

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 <u>Non-Committee Reviews</u>.
- 1.2 The process begins when the IRB chair instructs IRB staff to designate an <u>Experienced IRB</u> <u>Member</u> to conduct <u>Non-Committee Reviews</u>.
- 1.3 The process ends when the IRB member has been noted in the IRB roster to conduct <u>Non-</u> <u>Committee Reviews</u>.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

4 **RESPONSIBILITIES**

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Obtain from the IRB chair the name of the IRB member designated to conduct <u>Non-Committee</u> <u>Reviews</u>.
- 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 <u>Designated</u> <u>Reviewer</u>.
- 5.5 Use the "Update Eligible Designated Reviewers" activity to indicate that the IRB member is a <u>Designated Reviewer</u>.

6 MATERIALS

6.1 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

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