
Study Team
Training and Qualifications

1. Training standards:

- The Reviewing IRB sets minimum training standards. Relying Institutions may establish additional requirements but may not eliminate any requirements.
- Any additional institutional requirements should be met before the study is initiated at the Relying Institution. The Reviewing IRB's approval is issued once the Relying Institutions confirms that the minimum training requirements have been met.
- The minimum training requirements for key personnel or involved study members (as per NIH GCP policy) consist of: CITI training, NIH HSP Training or GCP (for clinical trials only).

2. Qualification of the study team:

- The qualifications of the PI and study personnel are determined by the Relying Institution.
- The Relying Institution confirms to the Reviewing IRB that study personnel qualifications have been met prior to IRB approval.

3. Target return time for review of IRB documents:

- 5-7 days

4. Significant Modifications:

a. Pre- approval – N/A

b. Post approval

PI initiated changes lead to modification submission to the Reviewing IRB. Other study team members' changes are reviewed and approved by the Relying Institution.