 An IRB meeting had adjourned, and the IRB chair/HRPP Director/designee had approved the minutes pending committee adoption of the approved minutes An IRB staff member had conducted an administrative review and had verified that conditions 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 to the decision.

3.4 The IRB Office has a performance standard/goal to complete communication of review results to investigators within two (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 to outside agencies is to take place within 1 to 30 business days from the determination of a reportable problem as required by the outside agency.

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 **3.004 (HRP-031) - SOP - Non-Committee Review Preparation**.

5.2 For initial reviews, continuing reviews, modifications, or Reportable New Information (Reportable Events):

5.2.1 Refer to **3.204 (HRP-302) - WORKSHEET - Approval Intervals** to calculate approval intervals (if applicable).

5.2.2 For approvals for initial (full-board) or continuing review, set a deadline for receipt of the continuing review application 8 weeks before study expiration.

5.2.3 Stamp all consent documents with the approval date on all pages and send letters within applicable time frames.

5.2.3.1 Letter is generated and confirmed by designee by the signatory specified in the template letter.

5.2.3.2 Send the letter to the inside addresses and cc list as directed by the letter template.

5.2.3.3 Upload and log the correspondence letter as a private comment in the study workspace.

5.2.4 For continuing reviews or modifications to studies, where enrollment is suspended, the suspension of enrollment remains until such time as the IRB lifts the suspension.

5.2.5 The eIRB+ system automatically updates the list of studies when an IRB approves a change in study title, Principal Investigator, or research staff.

5.3 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:

The IRB Office has a performance standard/goal for communication of Review Results and to send all applicable letters to the Principal Investigator within 2 business days.

5.3.1.1 Letter is generated and confirmed by designee by the signatory specified in the template letter.

5.3.1.2 Send the letter to the inside addresses and cc list as directed by the letter template.

5.3.1.3 Upload and log the correspondence letter as a private comment in the study workspace.

5.3.1.4 Use **10.302 (HRP-520) - LETTER - External Report** to send to outside agencies within 1 to 30 business days from the determination of a reportable problem, as required by the outside Agency. Upload and log the correspondence letter as a private comment in the study workspace.

6 MATERIALS

6.1 3.004 (HRP-031) - SOP - Non-Committee Review Preparation.
6.2 3.204 (HRP-302) - WORKSHEET - Approval Intervals.
6.3 10.302 (HRP-520) - LETTER - External Report.

7 REFERENCES

7.1 45 CFR §46.108(3)(i).
7.2 45 CFR §46.207.
7.3 45 CFR §46.306(2)(C).
7.4 45 CFR §46.306(2)(D).
7.5 45 CFR §46.407.
7.6 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996).
7.7 21 CFR §56.108(a)(1).
7.8 21 CFR §50.24(e).
7.9 21 CFR §50.54(b).