

SOP: Designated Reviewers		
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1. PURPOSE

- 1.1. This procedure establishes the process for a member of the HSPP staff or IRB Chair to designate one or more IRB member(s) who can conduct Non-Committee Reviews. The process begins when a member of the HSPP staff or IRB Chair instructs IRB staff to designate an Experienced IRB Member to conduct Non-Committee Reviews. The process ends when the IRB member(s) has/have been noted in the IRB roster to conduct Non- Committee Reviews.

2. REVISIONS FROM PREVIOUS VERSION

- 2.1. None.

3. POLICY

- 3.1. HSPP maintains official IRB rosters for the OHRP/FDA Registration. IRB rosters are also maintained in eIRB in the HRP-601 eIRB Committee Member Profile

4. RESPONSIBILITIES

- 4.1. IRB staff members carry out these procedures.

5. PROCEDURE

- 5.1. Confirm with the HSPP Executive Director which Experienced IRB member(s) may be designated to conduct Non- Committee Reviews.
- 5.2. Update the “eIRB Committee Member Profile: IRB Roster (HRP-601) to indicate that the IRB member is a Designated Reviewer.
- 5.3. Use the “Update Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.
- 5.4. An IRB member(s) is notified of his/her/their designation as a Non-Committee Reviewer for a specific submission via email by the eIRB system.
- 5.5.

6. MATERIALS

- 6.1. HRP-601 eIRB Committee Member Profile: IRB Roster

7. REFERENCES

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