CRSO: IN THE KNOW

Qualifications and Training Documentation
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Lack of study team member qualifications and training documentation are the most common findings discovered in SOM clinical studies that are audited/reviewed by UNC's Clinical Trials Quality Assurance (CTQA) program. In fact, incomplete and/or inaccurate qualifications and documentation of training were identified in 80% of the reviews conducted over the past 5 years. Take a moment to consider how you can ensure you are prepared and meeting the requirements.

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Investigators are responsible for ensuring that all research activities are conducted by personnel qualified by education, training, and experience to perform delegated study-related duties and must maintain adequate documentation of those qualifications. With the adage 'if it isn't documented, it didn't happen,' the documentation of training is arguably as important as the training itself.

Consider these tips to ensure current and complete qualifications and training records:

1. Define standards for documentation of qualifications and training in an SOP or other process document. Qualifications and training documentation is required for all study personnel, which may include personnel not employed by UNC SOM, throughout the life of the study.
2. Delegate responsibility for documentation to team members who are adequately trained in good documentation practices.
3. Obtain and file qualifications and training documents in the in the regulatory blinder/trial master file:
   - **Up-to-date curriculum vitae (CV)** for all investigators.
   - **Signed FDA 1572s or investigator statements** for studies conducted under and IND or IDE.
   - **Licenses and certifications**, as applicable.
   - **Financial disclosure statements**
   - **Certificates of completion** for more formal training such as CITI Human Subjects Protection (HSP), CITI Good Clinical Practice (GCP), SOM or UNC Health HIPAA, Responsible Conduct of Research (RCR), etc. Some Institutional training certificates can be generated directly from the UNC-CH OHRE Training Certificate Generator.

- **Training log of study-specific training** such as: training delivered at a site initiation visit, training on the consent process, on-going training for modifications to study procedures, training of new staff onboarded after the site initiation visit, training on utilizing electronic data capture systems, training on adverse event (AE) and serious adverse events (SAE) reporting. The UNC Office of Clinical Trials (OCT) provides a training log template for this purpose, but the study team may also develop their own training logs and templates. Training logs generally include: date of training, name of trainer and affiliation (if applicable), title of course or training topic, trainee name and role, trainee signature and date.
- **Sponsor training documentation forms**, as applicable.

4. Routinely review qualifications and training documentation to ensure that it is current and complete.
5. Provide and document ongoing training in essential documentation procedures.
6. Make available all qualifications and training documentation for verification by sponsor and institutional personnel and for inspection by external auditors.

More Information Available

Coming in early 2022: A new version of the SOM Personnel Profile and Training System (PaTS) that will provide additional support for team member training documentation.

If you have questions regarding qualifications and training documentation requirements for clinical research teams, please contact us at crso@med.unc.edu.

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