1. PURPOSE

1.1. This procedure establishes the process to designate or remove <Experienced IRB Member> from the list of IRB members who can conduct <Non-Committee Review>.

1.2. This procedure begins when [IRB Executive Chair] considers adding or removing a <Designated Reviewer>.

1.3. This procedure ends when the [IRB Executive Chair] notifies HRPP staff of a new <Designated Reviewer> or the removal of a <Designated Reviewer>.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. The [IRB Executive Chair] carries out these procedures.

4. PROCEDURE

4.1. To add a <Designated Reviewer>

4.1.1. Review the IRB roster and ensure that the proposed individual is an IRB member.

4.1.2. Verify that the IRB member is an <Experienced IRB Member>.

4.2. To remove a <Designated Reviewer> no criteria need be followed.

4.3. Notify the HRPP staff member managing the IRB roster of the decision to add or remove an IRB member and have that HRPP staff member update the IRB roster.

4.4. Notify the individual of the decision.

5. REFERENCES

5.1. 21 CFR §56.110

5.2. 45 CFR §46.110