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 or IRB manager has approved the
            minutes.
       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
   1.4 Replaces version dated 7/18/2012.
3. POLICY
   a. The IRB reports its findings and actions to the investigator.
   b. The IRB reports its findings and actions to the institution.
   c. 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.
   d. These reporting procedures are to be completed within 2 business days of the IRB meeting or
      receipt of the completed Non-Committee Review materials.
   e. 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.
   f. Contact information is maintained in the InfoEd System.
   g. The list of protocols is maintained in the InfoEd System.
   h. Receipt deadlines are maintained in the InfoEd System.
4. RESPONSIBILITIES
   a. IRB staff members carry out these procedures.
5. PROCEDURE
   a. If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow “SOP:
      Non-Committee Review Preparation.”
   b. If information about the investigator or research staff were changed, update the contact information.
   c. If the title, principal investigator, or research staff for a protocol changed, update the list of protocols
   d. For approvals for initial or continuing review, add a deadline for receipt of the continuing review
      application 30 days before study expiration.
   e. If the review indicated “Modifications Required to Secure Approval,” add a deadline to receive a
      response within 90 days.
   f. Refer to “WORKSHEET: Calculation of Approval Intervals” to calculated approval intervals.
   g. Stamp all consent documents with the IRB approval period.
   h. Refer to “WORKSHEET: Communication of Review Results” and send all applicable letters.
       i. Send the letter to the inside addresses and cc list as directed by the letter.
       ii. Attach stamped consent documents to the letter.
   i. Update the status of the research in the database.
   j. Update the protocol list.
   k. Follow “SOP: IRB Records.”
6. MATERIALS
a. InfoEd System
b. SOP: Non-Committee Review Preparation
c. SOP: IRB Records
d. WORKSHEET: Communication of Review Results
e. WORKSHEET: Calculation of Approval Intervals and Expiration Dates

7. REFERENCES
b. 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66