SOP: Non-Committee Review Conduct

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. Change from departmental exempt determiner to a PPHS staff member who is a Certified IRB Professional (CIP).
   2. Added 5.4
3. POLICY
   1. The Designated Reviewer may not disapprove research.
   2. The Designated Reviewer utilizes all applicable worksheets in the review of research.
   3. All applicable criteria for approval in HRP-314 - WORKSHEET - Criteria for Approval must be satisfied in order for the research to be approved using the expedited procedure.
   4. All applicable criteria for approval in HRP-312 - WORKSHEET - Exemption Determination must be satisfied for research to be determined to be exempt.
   5. All exempt determinations are made by a PPHS staff member who is a CIP.
4. RESPONSIBILITIES
   1. The Designated Reviewer carries out these procedures.
   2. Exempt determinations are made by a PPHS staff member who is a CIP.
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
      4. Human Research approved using the expedited procedure, or
      5. Human Research that requires review by a convened IRB.
   3. If the study was submitted for an exempt determination and if the determination is that the research is not exempt from IRB review, communication will be sent to the research team, indicating that a formal application to the IRB is necessary.
   4. sIRB external site activation: If ISMMS is serving as the sIRB, determine whether external sites can be activated using the expedited review procedure or if the sites need to be reviewed and activated during a convened meeting. When the expedited procedure is used, the Designated Reviewer must specify the criteria for when the addition of an investigative site is considered an expedited modification.
   5. If consultation is needed follow HRP-051 - SOP - Consultation.
   6. Execute the “Submit Designated Review” activity.
   7. 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-312 - WORKSHEET - Exemption Determination
   3. HRP-314 - WORKSHEET - Criteria for Approval
7. REFERENCES
   1. 21 CFR §56.110(b).
   2. 45 CFR §46.110(b).
   3. AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3, II.5.A