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| **PARTICIPANT ELIGIBLITY SELF-ASSESSMENT TOOL****GENERAL INSTRUCTIONS** – delete this box before using. **NOTE: This form is designed to be a starting point on eligibility criteria review and documentation self-assessment. Update it as necessary to meet the needs of your specific study.** * Decide which participants you will review to assess eligibility criteria and documentation adherence. It’s best practice to review all eligibility for all participants.
* Each participant you review should have their own form. Enter their Study/Participant/Subject ID.
* List all of the inclusion/exclusion criteria on the assessment tool. Add rows as needed to accommodate your study’s criteria. Make sure that you take into account the IRB-approved protocol version that was in place at the time the subject was enrolled.
* Criteria should be assessed so that inclusion criteria are all “yes” and that exclusion criteria are “no”. Study teams should pay careful attention to double-negatives and possible confusing criteria when assessing for “yes” and “no”.
* Check for source data/documents for each of the criteria listed.
* Source documentation should show that each criterion was performed/assessed before the participant started participating in the study activities. Source documentation should also show that each criterion was performed/assessed by someone on the study who is qualified by education, training, experience, etc. to perform the procedures and assessments.
* Ensure that your source documentation meets the ALCOA-C standard: Attributable, Legible, Contemporaneous, Original, Accurate, and Complete.
* Keep these completed Self-assessment forms as documentation of on-going oversight of your monitoring of the conduct of the study.
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| **Date of Eligibility Self-Assessment Review:** \_\_\_\_\_\_\_\_\_\_ | **Name Performing Eligibility Self-Assessment Review:** \_\_\_\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

| **Participant ID:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **Eligibility Criteria** | **Criteria** | **Criteria assessed by a research team member qualified to assess Eligibility** | **Source Documentation Available** | **Source Documentation Meets ALCOA-C\* Standard** |
| *Inclusion Criteria (all should be yes)* |
| [Insert full criterion directly from IRB-approved protocol] | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [Insert full criterion directly from IRB-approved protocol] | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| *Exclusion Criteria (all should be no)* |
| [Insert full criterion directly from IRB-approved protocol] | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [Insert full criterion directly from IRB-approved protocol] | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| *\*ALCOA-C: Attributable (signed and dated), Legible, Contemporaneous, Original, Accurate, Complete* |

| **Notes on identified issues above –** *Review HRPP Policy* [*6.6.3.2*](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.3.2) *and* [*6.6.3.4*](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.3.4) *for Reporting Requirements. Review* [*Reporting Charts and Algorithm*](https://www.bumc.bu.edu/irb/maintaining-irb-approval/monitoring-and-reporting/) *for more info.* *Studies approved by an external IRB should review those policies for all requirements.*  |
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| *Inclusion Criteria all marked as Yes*  | [ ]  Yes[ ]  No, requires explanation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| *Exclusion Criteria all marked as No* | [ ]  Yes[ ]  No, requires explanation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| *Source Documentation Available for All Criteria* | [ ]  Yes[ ]  No, requires explanation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| *Source Documentation Meets ALCOA-C Standard for All Criteria* | [ ]  Yes[ ]  No, requires explanation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| *General Notes* | [ ]  N/A, no general notes\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |