

**Blood and Marrow Transplant Clinical
Trials Network**

Protocol Deviation/Violation Review Form (PDR)

Web Version: 1.0; 3.00; 08-15-17

Segment (PROTSEG): 0

Deviation/Violation Date (PDDATE):

Deviation/Violation Num (PDSEQNUM):

1. Date event reviewed:(PDREVDT)

(mm/d/yyyy)

2. Event summary:(PDREVSUM)

3. Does the event qualify as a reportable protocol deviation/violation?(PDRQUAL)

1 - Yes 2 - No

4. Confirm deviation/violation category:(PDRCATEG)

01 - Treatment Assignment
02 - Treatment Administration
03 - Unblinding
04 - Eligibility
05 - Consent Related
*Additional Options Listed Below

Specify other:(PDRCATSP)

5. Confirm reason for deviation/violation:(PDRREASN)

01 - Clinic Error
02 - Pharmacy Error
03 - Physician or PI Decision
04 - Subject Refusal
05 - Subject Compliance Error
*Additional Options Listed Below

Specify other:(PDRRSNSP)

6. Is this event reportable to the DSMB?(PDRDSMB)

1 - Yes 2 - No

7. Date to be reported to the DSMB:(PDRDMSF)

Spring Fall Year:(PDRDSMYR) (xxxx)

8. Will this event be included in the Core Consortia Center Performance Report?
(PDRCCPR)

1 - Yes 2 - No

9. Does this event require additional site re-training or a CAPA?(PDRCAPA)

1 - Yes 2 - No

If yes, specify:(PDRCAPSP)

10. Review complete?(PDRRECOM)

1 - Yes 2 - No

11. BMT CTN Project Director reviewed?(PDRPDREV)

1 - Yes 2 - No

Comments:(PDRCOMM)

Additional Selection Options for PDR

Deviation/Violation Num (*PDSEQNUM*) (key field):

- 01 - 1st Deviation/Violation of the Day
- 02 - 2nd Deviation/Violation of the Day
- 03 - 3rd Deviation/Violation of the Day
- 04 - 4th Deviation/Violation of the Day
- 05 - 5th Deviation/Violation of the Day
- 06 - 6th Deviation/Violation of the Day
- 07 - 7th Deviation/Violation of the Day
- 08 - 8th Deviation/Violation of the Day
- 09 - 9th Deviation/Violation of the Day
- 10 - 10th Deviation/Violation of the Day

Confirm deviation/violation category:

- 06 - Assessment/Procedure Non-compliance
- 07 - Protocol-prohibited Agent or Treatment
- 08 - Data Breach
- 09 - Documentation
- 10 - PI Oversight
- 99 - Other, specify

Confirm reason for deviation/violation:

- 99 - Other, specify