



SOP: Designated Reviewers				
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1 PURPOSE

- 1.1 This procedure establishes the process for an IRB chair to designate IRB members who can conduct Non-Committee Reviews.
- 1.2 The process begins when the IRB chair instructs HSRO staff to designate an Experienced IRB Member to conduct Non-Committee Reviews.
- 1.3 The process ends when the IRB member has been noted in the IRB roster to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None
- 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.

4 RESPONSIBILITIES

- 4.1 HSRO staff members carry out these procedures.

5 PROCEDURE

- 5.1 Obtain from the IRB chair the name of the IRB member designated to conduct Non-Committee Reviews.
- 5.2 Review list of IRB members designated to conduct Non-Committee Reviews in the “Assign Designated Reviewer” activity.
- 5.3 Verify that the IRB member is an Experienced IRB Member.
- 5.4 Update HRP-601 - DATABASE - IRB Roster to indicate that the IRB member is a Designated Reviewer.
- 5.5 Use the “Update Eligible Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.

6 MATERIALS

- 6.1 TEMPLATE LETTER HRP-600 Appointment of Designated Reviewer
- 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-9, II.2.A, II.2.B, II.2.D, II.2.F-II.2.F.3