UNC SCHOOL OF MEDICINE

Qualifications and Delegation Documentation Self-Assessment

Self-assessment in clinical research is a proactive, ongoing quality assurance approach to promote due diligence by ensuring that the study is conducted as written by the protocol and identifying areas of improvement.

This form serves as a guide for investigators and/or designated study team members to complete a self-assessment of the qualifications and delegation documentation. The self-assessment can be utilized at any timepoint during the study.

Instructions for preparing for the self-assessment:

- *Identify and review all documentation of education, training, and experience.*
- *Identify and review all documentation of delegation.*
- *Print or download a copy of the self-assessment tool from the CRSO website for each participant. The self-assessment tool consists of four sections: General Information, Records Review (Part A. Documentation of education, training, and experience, and Part B. Documentation of Delegation of Study-Related Tasks), Findings, and Attestation.*

Instructions for completing the self-assessment tool:

- *Start by providing information about the team member completing the self-assessment and the study in the General Information section.*
- *Next, respond to the questions in Parts A and B of the Records Review section. Explain any response of NA, and as applicable, provide context for any response in the Comments column.*
- *In the Findings section, describe any response of 'No' to Parts A and B.*
- *Complete the attestation and obtain the requisite signatures.*
- *Share the findings with the study team and collectively develop a quality improvement plan.*
- *File the self-assessments in the research record as documentation of on-going oversight of the study.*

Tips for utilizing the electronic fillable self-assessment tool:

- *Open the downloaded form with Adobe Acrobat Reader directly from the saved file location (do not open via the web browser, as this will not enable all functions).*
- *Tooltips are available for each question by hovering over the respective response field.*
- *Yes/No/NA check marks can be undone by pressing **Cltrl+Z**. Once you move to the next field, you can only switch your response to one of the other options, not undo your response entirely.*
- *Digital signatures may be added via the Adobe Acrobat Reader. Based on the nature of this form, "verified" signatures are not required (e.g., DocuSign).*
- *Remember to save the final version of the form by clicking **File > Save** (or **File > Save As**).*
- *To share the form as an attachment, click the Adobe Acrobat Reader e-mail button in the right-hand corner and deselect add link.*

If you have questions about how to complete the self-assessment process or tool, please email the SOM CRSO at crso@med.unc.edu.

General Information					
Date of Self-Assessment		Name of Assessor		Role	
IRB Study ID		PI Name			
Study Title					

Records Review

Part A. Documentation of education, training, and experience

Training documentation may be in the form of a training completion certificate on file or in a central database (UNC-Chapel Hill Human Research Ethics Training Database, UNC SOM Clinical Research Personnel Profile and Training System (PaTS), etc.), or in a training log (UNC-Chapel Hill OCT Training Log Template).

Question	Yes	No	NA	Comments
"The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies)." ICH E6 GCP (4.1.1)				
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 licenses covering dates of the research activities on file for the investigator and other personnel as applicable?	☐	☐	☐	
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 completed the Core CITI Human Subjects Research Protection training?	☐	☐	☐	
4. Have investigators and study personnel completed the CITI Human Subjects Research Protection Refresher training, 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.				
5. Have investigators and study personnel completed CITI GCP training, as applicable?	☐	☐	☐	
The National Institutes of Health (NIH) requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant receive instruction in responsible conduct of research. 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.				
6. Have investigators and study personnel completed Responsible Conduct of Research Training, as applicable?	☐	☐	☐	
Research Conflict of Interest (COI) training is required for all individuals involved in research.				

7. 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." All School of Medicine employees must complete the HIPAA Privacy and Security Rule Training module. 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.				
8. Have investigators and study personnel completed HIPAA training?	☐	☐	☐	
Completion certificates for EHS safety training are available in the UNC-Chapel Hill UNC-Chapel Hill EHS Compliance Portal.				
9. Have investigators and study personnel completed EHS Safety training applicable to the study?	☐	☐	☐	
10. Have investigators and study personnel completed study-specific training (site initiation, all versions of the protocol, all versions of the Investigator Brochure, etc.), as applicable?	☐	☐	☐	
Human subjects research policies, procedures, and standards are available on UNC-Chapel Hill's policies website. SOM SOPs in effect are located on the SOM Clinical Research Support Office website.				
11. Have investigators and study personnel reviewed polices, SOPs, work instructions 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 Office of Clinical Trials website.				
12. Is delegation of study-related tasks documented in writing (i.e., paper or an approved electronic system) in a DOA log?	☐	☐	☐	
13. Does the DOA log describe the specific responsibilities of each study team member?	☐	☐	☐	
14. Does the DOA log specify dates of involvement (i.e., start date and stop date, if applicable)?	☐	☐	☐	
15. Have listed study personnel indicated understanding of the delegated tasks by signing, initializing, and dating the document, as applicable?	☐	☐	☐	
16. Has the PI initialized/signed and dated each delegation entry as they are recorded?	☐	☐	☐	
17. Does the DOA log identify that study personnel are qualified through education, training, and experience, including licensure, to perform the delegated task (e.g., can refer to an individual's CV on file)?	☐	☐	☐	
18. Has the DOA log been updated with any change in personnel?	☐	☐	☐	

Findings

Describe any responses of 'No' to the questions in Records Review Part A and B and provide the corresponding question number.

Question Number	Findings
1	
1	
1	
1	

Attestation

I certify to the following statements:

☐ All the information provided in this document is accurate and complete.

☐ Any findings of noncompliance will be promptly and appropriately documented and addressed. As applicable, noncompliance will be addressed by implementing immediate corrections to protect participants; initiating reporting to the IRB, Sponsor, or other applicable parties; identifying the causal factors (i.e., Root Cause Analysis); and developing and implementing a Corrective and Preventative Action (CAPA) plan.

Assessor's Signature		Date	
Principal Investigator's Signature		Date	