

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 None.

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 Determine the required level of review. (Not Human Research, Human Research not Engaged, exempt Human Research (including exempt Human Research that requires Limited IRB Review), Human Research approved using the expedited procedure, or Human Research that requires review by a convened IRB.
- 5.3 If consultation is needed follow "SOP: Consultation (HRP-051)."
- 5.4 Execute the "Submit Designated Review" activity.

6 MATERIALS

- 6.1 SOP: Consultation (HRP-051)
- 6.2 WORKSHEET: Limited IRB Review and Broad Consent (HRP-319)

7 REFERENCES

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