**Instructions**

* Decide how many participant records you will review to assess protocol adherence. If you are doing these self-assessments on-going, it is a good idea to define a process where you decide what percentage of participant records you will evaluate since your last assessment. For example, if you are enrolling fewer than 10 participants, your process might be that you will assess records from all participants enrolled since the last assessment. Alternatively, if your study is recruiting a large number of participants, you might decide to review only a certain percentage of participant records, such as 10%. Whatever you decide, if you do uncover any problems during your assessment, you might at that point widen your scope of review. Any deviation from the protocol should be reported to the IRB as appropriate.
* Complete the heading information on the form.
* List all inclusion/exclusion criteria on the assessment tool. Add rows as needed to accommodate your study’s criteria.
* Your documentation should show that each criterion was performed/assessed after obtaining informed consent and before the participant started participating in the study activities.
* Your source documentation should show when each criterion was performed/assessed and 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.
* It is important to keep these completed forms as documentation of on-going oversight of the study.

|  |  |
| --- | --- |
| **Study Title:** |  |
| **IRB Protocol #:** |  |
| **Staff Member Completing Self-Assessment:** |  |
| **Self-Assessment Date:** |  |

|  |  |
| --- | --- |
| **Items to Assess** | **Participants** |
| *001* | *002* | *003* | *004* | *005* | *006* | *007* | *008* |
| **Inclusion Criteria** |
| [list here] | *Y* |  |  |  |  |  |  |  |
| [list here] | *Y* |  |  |  |  |  |  |  |
| **Exclusion Criteria** |
| [list here] | *N* |  |  |  |  |  |  |  |
| [list here] | *N* |  |  |  |  |  |  |  |
| **Assessment** |
| Met all inclusion and no exclusion? (If N, describe in Notes) | *Y* |  |  |  |  |  |  |  |
| Source doc for each criterion is in participant’s file? (If N, describe in Notes) | *Y* |  |  |  |  |  |  |  |

**Notes:**