

## SOP: Designated Reviewers

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### 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