

SOP: Non-Committee Review Preparation				
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1. PURPOSE

- 1.1 This procedure establishes the process to prepare for Non-Committee Review.
- 1.2 The process begins when an IRB staff member receives a submission.
- 1.3 The process ends when the IRB staff member moves the submission to the queue in the electronic system that is designated for Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Updated to reflect process with electronic submissions.

3 POLICY

- 3.1 IRB Rosters are maintained use DATABASE: IRB Roster (HRP-601).
- 3.2 Submissions identified for Non-Committee Review are moved to a queue in the electronic system that is solely for Non-Committee Review.
- 3.3 Individuals listed as Designated Reviewers on DATABASE: IRB Roster (HRP-601) select submissions from the queue in the electronic system that is designated for Non-Committee Review.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Screen incoming submission to ensure all required documentation has been submitted using WORKSHEET: Review Materials (HRP-301),” or equivalent.
- 5.2 Refer to WORKSHEET: Eligibility for Review Using the Expedited Procedure (HRP 313) to determine whether the submission can be referred for Non-Committee Review.
- 5.3 Move submissions that involve only minimal risk and appear to fit the requirements for Non-Committee Review to the queue designated in the electronic system for Non-Committee Review.
- 5.4 Designated reviewers pull submission he queue designated in the electronic system for Non-Committee Review.

6 MATERIALS

- 6.1 CHECKLIST: Non-Committee Review (HRP 402)
- 6.2 DATABASE: IRB Roster (HRP-601)
- 6.3 WORKSHEET: Review Materials (HRP 301)
- 6.4 WORKSHEET: Eligibility for Review Using the Expedited Procedure (HRP 313)

7 REFERENCES

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