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 a new IRB Member is appointed to an IRB Panel.

1.3 The process ends when the IRB member has been noted in the IRB roster to conduct Non-Committee Reviews.

2 PREVIOUS VERSION

2.1 Revised from version dated 08/01/2015

3 POLICY

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

3.2 The IRB Chair is notified when a new IRB Member is appointed to a Panel and listed on the IRB Roster. All IRB Members listed on the IRB Roster are considered IRB Chair appointed Designated Reviewers.

4 RESPONSIBILITIES

4.1 The IRB Chair and IRB Office staff members carry out these procedures.

4.2 The IRB Office staff is responsible for determining specific expertise needed and assigning submissions to Experienced IRB Members who can conduct Non-Committee Reviews.

5 PROCEDURE

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

5.2 Update the “DATABASE: IRB Roster (HRP-601)” to indicate that the IRB member is a Designated Reviewer.

5.3 Review list of IRB members designated to conduct Non-Committee Reviews in the “Assign Designated Reviewer” activity.

5.4 Use the “Update Eligible Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)

7 REFERENCES

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).