

**SOP: Non-Committee Review Preparation**

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HRP-031	12/6/18	T. Bechert	G. Ostrander	1 of 1

**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 For individuals who are provided materials to review, prepare the review materials using the “WORKSHEET: Review Materials (HRP-301)” and include all materials listed under the columns according to the individual’s role.
- 5.4 Execute the “Assign Designated Reviewer” activity to send to the Designated Reviewer within three business days of receipt of a complete submission.

**6 MATERIALS**

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

**7 REFERENCES**

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