**Protocol Deviations and Violations Tracking Log**

**Protocol Number:**

**Title:**

**Principal Investigator:**

Use this log to document protocol deviations and violations and to track reports to the IRB. Protocol deviations become protocol *violations* when they adversely affect, or have the *potential* to adversely affect, the rights, safety, and welfare of subjects or the integrity of the data. Protocol violations may also meet noncompliance criteria. Some deviations/violations may also meet the criteria for **u**nanticipated **p**roblems **i**nvolving **r**isks to **s**ubjects or **o**thers (UPIRSOs). UPIRSOs and protocol *violations* (possible noncompliance) require **prompt** reporting to the IRB (deviations are reported to the IRB at continuing review). Refer to the UT Southwestern Human Research Protection Program’s (HRPP) Reportable Event policy for definitions, examples, and reporting requirements of UPIRSOs, protocol deviations, protocol violations, noncompliance, and other research-related incidents at <http://www.utsouthwestern.edu/research/research-administration/irb/study/reportable.html>.

|  |  |  |
| --- | --- | --- |
| **Deviations/Violations** | **Answer these questions in order (1 🡪 2)** | **Initials &****Date** |
| **Ref.****No.** | **Subject****ID** | **Date Deviation/Violation****Occurred** | **Date Deviation/Violation Identified****by PI** | **Brief Deviation/Violation Description** | **Question 1**Was this deviation/violation necessary to avoid immediate apparent harm ***OR*** unexpected, related, & suggestive of greater risk of harm to subject(s) or others?If “Yes” – **Promptly** report it to the IRB as a **UPIRSO** (via the eIRB reportable event (RE) form) and include it on the Event/UPIRSO tracking log | **Question 2**Did this deviation/violation adversely affect or have the potential to adversely affect the:1. rights, safety, or welfare of the subject(s)

 ***OR***1. integrity of the data?

If “Yes” to either (a) or (b) above – **Promptly** report it to the IRB as a **Protocol Violation (possible noncompliance)** via the eIRB RE form | **Initials & date of person****completing****log** |
| **1** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **2** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **3** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **4** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **5** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **6** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **7** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **8** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **9** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **10** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **11** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **12** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **13** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **14** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |
| **15** |       |       |       |       | [ ]  **No** (go to question 2)[ ]  **Yes – UPIRSO promptly reported to the IRB on:**        | [ ]  **No** [ ]  **Yes – Protocol violation/possible noncompliance promptly reported to the IRB on:**        |  |