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| **PROTOCOL ADHERENCE SELF-ASSESSMENT TOOL****GENERAL INSTRUCTIONS** – delete this box from the completed form. **NOTE: This form is designed to be a starting point on protocol adherence self-assessment. Update it as necessary for your specific study.** * Decide which participants you will review to assess protocol adherence.
* Depending on the length of an individual’s study participation and other factors, including risk, complexity of study design, etc., it might make sense to review participants early and often in their enrollment. For other studies, it might make sense to review adherence when a participant has completed data collection. For example, if a study has a several year long term follow-up period but active engagement in the study is completed within 6 months, reviewing up to that 6 Month date and then again when long term follow-up is completed could work. Another example could be that protocol adherence is reviewed midway through the intervention period, again when the intervention is complete, and one final time when data collection is complete.
* The review table below has space to review 3 subjects. Fill in the correct names for study visit and/or interaction in the left column. Then, under the visit names in the left column, fill in the details of the various procedures that that take place for each study visit. Add more rows as necessary depending on the number of procedures for each study visit/interaction.
* Use a new form if you are reviewing more than 3 participants at one time.
* Make sure you are using the IRB-approved protocol version that was in place at the time of the study visit or interaction as the “standard” to which you are conducting your self-assessment. Be careful as you may have new or different procedures if you have had protocol amendments.
* Review the study documentation for each visit/interaction carefully to ensure that there is sufficient documentation to show what happened at each study visit and who on the study team performed the procedures and collected the data.
* 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 Self-Assessment Review:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Name Performing Self-Assessment Review:** \_\_\_\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Protocol Adherence Self-Assessment Review** |
| **Visit + Procedure/Assessment** | **Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **[Visit Name or Number]** | Date | Done per protocol | Documented per protocol and ALCOA-C | Date | Done per protocol | Documented per protocol and ALCOA-C | Date | Done per protocol | Documented per protocol and ALCOA-C |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| **[Visit Name or Number]** |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| **[Visit Name or Number]** |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| **[Visit Name or Number]** |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |
| [list procedure or assessment] |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No |

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| **Participant ID** | **Notes on identified issues above – Any “No” requires further documentation.** *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.*  |
| [ ]  ***No identified issues on any participant reviewed as listed above. Below sections in this table may remain blank.***  |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |