HRP-032 | 10/9/2024 | Author: T. Bechert | Approver: J. Opalesky

**SOP: Non-Committee Review Conduct**

1. **PURPOSE**
   1. This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review or a Limited IRB 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. Added reference to limited IRB review to purpose section; 2/1/24.
   2. Removed reference to HRP-402, added grant review NHSR instruction, added process instructions to layer documents, clarified timing for confidentiality agreement and conflict of interest policy review for IRB consultants; 10/9/24.
3. **POLICY**
   1. The Designated Reviewer may not disapprove research.
   2. The Designated Reviewer utilizes all applicable worksheets in the review of research.
   3. IRB consultants will sign a confidentiality agreement and conflict of interest policy review statement in advance of receiving materials or reviewing and consulting on studies
   4. 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.
   5. All applicable criteria for approval in HRP-312 - WORKSHEET - Exemption Determination must be satisfied for research to be determined to be exempt (including applicable criteria for Limited IRB Review in HRP-319 - WORKSHEET - Limited IRB Review when appropriate).
4. **RESPONSIBILITIES**
   1. The Designated Reviewer carries out these procedures.
5. **PROCEDURE**
   1. Review all materials.
      1. This includes the completed HRP-401 - CHECKLIST - Pre-Review and any previously completed special determination checklists uploaded to the Admin Docs tab.
   2. If an initial review or a modification to add a new special determination, download the checklist(s) from the shared drive or Admin Docs tab and complete with the review.
   3. 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.
   4. If consultation is needed follow HRP-051 - SOP - Consultation.
   5. Obtain a signed confidentiality statement and conflict of interest policy review statement for all IRB meeting guests and consultants.

* 1. Execute the “Finalize Review” activity. Reference any special determination checklists completed as part of the review.
     1. For Center or Institute Administrative Grant Review submissions, finalize as Not Human Subjects Research.
     2. Upload any relevant completed checklists using the “Upload Administrative Documents” activity.
        1. Layer revised checklists, when applicable, over the previous version unless adding a new determination.
     3. Complete review within 10 business days (or provide notification of any extenuating circumstances).

1. **MATERIALS**
   1. HRP-051 - SOP - Consultation
   2. HRP-312 - WORKSHEET - Exemption Determination
   3. HRP-313 - WORKSHEET - Expedited Review
   4. HRP-314 - WORKSHEET - Criteria for Approval
   5. HRP-319 - WORKSHEET - Limited IRB Review
   6. HRP-402 - CHECKLIST - Non-Committee Review
   7. HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
   8. HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
   9. HRP-412 - CHECKLIST - Pregnant Women
   10. HRP-413 - CHECKLIST - Non-Viable Neonates
   11. HRP-414 - CHECKLIST - Neonates of Uncertain Viability
   12. HRP-415 - CHECKLIST - Prisoners
   13. HRP-416 - CHECKLIST - Children
   14. HRP-417 - CHECKLIST - Cognitively Impaired Adults
   15. HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research
   16. HRP-441 - CHECKLIST - HIPAA Waiver of Authorization
2. **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