1. PURPOSE

1.1. This procedure establishes the process for a member of the HRPP 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 HRPP 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. HRPP maintains official IRB rosters for the OHRP/FDA Registration. IRB rosters are also maintained in eIRB+ in the **2.306 (HRP-601) -DATABASE - IRB Committee Member Profile (in eIRB+).**

4. RESPONSIBILITIES

4.1. IRB staff members carry out these procedures.

5. PROCEDURE

5.1. Confirm with the HRPP Director which Experienced IRB member(s) may be designated to conduct Non- Committee Reviews.

5.2. Update the **2.306 (HRP-601) -DATABASE - IRB Committee Member Profile (in eIRB+)** 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.

6. MATERIALS

6.1. 2.306 (HRP-601) – DATABASE – IRB Committee Member Profile (in eIRB+).

7. REFERENCES

7.1. 21 CFR §56.110(b).

7.2. 45 CFR §46.110(b).