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.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. HSPP maintains official IRB rosters for the OHRP/FDA Registration. IRB rosters are also maintained in eIRB using in the HRP-601 eIRB Committee Member Profile.
   2. In order to prepare for a Non-Committee review, individuals 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. For IRB Staff will select the appropriate checklist from the HRP-301 - WORKSHEET and worksheet that need to be considered during a non-committee review
   2. Add to the review materials:
      1. HRP-402 - CHECKLIST - Non-Committee Review.
      2. Any relevant minutes or correspondence.
   3. Refer to HRP-601 - eIRB Committee Member Profile and select a Designated Reviewer.
      1. 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. Use the “Assign Designated Reviewer” activity and select a Designated Reviewer upon receipt of a complete submission.
      3. Execute the “Assign Designated Reviewer” activity
6. MATERIALS
   1. HRP-301 - WORKSHEET - Review Materials
   2. HRP-402 - CHECKLIST - Non-Committee Review
   3. HRP-601 - eIRB Committee Member Profile
7. REFERENCES
   1. 21 CFR §56.110(b)
   2. 45 CFR §46.110(b)