

Blood and Marrow Transplant Clinical  
Trials Network

Protocol Deviation/Violation Form (PDV)

Web Version: 1.0; 1.01; 03-13-17

Segment (PROTSEG): 0

Deviation/Violation Date (PDDATE):

Deviation/Violation Num (PDSEQNUM):

1. Date deviation/violation identified:(PDVIDTDT)

(mm/dd/yyyy)

2. Record deviation/violation category:(PDVCATEG)

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

Specify other:(PDVCATSP)

3. Record reason for deviation/violation:(PDVREASO)

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

Specify other:(PDVREASP)

4. Deviation/violation description:(PDVDESCR)

5. Did the deviation/violation result in the discontinuation of study therapy?  
(PDVSTDIS)

1 - Yes  2 - No

Note: The patient must still be followed for all endpoints regardless of whether the patient continues to receive study therapy.

6. Does the deviation/violation meet IRB of record reporting requirements?  
(PDVIRBRE)

1 - Yes  2 - No

7. Specify type of notification to the IRB per institutional policy:(PDVIRBOU)

1 - Expedited Reporting  
2 - Reportable at Time of Annual Review

8. Expedited reporting date:(PDVIRBDT)

(mm/dd/yyyy)

9. Was any corrective action taken?(PDVCORRC)

1 - Yes  2 - No

10. Record corrective action:(PDVCORSP)

Comments:(PDVCOMM)

## Additional Selection Options for PDV

**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

**Record 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

**Record reason for deviation/violation:**

- 99 - Other, specify