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 IRB 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

3 POLICY

3.1 IRB rosters are maintained using the “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 Non-Committee Reviews.

5.2 Verify that the IRB member is an Experienced IRB Member.

5.3 Update the IRB roster to indicate that the IRB member is a Designated Reviewer.

6 MATERIALS

6.1 DATABASE: IRB Roster

7 REFERENCES

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).