



Participant Eligibility 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 eligibility screening process for the study. The self-assessment can be utilized at any timepoint during the study.

Instructions for preparing for the self-assessment:

- Randomly select a minimum of five research participants for the assessment.
- Access the eligibility criteria in the IRB-approved study application and/or study protocol that was in place at the time of enrollment of each participant.
- Identify and review all source documentation used to determine eligibility for each participant (lab results, medical records, questionnaires, data collection tools, etc.).
- Access a copy of the eligibility checklist or other documentation used to verify and document eligibility.
- Print or download a copy of the self-assessment tool from the [CRSO website](#) for each participant. The self-assessment form consists of four sections: General Information, Records Review (Part A. Eligibility Verification and Part B. Eligibility Screening Process), Findings, and Attestation.
- Update Part A of the Records Review section with the study-specific eligibility criteria from the IRB application or protocol.

Instructions for completing the self-assessment tool:

- Start by providing information about the person completing the self-assessment, the study, and the selected participant in the General Information section.
- In Part A of the Records Review section, respond either 'Yes' or 'No' to each inclusion and exclusion criterion to indicate whether the participant is eligible based on available source documentation. Indicate the source document(s) that supports the eligibility determination. The participant is eligible for the study if all responses to the inclusion criteria are 'Yes' or exclusion criteria are 'No.' The eligibility verification result is recorded in Question 1.
- In Part B of the Records Review section, answer Questions 2-8 to assess the eligibility screening process.
- In the Findings section, explain/describe any response of 'No' to questions 1-8.
- 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 **Ctrl+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.

Part B. Eligibility Screening Process

Answer Questions 2-8 about the eligibility screening process. Explain any response of NA, and as applicable, provide context for any response in the Comments column.

Question	Yes	No	NA	Comments
2. Was eligibility confirmed prior to initiating any study procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is there a complete participant eligibility checklist or other documentation on file verifying eligibility of the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. If the eligibility verification was not completed by the PI, was the delegation to a qualified team member appropriately documented in the form of a Delegation of Authority (DOA) Log or other documentation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Are the source documents for each criterion in the participant's research or medical record?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Do all source documents meet ALCOA standards ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. If the participant was ineligible for the study but was enrolled, was the eligibility violation identified and reported to the IRB as a Promptly Reportable Information (PRI) submission?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. If the participant was ineligible for the study (screen-failure), was information about the participant stored and/or disposed of as described in Question B.1.6. of the IRB application?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Findings

Describe any responses of 'No' to Questions 1 through 8 and provide the corresponding question number.

Question Number	Findings

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	