



SOP: Non-Committee Review Preparation

NUMBER	APPROVED BY	EFFECTIVE DATE	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 Office staff member identifies an application as being possibly eligible for Non-Committee Review.
- 1.3 The process ends when the IRB Office staff member provides the materials to the Designated Reviewer.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 05/20/2020

3 POLICY

- 3.1 Non-Committee Reviews are completed by Designated Reviewers (Experienced IRB Members who have been designated by the IRB Chair to conduct Non-Committee Reviews).
- 3.2 Designated Reviewers are indicated on the IRB Rosters.
- 3.3 IRB rosters are maintained using "DATABASE: IRB Roster (HRP-601)."
- 3.4 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 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 Office staff members carry out these procedures.

5 PROCEDURE

- 5.1 Prepare materials for Non-Committee Review using the WORKSHEET: Review Materials (HRP-301).
- 5.2 Complete Pre-Review and execute the Pre-Review activity.
- 5.3 Refer to "DATABASE: IRB Roster (HRP-601)" and select a Designated Reviewer considering expertise, representative capacity (as needed), and availability.
- 5.4 Use the "Assign Designated Reviewer" activity and select a Designated Reviewer.
- 5.5 Execute the "Assign Designated Reviewer" activity to send to the Designated Reviewer.

6 MATERIALS

- 6.1 SOP: Designated Reviewers (HRP-030)
- 6.2 WORKSHEET: Review Materials (HRP-301)
- 6.3 DATABASE: IRB Roster (HRP-601)
- 6.4 CHECKLIST: Non-Committee Review (HRP-402)

7 REFERENCES

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