OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
Clinical Research Compliance

Qualifications and Delegation Documentation Self-Assessment

Self-assessment in clinical research is a proactive, ongoing quality assurance practice aimed at protecting participants and enhancing the overall integrity of the study. This form serves as a guide for investigators and/or designated study team members to evaluate the qualifications and delegation documentation. The self-assessment can be utilized at any timepoint during the study.

Preparation:

- *Review all documentation related to education, training, and experience.*
- *Review all documentation of delegation.*
- *Print or download a copy of the self-assessment tool from the CRCO website. The self-assessment tool is organized as follows:*
  - *Self-Assessment and Study Details*
  - *Records Review (with Parts A and B covering documentation of education, training, and experience, and delegation of study tasks*
  - *Findings*
  - *Attestation*

Completing the self-assessment:

1. ***Self-Assessment and Study Details:*** *Provide details about the assessor and the study.*
2. ***Records Review:*** *Answer the questions in Parts A and B. Explain any 'NA' responses and provide context for any response in the Comments column.*
3. ***Findings:*** *Explain/describe any 'No' responses in Parts A and B.*
4. ***Attestation****: Complete the attestation and obtain signatures.*
5. ***Quality Improvement:*** *Share the findings and engage the study team in developing a Corrective and Preventative (CAPA) or Quality Improvement plan, as applicable.*
6. ***Documentation:*** *File the self-assessments in the research record as documentation of ongoing oversight of the study.*

Utilizing the electronic fillable version:

- *Open the form with Adobe Acrobat Reader from the saved file location (not via a web browser).*
- *Undo Yes/No/NA check marks with **Ctrl+Z** ; once you move to the next field, you can only switch responses (not undo your response).*
- *Add electronic signatures; "verified" signatures are not required.*
- *Save the final version of the form by clicking **File > Save** (or **File > Save As**).*
- *To share the form, click the Adobe Acrobat Reader email button and deselect "add link."*

If you have questions about how to complete the self-assessment, please email the CTQA at ctqa@unc.edu.

Self-Assessment Details		Study Details	
Date of self-assessment		Name of PI	
Name of assessor		Study Title	
Role of assessor		IRB Study Number	
		Name of Reviewing IRB	

Records Review

Part A. Documentation of education, training, and experience

Documentation to look for:

- ***Completion Certificates****: Certificates indicating the completion of training.*
- ***Training Status Reports****: Reports from the central databases showing the current training status of each investigator and study personnel UNC-Chapel Hill Human Research Ethics Training Database.*
- ***Training Logs****: Logs that detail all training activities, including dates and types of training completed (UNC-Chapel Hill Training Log Template).*

Question	Yes	No	NA	Comments
According to ICH E6 GCP 4.1.1, investigators should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial. They must meet all qualifications specified by applicable regulatory requirements and provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, IRB/IEC, and/or regulatory authorities.				
1. Is there a CV, biosketch, or other applicable statement of qualification on file for the investigator?				
License verification portals: Licensee Search | North Carolina Medical Board; License Verification | North Carolina Board of Nursing; North Carolina Board of Pharmacy				
2. If licensure is required, are the licenses for the investigator and other applicable personnel, covering the dates of the research activities, on file?				
A Core CITI Course in the Protection of Human Research Subjects is required by all UNC-Chapel Hill investigators and study personnel engaged in human subjects research. A CITI refresher course in the Protection of Human Research Subjects is required every 3 years. A completion report is sent to each individual by email, but training status is also available in the UNC-Chapel Hill Human Research Ethics Training Database.				
3. Have investigators and study personnel fulfilled the CITI Human Subjects Research Protection and CITI Refresher training requirements, as applicable.				
CITI Good Clinical Practice (GCP) training is required for all UNC-Chapel Hill investigators and study personnel who are involved in the design, conduct, or reporting of clinical trials involving human subjects. A completion report is sent to each individual by email but training status is also available in the UNC-Chapel Hill Human Research Ethics Training Database.				
4. Have investigators and study personnel completed the CITI Good Clinical Practice (GCP) training, if required?				
Federal agencies, including the National Institutes of Health (NIH) and the National Science Foundation (NSF) require that all trainees, fellows, participants, and scholars receiving support through any training, career development award (individual or institutional), research education grant, or dissertation research grant must receive instruction in the Responsible Conduct of Research (RCR). Training may consist of an approved course or completion of the appropriate CITI (Collaborative Institutional Training Initiative) module, or a combination of these. For more information, see the Responsible Conduct of Research page.				
5. Have investigators and study personnel fulfilled the Responsible Conduct of Research training requirements, as applicable?				
Research Conflict of Interest (COI) training is required for all individuals involved in research.				
6. Have investigators and study personnel completed the required COI training?			—	
HIPAA training is required for all UNC-Chapel Hill personnel who "have access to protected health information (PHI) and its transmission." A completion report is sent to each individual by email, but a training completion certificate is also available in the UNC-Chapel Hill EHS Compliance Portal.				

Question	Yes	No	NA	Comments
7. Have investigators and study personnel completed the HIPAA training, if required?				
Completion certificates for EHS safety training are available in the UNC-Chapel Hill UNC-Chapel Hill EHS Compliance Portal.				
8. Have investigators and study personnel completed the EHS Safety training applicable to the study?				
9. Have investigators and study personnel completed study-specific training (site initiation, all versions of the protocol, all versions of the Investigator Brochure, etc.)?				
Human subjects research policies, procedures, and standards are available on UNC-Chapel Hill's Electronic Policy Repository. The Clinical Research Policy Matrices identify core clinical research policies, standards, and procedures that pertains to UNC-Chapel Hill ("University") and UNC Health.				
10. Have investigators and study personnel reviewed University and UNC Health policies, standards, and procedures applicable to the study?				
Part B. Documentation of Delegation of Study-Related Tasks				
Question	Yes	No	NA	Comments
UNC-Chapel Hill requires investigators to maintain a Delegation of Authority (DOA) log. A DOA log template is available on the Clinical Research Compliance Office website.				
11. Is the delegation of study-related tasks documented in a DOA log?				
12. Does the DOA log specify the responsibilities of each study team member?				
13. Does the DOA log include the dates of involvement (i.e., start date and stop date, if applicable)?				
14. Have the listed study personnel acknowledged their understanding of the delegated tasks by signing, initializing, and dating the document, as applicable?				
15. Has the Principal Investigator (PI) signed and dated each delegation entry as it is recorded?				
16. Does the DOA log confirm that study personnel are qualified through education, training, and experience, including licensure, to perform the delegated tasks?				
17. Has the DOA log been updated to reflect any changes in personnel?				

Findings

Describe any responses of 'No' to Questions 1 through 17.

Question Number	Findings
Select Question	
Select Question	
Select Question	
Select Question	

Attestation

I certify to the following statements:

All the information provided in this self-assessment is accurate and complete.

Any findings of noncompliance will be promptly and appropriately documented and addressed. If applicable, noncompliance will be managed by:

- Implementing immediate corrections to protect participants.
- Reporting to the IRB, Sponsor, or other relevant parties.
- Conducting a Root Cause Analysis (RCA) to identify causal factors.
- Developing and implementing a Corrective and Preventative Action (CAPA) plan.

Assessor's Signature		Date	
Principal Investigator's Signature		Date	