OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
Clinical Research Compliance

Informed Consent 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 IRB-approved informed consent process at any stage in the study and identify areas of improvement.

Preparation:

- *Refer to OHRE SOPs 1101 and 1201 for informed consent procedures and requirements.*
- *Randomly select **a minimum of five research participants** for the assessment.*
- *Access the IRB application in IRBIS to review the IRB-approved informed consent process (Part D) and Informed Consent Forms (ICFs) relevant to the selected participants.*
- *Print or download a copy of the self-assessment tool from the CRCO website for each participant. The self-assessment form is organized as follows:*
  - *Self-Assessment and Study Details*
  - *Records Review (with parts A-D covering various aspects of the consent process)*
  - *Findings*
  - *Attestation*
  - *Appendix A: Informed Consent Form Details*

Completing the self-assessment:

1. ***Self-Assessment and Study Details:** Provide details about the assessor, the selected participant, and the study.*
2. ***Records Review:** Answer the questions in Parts A through D as applicable. The prompts in the yellow fields will indicate which sections apply to each participant. Explain any 'NA' responses and provide context for any responses in the Comments column.*
3. ***Findings:** Explain/Describe any 'No' responses in Parts A through D, including any findings identified in Appendix A.*
4. ***Attestation:** Complete the attestation section 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	
Participant ID		Name of Reviewing IRB	

Records Review

Part A. Informed Consent Process

Question	Yes	No	NA	Comments
1. Is the person(s) who obtained informed consent for the participant authorized for this task? • The consenter is listed on the personnel list in IRBIS. • The consenter's role matches the role identified for obtaining informed consent in Section D.1.5 of the IRB application. • If the PI has delegated this responsibility, the delegation is documented (e.g., in a delegation of authority log)				
2. Has the person(s) who obtained informed consent completed study-specific informed consent training? (Check training logs)				
3. For studies enrolling adults, was informed consent obtained and documented as described in Section D.1.2. of the IRB-approved application?				
4. Was informed consent obtained before any research activities were conducted with the participant?				
5. Was reconsent obtained in accordance with the IRB-approved reconsent plan? *If reconsent was not required, check 'NA' and indicate so in Comments.*				
6. Were deviations from the IRB-approved consent process for the participant documented, addressed, and reported according to IRB and Sponsor requirements? *If no applicable deviations were identified, check 'NA' and indicate so in Comments.*				
7. Is there comprehensive documentation in the research record confirming that the participant was fully informed and consented voluntarily (i.e., a signed and dated ICF, a consent packet checklist, detailed consent process notes, participant information sheets, audio or video recordings of the consent process, documentation of questions asked and answered, a document distribution log, etc.				

Children				
☐ NA, the study is not enrolling children, or the participant is not a child. Move to Part B.				
Question	Yes	No	NA	Comments
8. Was parental permission obtained as described in Section D.1.1. of the IRB approved application?				
9. When permission is required from both parents, was the permission of both parents obtained, unless one parent is deceased, unknown, incompetent, not reasonably available, or has legal responsibility for the care and custody of the child? *"Not reasonably available" is not intended to mean that a parent is temporarily unavailable. For more information, see HHS OHRP SACHRP Recommendations: Attachment D – Parental Permission in Research Involving Children.*				
10. When permission from both parents is required but only one parent provided consent due to the other being deceased, unknown, incompetent, not reasonably available, or lacking legal responsibility for the child, were these circumstances assessed and documented adequately?				
11. Was minor assent obtained as described in in Section D.1.1. of the IRB approved application?				
Part B. Written Documentation of Informed Consent				
☐ NA, the IRB granted a waiver of written documentation of informed consent that applies to the participant (based on information provided in IRB Application, Section D.2.1). Move to Part C.				
Please summarize the signed and dated Informed Consent Forms (ICFs) found in Appendix A: Informed Consent Forms Details before responding to the questions below.				
Question	Yes	No	NA	Comments
12. Are all the ICFs approved by the IRB?				
13. Was the correct ICF form used? (e.g., an 8-year-old received the assent form for children ages 7-14 rather than the assent for 15–year-olds)?				
14. Was the most up-to-date version of the ICF used (i.e., the latest IRB-approved version)?				
15. Were the consent options (e.g., yes/no checkboxes) on the ICF(s) completed? If there were no options in the ICF, check 'NA' and indicate so in Comments.				
16. Does the signed ICF(s) include all pages?				

Question	Yes	No	NA	Comments
17. Did all parties involved in the consent process (such as the participant and the person obtaining consent) sign the ICF on the same date?				
18. Are the ICF(s) free of any handwritten changes, corrections, or additions (e.g., updated contact information for the PI)?				
19. Is there documentation in the research record (e.g., consent process checklist, notes) that the person providing informed consent received a copy of their signed ICF?				
20. Is a copy of the ICF filed in the participant's medical record if required by the IRB-approved consent process?				
21. Are all signed ICFs stored as described in response to Question A.9.2. in the IRB Application (with or separately from the research data)?				

Part C. Waiver of Written Documentation of Informed Consent

☐ NA, Written documentation of informed consent is required, and Part B is completed. Move to Part D.

Question	Yes	No	NA	Comments
22. Does the consent documentation for the participant reflect the IRB-approved consent process (i.e., a copy of the ICF without signature lines is included in the participant's chart and a narrative note indicates that the ICF was used as a script for the consent discussion)?				
23. If the IRB requires that the person providing consent receives a written statement about the research (Section D.1, D.2.1), was the distribution of this statement recorded in a distribution log, note, or other documentation?				

Part D. Special Consent Circumstances				
Limited English Proficiency				
☐ NA, the person providing informed is proficient in English (i.e., the person understands and communicates effectively in English). Go to the Low Literacy section.				
Question	Yes	No	NA	Comments
24. Was the oral presentation observed by a witness fluent in both English and the language used for the presentation? *The witness must be an impartial third party that is not associated with the clinical investigation (e.g., a patient advocate, clinical staff not involved with the research). The person obtaining informed consent or a person who is otherwise involved in the study may not serve as the witness. When an interpreter is required, the interpreter may serve as the witness.*				
25. Did an interpreter fluent in both English and the language of the oral presentation assist the person obtaining consent? *Unless the person obtaining consent is fluent in English and the language of the oral presentation, an interpreter will be necessary to facilitate the consent discussion.*				
26. Did the interpreter assist with ongoing informed consent (e.g., reconsent for protocol changes)?			—	
27. Was the assistance of an interpreter for initial and ongoing informed consent documented in the research record?				
28. If the IRB requires written documentation of informed consent, was it documented using one of the following IRB-approved methods, as applicable? a. **Long form:** An appropriately translated long form as described in IRB Application Section D.1.4 and in UNC OHRE SOP 1101: Enrollment of persons with limited English-language proficiency (Section 2.7.1). This form must be appropriately translated into a language understandable by the individual and include all the required elements (i.e., the adult consent form, parental permission HIPAA authorization, etc.). b. **Short form** (unexpected): An appropriately translated short form stating that the required elements of informed consent were presented orally, along with a written summary in English of the information presented per UNC OHRE SOP 1101: Documentation of Informed Consent (Section 2.6).				

Question	Yes	No	NA	Comments
29. If an appropriately translated ICF was used, was the form signed by the person providing consent, the person obtaining consent and a witness?				
30. If the short form was used, did the person providing consent sign the short form, did the person obtaining consent sign the summary/long form, and did a witness sign both the long and short forms?				
31. If the short form was used for initial informed consent, was a translated copy of the IRB-approved English version of the long form submitted to the IRB for review and approval?				
32. If the short form was used, was the use of the short form reported to the IRB in the subsequent renewal or administrative review submission (progress report Item F.1)?				
Low Literacy				
☐ NA, the person providing consent can read and write. Go to the section on Diminished Decision-Making/Consent Capacity in Adults.				
Question	**Yes**	**No**	**NA**	**Comments**
33. If low literacy is apparent, was oral consent obtained in accordance with UNC OHRE SOP 1101: Oral Consent (Section 2.7.4)?				
34. Did a witness observe the oral presentation?				
35. If the IRB requires written documentation of informed consent, was informed consent documented using the short form stating that the required elements of informed consent have been presented orally and a written summary of the information presented orally?				
36. If the IRB requires written documentation of informed consent, was the short form signed by the person providing consent, was the summary (or long form) signed by the person obtaining consent, and were both documents signed by a witness?				
37. Was the use of the short form method reported to the IRB in the subsequent renewal or administrative review submission (progress report Item F.1)?				
38. Was the signed copies of the short form and the summary, and an audio file of the contents provided to the person providing consent?				

Diminished Decision-Making/Consent Capacity in Adults				
☐ NA, the participant can exercise independent decision-making to provide informed consent. The participant does not have and is not at risk for diminished decision-making capacity. Go to Findings.				
Question	Yes	No	NA	Comments
39. Has the IRB approved the enrollment of participants with impaired decision-making capacity (Section A.2.E. of the IRB application)?				
40. If it was determined that the participant has diminished decision-making capacity and cannot provide informed consent, was surrogate consent from an LAR obtained and documented according to item D.1.3 of the IRB application and UNC OHRE SOP 1201: Adults with Impaired Decision Making Capacity (Section 2.7)? *Impaired decision-making/decisional impairment must be established by a court finding of incompetence, a physician's determination, or a reasonable determination by the investigator or delegate, confirmed by a physician.*				
41. If surrogate consent was obtained by an LAR, was the LAR's eligibility identified and documented according to item A.2.E.3. of the IRB application and UNC OHRE SOP 1101: Who can act as a Legally Authorized Representative (LAR) for Decisionally Impaired Research Subjects in North Carolina (Section 2.3)? *If the LAR is a court-appointed legal guardian, a person with a health care power of attorney (HCPOA), or a person with a power of attorney, a copy of the relevant court order, HCPOA, or durable power of attorney must be obtained and kept in the research records.*				
42. If assent was feasible, was the participant's assent (affirmative agreement) to participate in the research obtained and documented as described in item D.1.3. of the IRB application? *Absence of an objection or an inability to object should not be considered "assent."*				
☐ NA, the participant has decisional impairment as established by a physician or court and does not require an assessment of decision-making capacity. Move to Findings.				

Question	Yes	No	NA	Comments
43. If diminished decision-making capacity was suspected at enrollment (and not already established by court order or physician determination), was consent capacity assessed and documented in accordance with item A.2.E.2. of the IRB-approved application and UNC OHRE SOP 1101: Determining a Potential Adult Subject's Ability to Consent to Research (Section 2.4)? *If decisional impairment has not already been established by a court finding of incompetence or by a physician's determination of decisional impairment and there are reasons to believe that a prospective participant may not be capable of making voluntary and informed decisions about research participation, the decision-making capacity of the participant must be evaluated. The IRB application/protocol should describe how decisional capacity will be evaluated, by whom it will be evaluated, and the criteria for evaluation. If an assessment tool is used, it should be uploaded with the IRB application.*				
44. Was the person assessing consent capacity authorized for this task? • The assessor is listed on the personnel list in the IRB application, unless an engagement exception applies. • The assessor's role is consistent with the role identified for assessing capacity in item A.2.E.2. of the IRB application. • If the PI has delegated the responsibility of assessing capacity, the delegation is documented (e.g., in the delegation of authority log.				
45. If diminished consent capacity was not established by assessment, was informed consent from the participant obtained? *Some participants may provide informed consent with adaptations, such as extra decision-making time, repetition, simplification, or involving a subject advocate or trusted family members. This should be established as part of the capacity assessment.*				

Question	Yes	No	NA	Comments
46. If the participant's decision-making capacity was expected to change (e.g., diminish, fluctuate, regain) during the study, were these changes managed according to item A.2.E.4 of the IRB application? Provisions may include, but are not limited to: • Including an LAR in the initial consent discussion to facilitate a potential transition to surrogate consent, and memorializing the participant's wishes regarding the research. • Re-evaluating consent capacity at regular intervals. • Obtaining informed consent from the participant if they regain capacity.				
47. If the participant regained consent capacity during the study, was informed consent from obtained from them?				

Findings

Describe any responses of 'No' to Questions 1 through 47.

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	

Appendix A: Informed Consent Forms Details

For each ICF, including initial and reconsent versions, provide the IRB approval and version date and indicate if it is signed and dated by the participant/ Legally Authorized Representative (LAR), parent(s)/guardian, person obtaining consent, and witness. Signatures can be wet or valid electronic signatures as per the IRB application. Explain any discrepancies or provide relevant context in the Comments section.

ICF Type	ICF Version Date	ICF IRB Approval Date	Participant or LAR Signature	Parent or Guardian Signature	Date person signed	Person Obtaining Consent Signature	Date person signed	Witness Signature	Date witness signed	Comments
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		
Select ICF Type			Y ☐ N ☐ NA ☐	Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		Y ☐ N ☐ NA ☐		