*HEADER:* PI NAME, Protocol or IRB Number, Protocol Short Title

**Subject Initials Subject ID# Page of**

**Subject Deviation/Unanticipated Problem Tracking Log**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # | Start Date | End Date | Description | Category  (see below) | **Does the deviation/UP have the potential to:** | | | Reported to IRB | PI Initials | Date of PI Initials |
| Impact Subject Safety\* | Affect Data Integrity\* | Affect Subject’s Willingness to Participate?\* |
|  |  |  |  |  | Yes  No  Not Applicable | Yes  No  Not Applicable | Yes  No  Not Applicable | \_\_ / \_\_ / \_\_\_\_  Not Applicable |  |  |
|  |  |  |  |  | Yes  No  Not Applicable | Yes  No  Not Applicable | Yes  No  Not Applicable | \_\_ / \_\_ / \_\_\_\_  Not Applicable |  |  |
|  |  |  |  |  | Yes  No  Not Applicable | Yes  No  Not Applicable | Yes  No  Not Applicable | \_\_ / \_\_ / \_\_\_\_  Not Applicable |  |  |
|  |  |  |  |  | Yes  No  Not Applicable | Yes  No  Not Applicable | Yes  No  Not Applicable | \_\_ / \_\_ / \_\_\_\_  Not Applicable |  |  |
|  |  |  |  |  | Yes  No  Not Applicable | Yes  No  Not Applicable | Yes  No  Not Applicable | \_\_ / \_\_ / \_\_\_\_  Not Applicable |  |  |

***\*If one or more is answered yes for any event, it must be reported to the IRB promptly (14 business days from notification of or becoming aware of the event). Please refer to the HSIRB Reportable Event guidance for additional information (<https://kb.wisc.edu/hsirbs/18324>).***

**OnCore Entry Instructions:** The Subject Deviation/UP form is not a separate eCRF in OnCore, but rather a standard part of the OnCore > Subject Console. To enter the data, click the ‘Deviations’ menu item on the left side menu bar within the Subject Console. Click ‘New’ and enter data obtained on the paper version of the form. Refer to <https://kb.wisc.edu/ictr/page.php?id=64625> for the instructions (requires NetID to access).

**Category:**

1. Consent Deviation
2. Drug/Device Administration/Accountability
3. Enrollment Deviation
4. Procedural Deviation
5. Loss of Confidentiality
6. Other (describe)