**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.
* Complete the list of research procedures that take place for each visit. Add rows as needed to accommodate your study protocol.
* For each participant file reviewed, note the participant ID # at the top of the appropriate column.
* Check to make sure that each of the procedures was done according to the protocol.
* In the “Documented & reviewed per protocol” column, you should note whether your source documentation shows that each procedure was performed/assessed and that each procedure was performed/assessed by someone on the study who is qualified by education, training, experience, etc. to perform the procedures and assessments. For example, if your protocol requires certain blood tests be in a specified time frame, your source documentation (i.e., your lab report) should show:
  + that the blood was drawn per the protocol specifications;
  + that the lab results were reviewed by someone who is qualified to review the results; and
  + who reviewed the results, when that person reviewed them, and that the review happened in a timely manner.
* 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:** |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Participant ID #** | *001* | | *002* | | *003* | | *004* | |
| **Study Procedures to Assess** | **Done per protocol?** | **Documented and reviewed per protocol?** | **Done per protocol?** | **Documented and reviewed per protocol?** | **Done per protocol?** | **Documented and reviewed per protocol?** | **Done per protocol?** | **Documented and reviewed per protocol?** |
| **Screening Visit** | | | | | | | | |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| **Baseline Visit** | | | | | | | | |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| **Month X Visit** | | | | | | | | |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| **Month X Visit** | | | | | | | | |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |

**Notes:**