

SOP: Non-Committee Review Preparation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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1 PURPOSE

- 1.1 This procedure establishes the process to prepare for a Non-Committee Review.
- 1.2 The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.
- 1.3 The process ends when the IRB staff member provides the materials to the Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using "DATABASE: IRB Roster (HRP-601)."
- 3.2 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in the "WORKSHEET: Review Materials (HRP-301)" according to their role: "Documents Provided to All IRB Members and Alternate IRB Members," "Additional Items Provided to Primary Reviewer," and "Additional Items Provided to Scientific/Scholarly Reviewer."

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Refer to "DATABASE: IRB Roster (HRP-601)" and select a Designated Reviewer.
 - 5.1.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.
- 5.2 Use the "Assign Designated Reviewer" activity and select a Designated Reviewer.
 - 5.2.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.
 - 5.2.2 Execute the "Assign Designated Reviewer" activity
- 5.3 Execute the "Assign Designated Reviewer" activity to send to the Designated Reviewer upon receipt of a complete submission.

6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 WORKSHEET: Review Materials (HRP-301)

7 REFERENCES

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