

SOP: Non-Committee Review Preparation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-031	11/17/2022	Huron	D. Durbin	1 of 2

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 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."

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Refer to HRP-601 - DATABASE - IRB Roster 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 Use the "Assign Designated Reviewer" activity and select a Designated Reviewer.
 - 5.1.3 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.
 - 5.1.4 Execute the "Assign Designated Reviewer" activity
- 5.2 For individuals who are provided materials to review, 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 Add to the review materials:
 - 5.3.1 HRP-402 - CHECKLIST - Non-Committee Review.
 - 5.3.2 Any relevant minutes or correspondence.
 - 5.3.3 All Conflict of Interest Management Plans (CMP).
- 5.4 Complete HRP-540 - LETTER - Designated Reviewer Materials and send to the Designated Reviewer within three business days of receipt of a complete submission.
- 5.5 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 HRP-301 - WORKSHEET - Review Materials
- 6.2 HRP-402 - CHECKLIST - Non-Committee Review
- 6.3 HRP-540 - LETTER - Designated Reviewer Materials
- 6.4 HRP-601 - DATABASE - IRB Roster

Huron HRPP Toolkit 4.3



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HRP-031	11/17/2022	Huron	D. Durbin	2 of 2

7 REFERENCES

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