

	SOP: Non-Committee Review Preparation		
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1 PURPOSE

- 1.1 This SOP establishes the process to assign a Designated Reviewer for Non-Committee Review.
- 1.2 The process begins when the Pre-Review of a submission is complete and an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.
- 1.3 Use the following worksheets when needed to judge eligibility for Non-Committee Review: HRP-310 - WORKSHEET - Human Subjects Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET - Expedited Review.
- 1.4 The process ends when the IRB staff member has notified and provides the materials to the assigned Designated Reviewer of the Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version.

3 SOP Statement

- 3.1 IRB rosters are maintained using HRP-601 - IRB Roster and in the electronic system.
- 3.2 Access to materials for review will be through the electronic system or will be provided otherwise upon request. Reviewers are expected to review, as applicable, the materials according to their role as described in HRP-045 - SOP - IRB Review Expectations.

4 RESPONSIBILITIES

- 4.1 IRB/HRPP staff members carry out these procedures.

5 PROCEDURE

- 5.1 Refer to the IRB Roster Sheet for eligible Designated Reviewers.
- 5.2 Use the 'Assign Reviewer' activity in the electronic system. Select the Designated Reviewer with the appropriate expertise.
 - 5.2.1 Execute the activity in the electronic system to notify the Designated Reviewer.
- 5.3 For individuals who are provided materials to review outside the electronic system, prepare the review materials using the HRP-301 - WORKSHEET - Review Materials and include all materials listed under the columns according to the individual's role.
 - 5.3.1 Notify the Designated Reviewer by email when review materials are provided outside the electronic system.

6 MATERIALS

- 6.1 IRB Roster Sheet
- 6.2 WORKSHEET: Human Subjects Determination (HRP-310)
- 6.3 WORKSHEET: Engagement Determination (HRP-311)
- 6.4 WORKSHEET: Exemption Determination (HRP-312)
- 6.5 WORKSHEET: Expedited Review (HRP-313)

7 REFERENCES

- 7.1 21 CFR §56.110(b)
- 7.2 45 CFR §46.110(b)
- 7.3 AAHRPP elements I.1.A, I.1.F, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3