UNC OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
Clinical Research Compliance

Clinical Trial Regulatory Document 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 tool serves as a guide for investigators and/or designated study team members to evaluate the regulatory documents at any stage in the study and identify areas of improvement. Additionally, the Clinical Trials Quality Assurance (CTQA) team will incorporate self-assessment information into their routine audits.

Important: If any noncompliance is identified in this assessment, please provide comments explaining the finding, and promptly address and correct these issues. For protocol deviations and/or noncompliance that is reportable, adhere to the sponsor's and the reviewing IRB's reporting requirements. Significant or repeated issues of noncompliance should be addressed with a written Corrective and Preventive Action (CAPA) plan.

Preparation:

- *Gather all essential and regulatory documents; reference OHRE SOP 1001 and GCP E6 (R2), Section 8.*
- *Print or save a copy of the self-assessment from the CRCO Website. The self-assessment form is organized as follows:*
  - *General Information*
  - *Records Review*
    - *Part A. Essential Regulatory Documents*
    - *Part B. Institutional Review Board (IRB) Information*
    - *Part C. Reporting Responsibilities*
    - *Part D. Staff Qualifications*
    - *Part E. Financial Information*
  - *Findings*
  - *Attestation*

Completing the self-assessment:

- ***Self-Assessment and Study Details:*** *Provide details about the assessor and the study.*
- ***Records Review:*** *Answer the questions in Parts A through E. Explain any 'NA' responses and provide context for any response in the Comments column.*
- ***Findings:*** *Explain/describe any response of 'No' to Parts A through E.*
- ***Attestation:*** *Complete the attestation and obtain signatures.*
- ***Quality Improvement*** *: Share the findings and engage the study team in developing a Corrective and Preventative (CAPA) or quality improvement plan, as applicable.*
- ***Documentation:*** *File the self-assessments in the research record as documentation of on-going oversight of the study.*
- ***Share with CTQA:*** *As applicable, send a copy of the completed assessment and the CAPA or quality improvement plan to CTQA@unc.edu.*

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, the audit process or developing a CAPA plan, 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. Essential Regulatory Documents

Question	Yes	No	NA	Comments
1. Are all copies of the Form FDA 1572 or equivalent (i.e. Investigator Agreement) signed and filed? • Ensure that the FDA 1572 or the Investigator Agreement is current and includes all sub-investigators and facilities.				
2. Are all Financial Disclosure forms signed and filed? • Ensure that each Sub-Investigator listed on the 1572 have a financial disclosure on file.				
3. Are all copies of protocols and protocol amendments filed?				
4. Are all copies of the protocol signature pages, Investigator Brochures signed and filed? • Ensure that package inserts are also filed. • For device study, file the device information sheet/manual.				
5. Is the Delegation of the Authority (DOA) log signed by all study staff? • Ensure that anyone on the DOA log is added to the IRB application prior to being added to the DOA. • Verify that tasks assigned to staff members on the DOA log are appropriate for their roles and qualifications. • The PI **must** sign off on all study staff delegated on the DOA log.				

Part B. Institutional Review Board (IRB) Information

Question	Yes	No	NA	Comments
1. Is the IRB Roster available and filed?				
2. Are all study staff listed on the IRB approved personnel list?				
3. Are all IRB submissions (e.g., initials/modifications/continuing reviews/promptly reportable information/study closure) filed?				
4. Are all IRB approval letters or acknowledgements filed? If the study is closed, a final report to the IRB is on file.				
5. Is there a copy of all versions of the approved Informed Consent Forms (ICFs) filed? Record all ICF versions in Appendix A., Informed Consent Versions.				

Part C. Reporting Responsibilities

Question	Yes	No	NA	Comments
1. If there are reporting requirements to the Sponsor or funding source (e.g. Serious Adverse Events (SAEs) or deviations), were reports submitted as required?				
2. Have all protocol deviations and noncompliance with IRB policies and procedures, federal regulations, or funding requirements been reported to the IRB per their requirements?				
3. Have all events that require prompt reporting been reported to the IRB?				
4. Have all events that require periodic reporting (e.g. Internal deaths considered unrelated to the study, anticipated (expected) SAEs) been reported at the time of continuing review?				

Part D. Staff Qualifications

Question	Yes	No	NA	Comments
1. Are the CVs and licenses of key personnel (including IDS pharmacists) filed?				
2. Are Training Logs available? • First review: All logs since initial approval • Subsequent review: Updated logs since the previous review.				
3. Have study staff members been trained on the following: • Investigational product (IB/Package Insert/Device Information sheet/Manual)? • All versions of the protocol?				
4. Have study staff members completed Good Clinical Practices (GCP) and Human Subjects Protection (HSP) training?				
5. Have all the required study staff completed the Conflict of Interest (COI) disclosure form? • If COI language is required in the ICF, ensure that it has been added to the ICF.				

Part E. Financial Information

Question	Yes	No	NA	Comments
1. Have all study-related costs and expenses been charged and reconciled for the following? • Study subject compensation has been submitted and completed (i.e., Tango cards, Greenphire cards, parking passes, meal reimbursements, gift cards, lodging reimbursements, etc.). • A Voucher Log is present and complete, and copies made and filed per subject. • Study related visits are entered into the billing coverage analysis (BCA).				
2. Have all Institutional required tax forms and/or Research Subject Excel Template been complete for all subjects? (Any subject receiving $400.00 or more dollars.)				
3. Have all subjects with Medicaid completed the required Medicaid Attestation Form?				

Findings

Describe any responses of 'No' to the questions in the Records Review Parts A, B, C, D, or F and provide the corresponding question number.

Question Number	Findings
Select Question	
Select Question	
Select Question	
Select Question	

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. 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	

Appendix A: Informed Consent Form Versions

For each ICF, including initial and reconsent versions, provide the ICF version and approval date. Explain any discrepancies or relevant context in the Comments section.

ICF Type	ICF Version Date	ICF IRB Approval Date	Comments
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