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 has approved the minutes.
   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 Minor revisions to clarify process; replaces version dated 4/6/2012.

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 two weeks of the IRB meeting or receipt of
       the completed Non-Committee Review materials.
   3.5 Contact information is maintained in the “IRB database.”
   3.6 Protocol information is maintained in the “IRB database.”

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.”
   5.2 If information about the investigator or research staff is changed, update the contact information in
       the IRB database.
   5.3 If the title, principal investigator, or research staff for a protocol changed, update the IRB database.
   5.4 Refer to “WORKSHEET: Calculation of Approval Intervals” to calculated approval intervals.
   5.5 For approvals for initial or continuing review, add a deadline for receipt of the continuing review
       application 45 days before study expiration.
   5.6 If the review indicated “Modifications Required to Secure Approval,” add a deadline to receive a
       response within 30 days.
   5.7 Ensure all consent documents are marked with the End Approval Date.
   5.8 Refer to “WORKSHEET: Communication of Review Results” and send all applicable letters
       generally within 10 working days and always within 30 days.
       5.8.1 Have letter signed by the signatory in the template letter.
       5.8.2 Send the letter to the inside addresses and cc list as directed by the letter.
       5.8.3 Attach stamped consent documents to the letter.
   5.9 Update the status of the research in the database.
   5.10 Follow “SOP: IRB Records.”

6 MATERIALS
   6.1 IRB database
   6.2 SOP: Non-Committee Review Preparation
   6.3 SOP: IRB Records
   6.4 WORKSHEET: Communication of Review Results
6.5 WORKSHEET: Calculation of Approval Intervals and Expiration Dates

7 REFERENCES


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