

SOP: Designated & Staff Reviewers

1 PURPOSE

- 1.1 This procedure establishes the process for documenting who can conduct Non-Committee Reviews.
- 1.2 The process begins when the IRB chair designates an Experienced IRB Member, or the IRB manager determines an IRB staff member can act as a Staff Reviewer, to conduct Non-Committee Reviews.
- 1.3 The process ends when the Experienced IRB Member or Staff Reviewer has been noted in the corresponding roster to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
- 3.2 Staff Reviewer rosters are maintained using HRP-602 - DATABASE - Staff Reviewer 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 Non-Committee Reviews.
 - 5.1.1 Verify that the IRB member is an Experienced IRB Member.
 - 5.1.2 Update HRP-601 - DATABASE - IRB Roster to indicate that the IRB member is a Designated Reviewer.
- 5.2 Obtain from the IRB manager the name of the IRB staff member eligible to act as a Staff Reviewer to conduct certain Non-Committee Reviews.
 - 5.2.1 Update HRP-602-DATABASE-Staff Reviewer to indicate that the IRB staff member is a Staff Reviewer.

6 MATERIALS

- 6.1 HRP-601 - DATABASE - IRB Roster
- 6.2 HRP-602 - DATABASE- Staff Reviewer

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