



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 notified and the designation is noted in the IRB roster to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDING PRINCIPLES

- 3.1 IRB rosters are maintained using the “DATABASE: IRB Roster (HRP-601).”

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 Verify that the IRB member is an Experienced IRB Member.
- 5.3 Send TEMPLATE LETTER HRP-600 Appointment of Designated Reviewer.
- 5.4 Update the “DATABASE: IRB Roster (HRP-601)” to indicate that the IRB member is a Designated Reviewer.

6 MATERIALS

- 6.1 TEMPLATE LETTER HRP-600 Appointment of Designated Reviewer
- 6.2 DATABASE: IRB Roster (HRP-601)

7 REFERENCES

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