



SOP: Non-Committee Review Preparation				
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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 11/13/2013
- 2.2 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

- 3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
- 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 HRP-301 - WORKSHEET - Review Materials 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.”
- 3.3 For continuing review of research, at least one IRB member is provided and reviews the complete protocol, including any protocol modifications previously approved by the IRB. The status report on the progress of the research includes the reported number of participants accrued and a summary since the last IRB review.

4 RESPONSIBILITIES

- 4.1 HSRO staff members carry out these procedures.

5 PROCEDURE

- 5.1 Use the “Assign Designated Reviewer” activity and select a Designated Reviewer.
 - 5.1.1 If no Designated Reviewer is available, or if available Designated Reviewers are unable to perform a Non-Committee Review in a timely manner such that review by the convened IRB would result in a more timely review, schedule the protocol to be reviewed by the convened IRB.
 - 5.1.2 Execute the “Assign Designated Reviewer” activity.

6 MATERIALS

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

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