

SOP: DESIGNATED REVIEWERS

Document No.:	Edition No.:	Effective Date:	Page:
CM-102	001	1 May 2015	Page 1 of 1

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