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# Protocol Deviation Tracking Log

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date of Deviation | Date of Discovery | Description | Category  (see below) | Did/will the event: | | | PI Initials | Date of PI Initials | Date Reported to IRB |
| Place subject(s) at greater risk of harm? (Y/N)  (including physical, psychological, economic, or social harm) | Cause actual harm to subject(s) or others?  (Y/N) | Preclude subject’s data from being included in analysis of study outcomes?  (Y/N) |
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**Category:**

1. Treatment/Intervention Error (i.e., subject received wrong treatment, incorrect dose/device, study treatment/intervention not administered per protocol)
2. Enrollment Deviation (i.e., enrollment of a subject that did not meet eligibility criteria)
3. Procedural Deviation (i.e., related to required assessments/procedures or timepoints, or institutional requirements such as OnCore data entry)
4. Privacy/Confidentiality Error (i.e., disclosure or release of identifiable subject data outside of the approved parties)
5. Other (describe)