Deviations Tracking Log

Protocol Number: *STU 102015-999*

Title: *A Phase I Study of . . .*

Principal Investigator: *Jane Doe, M.D.*

EXAMPLE

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 **u**nanticipated **p**roblems **i**nvolving **r**isks to **s**ubjects or **o**thers (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).

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

Events (Adverse and Non-Adverse) and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) Tracking Log[1]

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

EXAMPLE

Ref. No.	Subject ID	Dates & Report Type	Event	UPIRSO Criteria			Changes or Corrective Actions Made?	Reportable Event?	Initials & Date
		Report Type (initial or follow-up to a previous report) Use shaded space below as needed for follow-up info.	Brief Description of Event, Problem, or Outcome	If ALL three (3) questions below are answered *YES*, promptly report the UPIRSO to the IRB.[2]			If all 3 questions to the left are answered "Yes," changes or other corrective actions will be or have been made.[4,5]	If all questions to the left are answered "Yes," the event is likely a UPIRSO, so submit RE to IRB.[6]	Initials & date of person completing log
				#1: Is event UNEXPECTED?	#2: Is event PROBABLY or DEFINITELY RELATED[3] to participation in the research?	#3: Does event suggest a GREATER RISK of harm than previously known?			
1	5678	☑ Initial; date event occurred: 10/3/16 Date of PI awareness: 10/3/16	Subject administered incorrect study drug	☐ No ☑ Yes ☐ Insufficient Info	☐ No ☑ Yes ☐ Insufficient Info	☐ No ☑ Yes ☐ Insufficient Info	☐ No ☑ Yes	☐ No ☑ Yes; date reported to IRB: 10/4/16	KB 10/5/16
		☐ Follow-up Date(s):		☐ No ☐ Yes ☐ Insufficient Info	☐ No ☐ Yes ☐ Insufficient Info	☐ No ☐ Yes ☐ Insufficient Info	☐ N ☐ Y		
2	9999	☑ Initial; date event occurred: 10/15/16 Date of PI awareness: 10/20/16	Rash 2 days after last study drug administration	☐ No ☑ Yes ☐ Insufficient Info	☐ No ☐ Yes ☑ Insufficient Info	☐ No ☐ Yes ☑ Insufficien Info	☑ No ☐ Yes	☑ No ☐ Yes; date	KB 10/22/16
		☑ Follow-up Date(s): 11/16/16	Rash 1 day after study drug administration on 11/15/16	☐ No ☑ Yes ☐ Insufficient Info	☐ No ☑ Yes ☐ Insufficient Info	☐ No ☑ Yes ☐ Insufficient Info	☑ Yes	☑ Yes; date reported to IRB: 11/18/16	KB 11/19/16
3	8675	☑ Initial; date event occurred: 12/16/16 Date of Pi awareness: 12/19/16	Grade 3 anemia	☑ No ☐ Yes ☐ Insufficient Info	☐ No ☑ Yes ☐ Insufficient Info	☑ No ☐ Yes ☐ Insufficient Info	☑ No ☐ Yes	☑ No ☐ Yes; date reported to IRB:	JL 12/21/16
		☐ Follow-up Date(s):		☐ No ☐ Yes ☐ Insufficient Info	☐ No ☐ Yes ☐ Insufficient Info	☐ No ☐ Yes ☐ Insufficient Info	☐ No ☐ Yes	☐ ☐ reporte IRB:	

Include subject #5678 on both UPIRSO and deviation logs

Event is both a UPIRSO and major deviation

Not enough info yet. Sponsor determined event is "possibly related" to study drug, so no RE.

Rash is not identified as risk in IB, protocol, or ICD

Since it happened again so close to study drug administration, sponsor determined event is "probably related" to study drug, so submit RE.

Listed as risk in IB, protocol, and ICD

Report at CR

EXAMPLE

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) Form		
Protocol No./Title: *STU 102015-999 / A Phase I Study of . . .*	**PI Name:** *Jane Doe, M.D.*	**Subject ID:** *5678*

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.

Use this form to file in the subject's research chart. The reference # on this form corresponds to the reference # on the Event/UPIRSO tracking log.

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
- ☑ Additional training (**SPECIFY** who, what, & when below)
- ☐ Revision/addition of study checklists, flow charts, etc.
- ☑ 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
- ☑ 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*

EXAMPLE

Deviation Form		
Protocol No./Title: *STU 102015-999 / A Phase I Study of . . .*	**PI Name:** *Jane Doe, M.D.*	**Subject ID:** *5678*

Reference No. from Deviation Tracking Log:	**2**
Date of Deviation:	10/3/2016
Date of PI Awareness:	10/3/2016
Date Reported to IRB:	10/4/2016

Use this form to file in the subject's research chart. The reference # on this form corresponds to the reference # on the Deviation Tracking log.

1. Deviation Description:
   Subject was mistakenly administered the incorrect IV study medication due to pharmacy dispensing error.

2. Type of Deviation:
   - ☐ Exception (check one):
     - ☐ Implemented after receiving IRB approval (i.e., obtained prior approval from IRB before implementing)
     - ☐ Implemented before receiving IRB approval – **Submit RE as major deviation**
   - ☐ Emergency Deviation – **Submit RE**
   - ☒ Major Deviation – **Submit RE**
   - ☐ Minor Deviation – Report at CR

3. Does deviation also meet UPIRSO criteria?
   - ☐ No
   - ☒ 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*