SOP: Non-Committee Review Conduct

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1 PURPOSE
   1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.
   1.2 The process begins when the Designated Reviewer has the provided materials.
   1.3 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
   2.1 Added reference to engagement determination.
   2.2 Section on level of review modified to clarify which materials are used for different types of review.

3 POLICY
   3.1 The Designated Reviewer may not disapprove research.

4 RESPONSIBILITIES
   4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE
   5.1 Review all materials.
   5.2 Make engagement determination if required using WORKSHEET: Engagement Determination.
   5.3 Determine the required level of review:
      5.3.1 Not Human Research. Use “WORKSHEET: Human Research Determination” to determine whether the activity is Human Research.
      5.3.2 Exempt Human Research. Use the "WORKSHEET: Exemption Determination" to determine whether the Human Research meets the exemption criteria and the organization's ethical requirements.
      5.3.3 Human Research approved using the expedited procedure. Use the “CHECKLIST: Eligibility for Review Using the Expedited Procedure” to determine whether the Human Research meets the criteria for expedited review.
      5.3.3.1 Use the “WORKSHEET: Criteria for Approval and Additional Considerations” to determine whether the Human Research can be approved.
      5.3.4 Human Research that requires review by a convened IRB.
   5.4 If consultation is needed follow “SOP: Consultation to the IRB.”
   5.5 Complete the “CHECKLIST: Non-Committee Review.”
   5.6 Return all materials and completed checklists to the IRB staff within 10 business days of receipt of materials.

6 MATERIALS
   6.1 CHECKLIST: Non-Committee Review
   6.2 SOP: Consultation to the IRB
   6.3 WORKSHEET: Criteria for Approval and Additional Considerations
   6.4 WORKSHEET: Eligibility for Review by Expedited Procedure
   6.5 WORKSHEET: Engagement Determination
   6.6 WORKSHEET: Exemption Determination
   6.7 WORKSHEET: Human Research Determination

7 REFERENCES
   7.1 21 CFR §56.110(b).
   7.2 45 CFR §46.110(b).