













**Blood and Marrow Transplant  
Clinical Trials Network**

**Laboratory/Diagnostics Form - Unexpected, Grade 3-5 Adverse Event (AE4)**

Web Version: 1.0; 3.00; 06-23-09

**Segment (PROTSEG):**  
**Date of Onset (ADVDATE):**  
**Event description (ADVENT):**

1. Report activation status: (AVSTAT\_C)

- 1-1 - Keep report active
- 2-2 - Deactivate - Report filed in error
- 3-3 - Deactivate - Key field error
- 9-9 - Deactivate - Other reason



**Laboratory Test Results**

2. Were relevant laboratory tests performed? (LABTSTPF)

1- Yes     2- No

*If Yes, record the relevant laboratory test results in the grid below.*

Test	Collection Date (mm/dd/yyyy)	Result (Include units)	Site Normal Range (Include units)
(ADLTST1) <input type="text"/>	(ADL1CD) <input type="text"/>	(ADL1RES) <input type="text"/>	(ADL1NORG) <input type="text"/>
(ADLTST2) <input type="text"/>	(ADL2CD) <input type="text"/>	(ADL2RES) <input type="text"/>	(ADL2NORG) <input type="text"/>
(ADLTST3) <input type="text"/>	(ADL3CD) <input type="text"/>	(ADL3RES) <input type="text"/>	(ADL3NORG) <input type="text"/>
(ADLTST4) <input type="text"/>	(ADL4CD) <input type="text"/>	(ADL4RES) <input type="text"/>	(ADL4NORG) <input type="text"/>
(ADLTST5) <input type="text"/>	(ADL5CD) <input type="text"/>	(ADL5RES) <input type="text"/>	(ADL5NORG) <input type="text"/>
(ADLTST6) <input type="text"/>	(ADL6CD) <input type="text"/>	(ADL6RES) <input type="text"/>	(ADL6NORG) <input type="text"/>
(ADLTST7) <input type="text"/>	(ADL7CD) <input type="text"/>	(ADL7RES) <input type="text"/>	(ADL7NORG) <input type="text"/>
(ADLTST8) <input type="text"/>	(ADL8CD) <input type="text"/>	(ADL8RES) <input type="text"/>	(ADL8NORG) <input type="text"/>
(ADLTST9) <input type="text"/>	(ADL9CD) <input type="text"/>	(ADL9RES) <input type="text"/>	(ADL9NORG) <input type="text"/>
(ADLTST10) <input type="text"/>	(ADL10CD) <input type="text"/>	(ADL10RES) <input type="text"/>	(ADL10NRG) <input type="text"/>

**Diagnostic Tests (EX: MR, CT Scan, Ultrasound)**

3. Were relevant diagnostic tests performed? (DXSTPF)

1- Yes     2- No

*If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.*

Test	Date Performed (mm/dd/yyyy)	Results/Comments
(ADDTST1) <input type="text"/>	(AD1DTDAT) <input type="text"/>	(AD1DTRES) <input type="text"/>
(ADDTST2) <input type="text"/>	(AD2DTDAT) <input type="text"/>	(AD2DTRES) <input type="text"/>

(ADDTS3) <input type="text"/>	(AD3DTDAT) <input type="text"/>	(AD3DTRES)
(ADDTS4) <input type="text"/>	(AD4DTDAT) <input type="text"/>	(AD4DTRES)
(ADDTS5) <input type="text"/>	(AD5DTDAT) <input type="text"/>	(AD5DTRES)
(ADDTS6) <input type="text"/>	(AD6DTDAT) <input type="text"/>	(AD6DTRES)
(ADDTS7) <input type="text"/>	(AD7DTDAT) <input type="text"/>	(AD7DTRES)
(ADDTS8) <input type="text"/>	(AD8DTDAT) <input type="text"/>	(AD8DTRES)
(ADDTS9) <input type="text"/>	(AD9DTDAT) <input type="text"/>	(AD9DTRES)
(ADDTS10) <input type="text"/>	(AD10DDT) <input type="text"/>	(AD10DTRS)

Comments: (AE4COMM)



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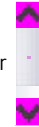
Review Form - Unexpected, Grade 3-5 Adverse Event (AE5)

Web Version: 1.0; 3.00; 06-17-09

Segment (PROTSEG):  
Date of Onset (ADVDATE):  
Event description (ADVENT):

1. Report activation status: (AVSTAT\_D)

- 1-1 - Keep report active
- 2-2 - Deactivate - Report filed in error
- 3-3 - Deactivate - Key field error
- 9-9 - Deactivate - Other reason



2. Reviewed: (AEREVIEW)

1- Yes  2 - No

3. Reviewed by: (ARFREVBY)

4. Review date: (ARFREVDT)

(mm/dd/yyyy)

5. Comment 1 - For Distribution: (ARCM1DIS)



6. Comment 2 - All Other Reviewers/Data Coordinating Center (ARCM2ALL)



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Medical Monitor Reviewer Form - Unexpected, Grade 3-5 Adverse Event (AE6)

Web Version: 1.0; 4.00; 08-10-09

Segment (PROTSEG):  
Date of Onset (ADVDATE):  
Event description (ADVENT):

1. Adverse event status: (AVSTAT\_E)

- 1-1 - Keep report active
- 2-2 - Deactivate - Report filed in error
- 3-3 - Deactivate - Key field error
- 9-9 - Deactivate - Other reason



2. Has this event been determined to be an unexpected, grade 3-5 adverse event? (AMDETER)

1- Yes     2 - No

3. Does this require expedited reporting to the DSMB? (AMEXPDSM)

1- Yes     2 - No

4. Do you recommend unblinding the patient? (AMUNBLIN)

1- Yes     2 - No

5. Do you recommend the patient be withdrawn from further protocol therapy? (AMWITHDR)

1- Yes     2 - No

6. Is the review complete? (AMREVDNE)

1- Yes     2 - No

7. If **No**, what additional information is required: (AMREVINF)



8. Medical Monitor event description: (AMMMEVDS)

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Comments: (AE6COMM)

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Demographics (DEM)

Web Version: 1.0; 5.00; 06-10-09

1. Name Code: (NAMECODE)

2. IUBMID # (if available): (IUBMID)

3. CRID # (CIBMTR Recipient ID): (CRIDNUM)

**Do NOT use IUBMID/UPN numbers in the CRID field.**

4. Gender: (GENDER)

 1 - Male  2 - Female

5. Date of Birth: (DOB)

6. Ethnicity: (ETHNIC)

7. Race: (RACE)

Specify race: (RACESP)

8. Secondary Race: (RACE2)

Specify secondary race: (RACE2SP)

Comments: (DEMCOMM1)

## Additional Selection Options for DEM

**Race:**

15-15 - South or Central American  
16-16 - Eastern European  
17-17 - Northern European  
18-18 - Western European  
81-81 - White Caribbean  
82-82 - North Coast of Africa  
83-83 - Middle Eastern  
-Black  
20-20 - Black (Not Otherwise Specified)  
21-21 - African American  
22-22 - African Black (Both Parents Born in Africa)  
23-23 - Caribbean Black  
24-24 - South or Central American Black  
29-29 - Black, Other Specify  
-Asian  
30-30 - Asian (Not Otherwise Specified)  
31-31 - Indian/South Asian  
32-32 - Filipino (Pilipino)  
34-34 - Japanese  
35-35 - Korean  
36-36 - Chinese  
37-37 - Other Southeast Asian  
38-38 - Vietnamese  
-American Indian or Alaska Native  
50-50 - Native American (Not Otherwise Specified)  
51-51 - Native Alaskan/Eskimo/Aleut  
52-52 - American Indian (Not Otherwise Specified)  
53-53 - North American Indian  
54-54 - South or Central American Indian  
55-55 - Caribbean Indian  
-Native Hawaiian or Other Pacific Islander  
60-60 - Native Pacific Islander (Not Otherwise Specified)  
61-61 - Guamanian  
62-62 - Hawaiian  
63-63 - Samoan  
-Other  
88-88 - Unknown  
90-90 - Other, Specify  
99-99 - Not Answered













