**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.

Protocol deviations should be reported to the IRB as described in: [IRB-HSBS ORIO Guidance](https://research-compliance.umich.edu/incident-reporing-aeorio), [IRBMED ORIO Guidance](https://az.research.umich.edu/medschool/guidance/other-reportable-information-or-occurrence-orio)

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| **STUDY INFORMATION** |
| HUM # | Click or tap here to enter text. |
| Study Title | Click or tap here to enter text. |
| PI Name | Click or tap here to enter text. |
| Date Self-Assessment Completed | Click or tap here to enter text. |
| Person Completing Self-Assessment | Click or tap here to enter text. |

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| **ASSESSMENT OF STUDY PROCEDURES*****Tailor this form to match study procedures*** |
| Study Proceduresto Assess | Participant #1 | Participant # 2 | Participant # 3 | Participant # 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 (window)** |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| [list procedure here] |  |  |  |  |  |  |  |  |
| **Baseline visit (window)** |  |  |  |  |  |  |  |  |
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| **Visit X (window)** |  |  |  |  |  |  |  |  |
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| **Visit X** |  |  |  |  |  |  |  |  |
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|  **Visit X** |  |  |  |  |  |  |  |  |
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**OBSERVATIONS AND FOLLOW-UP (describe any concerns noted above)**

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| **Participant ID** | **Observation** | **Follow-up actions** | **Date and Submission # of IRB reporting** | **Date FDA / sponsor notified, if applicable** |
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