1. PURPOSE
   1. This procedure establishes the process for communications after a protocol is reviewed.
   2. The process begins when:
      1. A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR
      2. An IRB meeting has adjourned, and the IRB chair or IRB manager has approved the minutes; OR
      3. An IRB staff member has verified that modifications required to secure approval have been made.
   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. None
3. POLICY
   1. The IRB reports its findings and actions to the investigator.
   2. The IRB reports its findings and actions to the institution.
   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.
   4. Communication of review results to investigators are to be completed within 10 business days of the IRB meeting or receipt of the completed Non-Committee Review materials.
   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 30 business days from the determination of a reportable problem.
4. RESPONSIBILITIES
   1. IRB staff members carry out these procedures.
5. PROCEDURE
   1. If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow “SOP: Non-Committee Review Preparation (HRP-031).”
   2. If the title, principal investigator, or research staff for a protocol changed, update the list of protocols.
   3. For initial reviews, continuing reviews or modifications:
      1. Refer to “WORKSHEET: Approval Intervals (HRP-302)” to calculate approval intervals (if applicable).
      2. For approvals for initial or continuing review, set a deadline for receipt of the continuing review application 30 days before study expiration.
      3. Stamp all approved long form consent documents with the approval date on the first and last page.
      4. Refer to “WORKSHEET: Communication of Review Results (HRP-303)” and send all applicable letters within 30 business days.
         1. Have letter signed by the signatory in the template letter.
         2. Send the letter to the inside addresses and cc list as directed by the letter.
            1. Attach stamped consent documents to the letter.
   4. 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:
      1. Refer to “WORKSHEET: Communication of Review Results (HRP-303)” and send all applicable letters to the Principal Investigator within 5 business days.
         1. Have letter signed by the signatory in the template letter.
         2. Send the letter to the inside addresses and cc list as directed by the letter.
      2. Use “LETTER TEMPLATE: External Report (HRP-520)” to send to outside agencies within 30 business days from the determination of a reportable problem.
6. MATERIALS
   1. SOP: Non-Committee Review Preparation (HRP-031)
   2. WORKSHEET: Communication of Review Results (HRP-303)
   3. WORKSHEET: Approval Intervals (HRP-302)
7. REFERENCES
   1. 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, 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)
   2. 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66