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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:
 - 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 3.014 (HRP-051) - SOP - Consultation.
- 5.4 If the Conflicts of Interest Committee has identified an institutional conflict of interest, review their recommendations or plans to manage, mitigate, or eliminate the conflict.
- 5.5 Complete 3.101 (HRP-402) - CHECKLIST - Non-Committee Review.
- 5.6 When research involves prisoners or prison employees, a prisoner representative IRB member is selected as the designated reviewer.
- 5.7 When research involves prisoners or prison employees, the prisoner representative designated reviewer completes 7.204 (HRP-415) WORKSHEET - Prisoners.
- 5.8 Execute the "Submit Designated Review" activity.
- 5.9 Return all materials and completed checklists to the IRB staff within 5 business days of receipt of materials.

6 MATERIALS

- 6.1 3.014 (HRP-051) - SOP – Consultation.
- 6.2 3.101 (HRP-402) - CHECKLIST - Non-Committee Review.
- 6.3 3.213 (HRP-319) - WORKSHEET - Limited IRB Review.
- 6.4 7.204 (HRP-415) - WORKSHEET – Prisoners.

7 REFERENCES

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