Deviation Tracking Log

Protocol Number: STU 102015-999
Title: A Phase I Study of . . .
Principal Investigator: Jane Doe, M.D.

Use this log to document deviations and track reports to the IRB. Types of deviations include exceptions, emergency deviations, major deviations, and minor deviations. Some deviations may also meet the criteria for unanticipated problems involving risks to subjects or others (UPIRSOs). Refer to the HRPP’s Reportable Event policy at http://www.utsouthwestern.edu/research/research-administration/irb/assets/policies-combined.pdf for definitions and reporting requirements. NOTE: Exceptions require prior IRB approval before implementing; otherwise, this constitutes a major deviation. Emergency deviations, major deviations, and UPIRSOs require prompt reporting to the IRB as a reportable event (RE). Minor deviations are reported to the IRB at continuing review (CR).

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Subject ID</th>
<th>Date of Deviation</th>
<th>Date of PI Awareness</th>
<th>Brief Deviation Description</th>
<th>Type of Deviation (check all that apply)</th>
<th>Method &amp; Date of IRB Reporting</th>
<th>Initials &amp; date of person completing log</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1234</td>
<td>10/1/16</td>
<td>10/5/16</td>
<td>Subject missed week 12 visit by 4 days due to her vacation</td>
<td>Exception (get IRB approval before implementing)</td>
<td>RE CR Other (specify)</td>
<td>KB 10/5/16 Reported at next CR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Event is outside PI’s control and does not majorly affect subject safety or data integrity.</td>
<td>Emergency deviation</td>
<td>Date reported: 9/15/17</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>5678</td>
<td>10/3/16</td>
<td>10/3/16</td>
<td>Subject administered incorrect study drug</td>
<td>Exception (get IRB approval before implementing)</td>
<td>RE CR Other (specify)</td>
<td>KB 10/5/16</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Event is both a major deviation and UPIRSO. Include subject #5678 on both UPIRSO and deviation logs.</td>
<td>Emergency deviation</td>
<td>Date reported: 10/4/16</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>9999</td>
<td>10/4/16</td>
<td>10/7/16</td>
<td>Enrolled subject in study despite being outside of protocol-specified hematocrit range (violation of eligibility criteria)</td>
<td>Exception (get IRB approval before implementing)</td>
<td>RE CR Other (specify)</td>
<td>KB 11/1/16 Noncompliance since beyond 5-day reporting requirement</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PI should have requested an exception &amp; gotten IRB approval before enrolling subject. Now event is a major deviation.</td>
<td>Emergency deviation</td>
<td>Date reported: 10/31/16</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Exception (get IRB approval before implementing)</td>
<td>RE CR Other (specify)</td>
<td>Date reported: <em><strong>EXAMPLE</strong></em></td>
</tr>
</tbody>
</table>

**NOTE:**
- Exceptions require prior IRB approval before implementing; otherwise, this constitutes a major deviation.
- Emergency deviations, major deviations, and UPIRSOs require prompt reporting to the IRB as a reportable event (RE).
- Minor deviations are reported to the IRB at continuing review (CR).
Events (Adverse and Non-Adverse) and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) Tracking Log

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Subject ID</th>
<th>Dates &amp; Report Type</th>
<th>Event</th>
<th>UPIRSO Criteria</th>
<th>Changes or Corrective Actions Made?</th>
<th>Reportable Event?</th>
<th>Initials &amp; Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5678</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>KB 10/5/16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Use shaded space below as needed for follow-up info.</td>
<td>Subject administered incorrect study drug</td>
<td>If ALL three (3) questions below are answered YES, promptly report the UPIRSO to the IRB.</td>
<td>If all 3 questions to the left are answered “Yes,” the event is likely a UPIRSO, so submit RE to IRB.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9999</td>
<td>Initial; date event occurred: 10/15/16 Date of PI awareness: 10/20/16</td>
<td>Rash 2 days after last study drug administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-up Date(s): 11/16/16</td>
<td>Rash is not identified as risk in IB, protocol, or ICD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>8675</td>
<td>Initial; date event occurred: 12/16/16 Date of PI awareness: 12/19/16</td>
<td>Grade 3 anemia</td>
<td>Listed as risk in IB, protocol, and ICD</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) Form**

<table>
<thead>
<tr>
<th>Protocol No./Title:</th>
<th>STU 102015-999 / A Phase I Study of...</th>
<th>PI Name:</th>
<th>Jane Doe, M.D.</th>
<th>Subject ID:</th>
<th>5678</th>
</tr>
</thead>
</table>

| Reference No. from Event/UPIRSO Tracking Log: | 1 |
| Date of Event: | 10/3/2016 |
| Date of PI Awareness: | 10/3/2016 |
| Date Event Reported to IRB: | 10/4/2016 |
| Follow-up date(s) (if any): | Click here to enter a date. |

1. Was event **unexpected** in terms of nature, severity, or frequency? **Yes**
2. Was event **probably or definitely related** to participation in the research? **Yes**
3. Does event suggest that the research places subjects or others at a **greater risk** of harm than was previously known or recognized? **Yes**

**NOTE:** If the answers to questions 1-3 above are **ALL “YES,”** promptly submit reportable event to IRB.

4. Briefly describe the event (attach additional pages or supplementary information as necessary and describe harm that occurred or potential harm that could have occurred to subject(s) or others, whether the incident is resolved, whether the subject(s) remains on study, etc.):

   **Subject was mistakenly administered the incorrect IV study medication due to pharmacy dispensing error. PI was alerted immediately after infusion. Subject was informed and medically monitored for 6 hours following infusion. Potential risks include [SPECIFY], but no AEs were reported or witnessed. Incident resolved. Subject remains on study.**

5. What actions were taken as a result of the UPIRSO? (Check all that apply)

   - [ ] No action
   - [X] Additional training (SPECIFY who, what, & when below)
   - [ ] Revision/addition of study checklists, flow charts, etc.
   - [X] Implementation of new processes or procedures
   - [ ] Protocol change without prior IRB approval to eliminate apparent immediate hazards to subjects or others (i.e., emergency deviation)
   - [ ] Modification of IB, protocol, informed consent, or informed consent process
   - [ ] Implementation of additional procedures for monitoring subjects
   - [ ] Notification of currently enrolled subjects
   - [ ] Notification of previously enrolled subjects
   - [ ] Suspension of the research
   - [ ] Termination of the research
   - [X] Other (specify below):

   _The IV bottles for this study were stored next to IV bottles for another study, which had very similar labeling. The two study drugs have been moved to separate refrigerators. New procedures such as [SPECIFY] have been implemented to prevent recurrence. All study pharmacists were retrained on study drug administration by the PI on 10/4/16. Ongoing training/education to occur every Friday throughout the study._

**Statement of Principal Investigator:** _I have personally reviewed this report and agree with the above assessment._

**PI Signature:** _Jane Doe, M.D._ **Date:** _10/5/2016_
1. Deviation Description:
   Subject was mistakenly administered the incorrect IV study medication due to pharmacy dispensing error.

2. Type of Deviation:
   - ☑ Emergency Deviation – Submit RE
   - ☑ Major Deviation – Submit RE
   - ☐ Minor Deviation – Report at CR

3. Does deviation also meet UPIRSO criteria?
   - ☑ Yes – Submit RE

4. Did deviation result in an AE?
   - ☑ No
   - ☐ Yes (describe):

5. Did subject continue in study?
   - ☑ Yes
   - ☐ No (explain):

6. Method of IRB Reporting:
   - ☑ RE (Reportable Event)
   - ☐ CR (Continuing Review)
   - ☐ Other (specify):

7. Actions taken to resolve or as a result of this deviation (if any):
   PI was alerted immediately after infusion. Subject was informed and medically monitored for 6 hours following infusion. The IV bottles for this study were stored next to IV bottles for another study, which had very similar labeling. The two study drugs have been moved to separate refrigerators. New procedures such as [SPECIFY] have been implemented to prevent recurrence. All study pharmacists were retrained on study drug administration by the PI on 10/4/16. Ongoing training/education to occur every Friday throughout the study.

8. Comments:

Statement of Principal Investigator: I have personally reviewed this report and agree with the above assessment.

PI Signature: Jane Doe, M.D. Date: 10/5/2016