HRP-031 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

**SOP: Non-Committee Review Preparation**

1. **PURPOSE**
   1. This procedure establishes the process to prepare for a Non-Committee Review.
   2. The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.
   3. The process ends when the IRB staff member provides the materials to the Designated Reviewer if the staff member does not conduct the designated review.
2. **REVISIONS FROM PREVIOUS VERSION**
   1. Revised system steps; 11/26/24.
3. **POLICY**
   1. IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
   2. For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in HRP-301 - WORKSHEET - Review Materials according to their role: “Documents Provided to All IRB Members and Alternate IRB Members,” “Additional Items Provided to Primary Reviewer,” and “Additional Items Provided to Scientific/Scholarly Reviewer.”
4. **RESPONSIBILITIES**
   1. IRB staff members carry out these procedures.
5. **PROCEDURE**
   1. Assign the reviewer:
      1. For initial review, complete the “Assign Single Reviewer” activity.
         1. For follow-on submissions, complete the “Send to Expedited” or “Send to Exempt” activity first, as appropriate.
      2. Identify the appropriate administrative staff reviewer or Designated Reviewer.
         1. Ensure the staff reviewer or Designated Reviewer is not a member of the study team.
         2. If no Designated Reviewer is available, or if available Designated Reviewers are unable to perform a Non-Committee Review in a timely manner such that review by the convened IRB would result in a more timely review, schedule the protocol to be reviewed by the convened IRB.
   2. Assign for review within three business days of receipt of a complete submission, or, proceed to conduct the designated review.
6. **MATERIALS**
   1. HRP-301 - WORKSHEET - Review Materials
   2. HRP-601 - DATABASE - IRB Roster
7. **REFERENCES**
   1. 21 CFR §56.110(b)
   2. 45 CFR §46.110(b)
   3. AAHRPP elements I.1.A, I.1.F, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3