Event Tracking Log

## **Instructions**

Use this log to document events and track reports to the IRB. Some, but not all, events require prompt reporting to the IRB as noted in the table below. Use the codes in the table to complete the Event Tracking Log. Add additional rows as necessary. Study teams are responsible for maintaining one continuous log within the overall regulatory binder that reflects all reportable events that have occurred in the study. **Please do not enter any subject identifiable data in the log.**

|  |  |  |
| --- | --- | --- |
| Event Type | Event Description | Method of IRB Reporting |
| NC – Non-Compliance | A failure to comply with applicable laws, regulations, institutional policies pertaining to the protection of human subjects or with the requirements or determinations of an IRB; and/or an accidental or unintentional departure from the IRB-approved procedures without prior sponsor or IRB approval (i.e., protocol deviation); that, in the investigator's judgment, **DOES NOT** adversely affect the risk/benefit ratio of the study; the rights, safety, or welfare of the participants or others; or the integrity of the study/data. Examples of NC and protocol deviations are found [here](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2660_Examples%20of%20non-compliance%20&%20serious%20non-compliance_v1.1_5.30.20.pdf). | **CR/SU** - Submit consolidated log as an attachment when submitting next **Continuing Review Application (or Status Update Report)**. Consolidated log should contain only those events occurring during the applicable approval period and not previously submitted to the IRB**.** In Kuali Research, use the *Renew* function to submit CR/SUs. |
| SNC – Serious Non-Compliance | A failure to comply with applicable laws, regulations, institutional policies pertaining to the protection of human subjects or with the requirements or determinations of an IRB; and/or an accidental or unintentional departure from the IRB-approved procedures without prior sponsor or IRB approval (i.e., protocol deviation); that, in the investigator's judgment, **DOES** adversely affect the risk/benefit ratio of the study; the rights, safety, or welfare of the participants or others; or the integrity of the study/data. Examples of NC and protocol deviations are found [here](https://www.lsuhsc.edu/administration/academic/ors/docs/HRP-2660_Examples%20of%20non-compliance%20&%20serious%20non-compliance_v1.1_5.30.20.pdf). | **PRNI** – **Reportable New Information** requiring **prompt** reporting. Submit within **3 or 5 business days** of becoming aware of the event. In Kuali Research, use the *Reportable Events* function to submit PRNIs.  **MOD** – Modification application (if applicable); In Kuali Research, use the *Amend* function to submit MODs. |
| ED - Emergency Deviation | Emergency deviations involve a planned or unplanned departure from the approved protocol to avoid an immediate hazard to the participant. Emergency deviations may occur without time for prospective IRB review and approval. | **PRNI** |
| UP – Unanticipated Problem | Any incident, experience, or outcome that (1) is unexpected (in terms of nature, severity, or frequency), (2) is related or possibly related to participation in the research, **AND** (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. | **PRNI** and **MOD** |
| NUP - Event that is NOT an UP | Any incident, experience, or outcome (including non-adverse, adverse and serious adverse events) that **DOES NOT** qualify as an UP. | **CR/SU** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1** |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |
| **7** |  |  |  |  |  |  |  |
| **8** |  |  |  |  |  |  |  |
| **9** |  |  |  |  |  |  |  |
| **10** |  |  |  |  |  |  |  |
| **11** |  |  |  |  |  |  |  |
| **12** |  |  |  |  |  |  |  |
| **13** |  |  |  |  |  |  |  |
| **14** |  |  |  |  |  |  |  |
| **15** |  |  |  |  |  |  |  |
| **16** |  |  |  |  |  |  |  |
| **17** |  |  |  |  |  |  |  |
| **18** |  |  |  |  |  |  |  |
| **19** |  |  |  |  |  |  |  |
| **20** |  |  |  |  |  |  |  |
| **21** |  |  |  |  |  |  |  |
| **22** |  |  |  |  |  |  |  |
| **23** |  |  |  |  |  |  |  |
| **24** |  |  |  |  |  |  |  |
| **25** |  |  |  |  |  |  |  |
| **26** |  |  |  |  |  |  |  |