1. PURPOSE
   1. This policy establishes the qualifications to be eligible to be designated as an IRB member who may conduct Non-Committee Reviews (“Designated Reviewer).
2. POLICY
   1. Prior to appointment as a Designated Reviewer, new IRB members must have completed and documented the following:
      1. Successful completion of all required CITI training
      2. Successful completion of formal IRB reviewer training (from either internal or industry source such as PRIM&R’s EROC course)
      3. Demonstrated ability to conduct consistently accurate non-committee reviews performed under the direct supervision of a qualified mentor.

2.2 Exemptions may be granted based on having met one or more of the following criteria:

2.2.1. Prior direct or indirect experience working in an IRB greater than 1 year.

2.2.2. Advanced regulatory knowledge such as related to IRB or HRPP administration, or human subject research protections.

2.2.3. Current IRB members who have demonstrated ability to conduct consistently accurate non-committee reviews without direct supervision of a qualified mentor and have met the training requirements named above.

1. REFERENCES
   1. None