**POST-IRB APPROVAL**

**PROTOCOL ADHERENCE SELF-ASSESSMENT**

**Purpose:** This form is for researchers to use to conduct a self-assessment of their IRB approved study to ensure that the regulatory and institutional requirements for protocol adherence/reporting are met. Please keep completed self-assessments with your study related records as documentation of on-going oversight of the study.

If you should have any questions or concerns regarding adhering to the IRB approved protocol, contact the Office of Research Compliance Review at [orcr-deptemail@umich.edu](mailto:orcr-deptemail@umich.edu).

Protocol deviations should be reported to the IRB as described in: [IRBMED ORIO Guidance](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting/other-reportable-information-or-occurrence-orio)

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| --- | --- |
| **STUDY INFORMATION** | |
| HUM # |  |
| Study Title |  |
| PI Name |  |
| Date Self-Assessment Completed |  |
| Person Completing Self-Assessment |  |

|  |  |  |  |  |  |  |  |  |
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| **ASSESSMENT OF STUDY PROCEDURES**  ***Tailor this form to match study procedures*** | | | | | | | | |
| Study Procedures  to Assess | Subject #1 | | Subject # 2 | | Subject # 3 | | Subject # 4 | |
| Documented per protocol?  Y/N | Within window?  Y/N | Documented per protocol?  Y/N | Within window?  Y/N | Documented per protocol?  Y/N | Within window?  Y/N | Documented per protocol?  Y/N | Within window?  Y/N |
| If no, describe in table below | If no, describe in table below | If no, describe in table below | If no, describe in table below | If no, describe in table below | If no, describe in table below | If no, describe in table below | If no, describe in table below |
| **Screening visit** |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| **Baseline visit** |  |  |  |  |  |  |  |  |
| - |  |  |  |  |  |  |  |  |
| - |  |  |  |  |  |  |  |  |
| **Month X Visit** |  |  |  |  |  |  |  |  |
| - |  |  |  |  |  |  |  |  |
| - |  |  |  |  |  |  |  |  |
| **Month X Visit** |  |  |  |  |  |  |  |  |
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| **Month X Visit** |  |  |  |  |  |  |  |  |
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**OBSERVATIONS AND FOLLOW-UP (describe any concerns noted above)**

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| **Subject ID** | **Observation** | **Follow-up actions** | **Date of IRB reporting** | **IRB response** | **Addt’l Notification**  ***(FDA, S-I, or Sponsor)*** |
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