

# Pre-2018 Common Rule

Human Subjects Research Office

SOP. Non-Committee Review Conduct				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-032	12/1/18	T. Bechert	G. Ostrander	1 of 1

# 1 PURPOSE

- 1.1 This procedure establishes the process for a <u>Designated Reviewer</u> to conduct a <u>Non-</u> <u>Committee Review.</u>
- 1.2 The process begins when the <u>Designated Reviewer</u> has the provided materials.
- 1.3 The process ends when the <u>Designated Reviewer</u> 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 <u>Designated Reviewer</u> may not disapprove research.

#### **4 RESPONSIBILITIES**

4.1 The <u>Designated Reviewer</u> carries out these procedures.

#### 5 PROCEDURE

- 5.1 Review all materials.
- 5.2 Determine the required level of review. (Not <u>Human Research</u>, <u>Human Research</u> not Engaged, exempt <u>Human Research</u>, <u>Human Research</u> approved using the expedited procedure, or <u>Human Research</u> 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)

# 7 REFERENCES

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