

SOP: Non-Committee Review Conduct

1 PURPOSE

- 1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review or a Limited IRB 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 None

3 POLICY

- 3.1 The Designated Reviewer may not disapprove research.
- 3.2 The Designated Reviewer utilizes all applicable worksheets in the review of research.
- 3.3 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.
- 3.4 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 and Broad Consent when appropriate).

4 RESPONSIBILITIES

- 4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

- 5.1 Review all materials.
- 5.2 Make the appropriate determination:
 - 5.2.1 Not Human Research,
 - 5.2.2 Human Research not Engaged,
 - 5.2.3 Exempt Human Research (including exempt Human Research that requires Limited IRB Review),
 - 5.2.4 Human Research approved using the expedited procedure, or
 - 5.2.5 Human Research that requires review by a convened IRB.
- 5.3 If consultation is needed follow HRP-051 - SOP - Consultation.
- 5.4 Complete HRP-402 - CHECKLIST - Non-Committee Review.
- 5.5 Return all materials and completed checklists to the IRB staff within 5 business days of receipt of materials.

6 MATERIALS

- 6.1 HRP-051 - SOP - Consultation
- 6.2 HRP-312 - WORKSHEET - Exemption Determination
- 6.3 HRP-314 - WORKSHEET - Criteria for Approval
- 6.4 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent
- 6.5 HRP-402 - CHECKLIST - Non-Committee Review

7 REFERENCES

- 7.1 21 CFR §56.110(b).
- 7.2 45 CFR §46.110(b).
- 7.3 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