1. PURPOSE
   1. This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.
   2. The process begins when the Designated Reviewer has the provided materials.
   3. The process ends when the Designated Reviewer completes the review and returns the completed materials to an IRB staff member.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. The Designated Reviewer may not disapprove research.
4. RESPONSIBILITIES
   1. The Designated Reviewer carries out these procedures.
5. PROCEDURE
   1. Review all materials.
   2. Determine the required level of review:
      1. Not Human Research,
      2. Human Research not Engaged,
      3. Exempt Human Research (including exempt Human Research that requires Limited IRB Review),
      4. Human Research approved using the expedited procedure, or
      5. Human Research that requires review by a convened IRB.
   3. If consultation is needed follow HRP-051 - SOP - Consultation.
   4. If the Conflicts of Interest Committee has identified an institutional conflict of interest, review their recommendations or plans to manage, mitigate, or eliminate the conflict.
   5. Complete HRP-402 - CHECKLIST - Non-Committee Review.
   6. When research involves prisoners or prison employees, a prisoner representative IRB member is selected as the designated reviewer.
   7. When research involves prisoners or prison employees, the prisoner representative designated reviewer completes HRP-415 CHECKLIST - Prisoners.
   8. Execute the “Submit Designated Review” activity.
   9. Return all materials and completed checklists to the IRB staff within 5 business days of receipt of materials.
6. MATERIALS
   1. HRP-051 - SOP - Consultation
   2. HRP-319 - WORKSHEET - Limited IRB Review
   3. HRP-402 - CHECKLIST - Non-Committee Review
   4. HRP-415 - CHECKLIST - Prisoners
7. REFERENCES
   1. 21 CFR §56.110(b)
   2. 45 CFR §46.110(b)