Blood and Marrow Transplant Clinical Trials Network

BMT AE Tracking Form (A99)

Web Version: 1.0; 1.02; 12-08-16

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

AE1 | AE2 | AE3 | AE4 | AE5 | AE6

1. Date event initially reported in AdvantageEDC:*(EVENTDT)* _____ *(mm/dd/yyyy)*
2. Overall event status:*(OVSTATUS)*
   - 1 - Open
   - 2 - Closed
   - 3 - De-activated; Did Not Qualify for Expedited Reporting to Any Entity
3. Is there enough information to send to the Medical Monitor?*(INFOTOMM)* ☐ 1 - Yes ☐ 2 - No
   4. If 'Yes', date event initially sent to Medical Monitor:*(DATETOMM)* _____ *(mm/dd/yyyy)*
   5. Indicate whether the Medical Monitor's review is complete:*(MMREVCMP)* ☐ 1 - Yes ☐ 2 - No
      6. If the Medical Monitor's review is not complete, indicate the event's review status:*(MMREVSTS)*
         - 1 - With Medical Monitor for Review
         - 2 - Pending Additional Info From Transplant Center
         - 3 - With EMMES AE Coordinator
         - 9 - Other
      7. If 'Other', specify:*(MMREVSPC)* _____
8. Does the event need to be reported on other Case Report Forms (CRFs)? *(OTHRCRF)* ☐ 1 - Yes ☐ 2 - No
   9. If 'Yes', specify other CRFs on which the event should be reported and whether this has been completed by the transplant center:*(OTHCRFSP)* _____

Reporting to DSMB

10. Does the event require expedited reporting to the DSMB?*(DSMBEX)* ☐ 1 - Yes ☐ 2 - No
    11. If 'Yes', date initial report must be circulated to the DSMB:*(DSMBIRDT)* _____ *(mm/dd/yyyy)*
    12. If 'Yes', date initial report circulated to the DSMB:*(DSMBSNDT)* _____ *(mm/dd/yyyy)*
13. Overall event reporting status to the DSMB:*(DSMBSTTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below
    14. If 'Other', specify:*(DSMBSTSP)* _____
15. DSMB report reviewer status:*(DSMBREVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other
    16. If 'Other', specify:*(DSMBROTH)* _____

Reporting to FDA

17. Does the event require expedited reporting to the FDA?*(FDAEX)* ☐ 1 - Yes ☐ 2 - No
    18. If 'Yes', date FDA must be notified:*(FDANOTDT)* _____ *(mm/dd/yyyy)*
    19. If 'Yes', date initial safety report must be circulated to the FDA:*(FDAIRDT)* _____ *(mm/dd/yyyy)*
    20. If 'Yes', date initial safety report circulated to the FDA:*(FDASNTDT)* _____ *(mm/dd/yyyy)*

21. Overall event reporting status to the FDA:*(FDASTTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

22. If 'Other', specify:*(FDASTSP)*

23. FDA report reviewer status:*(FDAREVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

24. If 'Other', specify:*(FDAROTH)*

Reporting to Pharma Company #1

25. Name of pharma company #1:*(PC1NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

26. Does the event required expedited reporting to pharma company #1?*(PC1EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

27. If 'Yes', date initial report must be circulated to pharma company #1:*(PC1IRDT)* *(mm/dd/yyyy)*

28. If 'Yes', date initial report circulated to pharma company #1:*(PC1SNTDT)* *(mm/dd/yyyy)*

29. Overall event reporting status to pharma company #1:*(PC1STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

30. If 'Other', specify:*(PC1STSP)*

31. Pharma company #1 report reviewer status:*(PC1REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

32. If 'Other', specify:*(PC1ROTH)*

Reporting to Pharma Company #2

33. Name of pharma company #2:*(PC2NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

34. Does the event require expedited reporting to pharma company #2?*(PC2EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

35. If 'Yes', date initial report must be circulated to pharma company #2:*(PC2IRDT)* *(mm/dd/yyyy)*

36. If 'Yes', date initial report circulated to pharma company #2:*(PC2SNTDT)* *(mm/dd/yyyy)*

37. Overall event reporting status to pharma company #2:*(PC2STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

38. If 'Other', specify:*(PC2STSP)*

39. Pharma company #2 report reviewer status:*(PC2REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

40. If 'Other', specify:*(PC2ROTH)*

Reporting to Pharma Company #3

41. Name of pharma company #3:*(PC3NAME)*
    - 1 - Celgene
    - 2 - Millennium
    - 3 - Pfizer
    - 4 - Miltenyi
    - 5 - Novartis

42. Does the event require expedited reporting to pharma company #3?*(PC3EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

43. If 'Yes', date initial report must be circulated to pharma company #3:*(PC3IRDT)* *(mm/dd/yyyy)*

44. If 'Yes', date initial report circulated to pharma company #3:*(PC3SNTDT)* *(mm/dd/yyyy)*

45. Overall event reporting status to pharma company #3:*(PC3STTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below

46. If 'Other', specify:*(PC3STSP)*

47. Pharma company #3 report reviewer status:*(PC3REVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other

48. If 'Other', specify:*(PC3ROTH)*

Reporting to Pharma Company #4

49. Name of pharma company #4:*(PC4NAME)*
    - 1 - Celgene
    - 2 - Millennium
    - 3 - Pfizer
    - 4 - Miltenyi
    - 5 - Novartis

50. Does the event require expedited reporting to pharma company #4?*(PC4EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

51. If 'Yes' date initial report must be circulated to pharma company #4:*(PC4IRDT)* *(mm/dd/yyyy)*

52. If 'Yes', date initial report circulated to pharma company #4:*(PC4SNTDT)* *(mm/dd/yyyy)*

53. Overall event reporting status to pharma company #4:*(PC4STTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below

54. If 'Other', specify:*(PC4STSP)*

55. Pharma company #4 report reviewer status:*(PC4REVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other

56. If 'Other', specify:*(PC4ROTH)*

Comments:*(A99COMM)*

Additional Selection Options for A99

Overall event reporting status to the DSMB:
6 - Pending Circulation of Quaternary Follow-Up Report
7 - Closed; Reporting Complete
9 - Other

Blood and Marrow Transplant Clinical Trials Network

BMT AE Tracking Communications Form (A9C)

Web Version: 1.0; 1.01; 12-08-16

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

	Status	Communication Date	Communication Type	Contact Name	Contact Role
Communication #1*(A9C1RPT)* ☐ Report	*(A9C1STS)* Pending Resolved	*(A9C1DT)* *(mm/dd/yyyy)*	*(A9C1TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C1NME)*	*(A9C1RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #2*(A9C2RPT)* ☐ Report	*(A9C2STS)* Pending Resolved	*(A9C2DT)* *(mm/dd/yyyy)*	*(A9C2TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C2NME)*	*(A9C2RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #3*(A9C3RPT)* ☐ Report	*(A9C3STS)* Pending Resolved	*(A9C3DT)* *(mm/dd/yyyy)*	*(A9C3TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C3NME)*	*(A9C3RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #4*(A9C4RPT)* ☐ Report	*(A9C4STS)* Pending Resolved	*(A9C4DT)* *(mm/dd/yyyy)*	*(A9C4TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C4NME)*	*(A9C4RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #5*(A9C5RPT)* ☐ Report	*(A9C5STS)* Pending Resolved	*(A9C5DT)* *(mm/dd/yyyy)*	*(A9C5TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C5NME)*	*(A9C5RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #6*(A9C6RPT)* ☐ Report	*(A9C6STS)* Pending Resolved	*(A9C6DT)* *(mm/dd/yyyy)*	*(A9C6TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C6NME)*	*(A9C6RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #7*(A9C7RPT)* ☐ Report	*(A9C7STS)*	*(A9C7DT)* *(mm/dd/yyyy)*	*(A9C7TYP)*	*(A9C7NME)*	*(A9C7RLE)*

	Pending Resolved		1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC		1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #8*(A9C8RPT)* Report	*(A9C8STS)* Pending Resolved	*(A9C8DT)* *(mm/dd/yyyy)*	*(A9C8TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C8NME)*	*(A9C8RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #9*(A9C9RPT)* Report	*(A9C9STS)* Pending Resolved	*(A9C9DT)* *(mm/dd/yyyy)*	*(A9C9TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C9NME)*	*(A9C9RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #10*(A9C10RPT)* Report	*(A9C10STS)* Pending Resolved	*(A9C10DT)* *(mm/dd/yyyy)*	*(A9C10TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C10NME)*	*(A9C10RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #11*(A9C11RPT)* Report	*(A9C11STS)* Pending Resolved	*(A9C11DT)* *(mm/dd/yyyy)*	*(A9C11TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C11NME)*	*(A9C11RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #12*(A9C12RPT)* Report	*(A9C12STS)* Pending Resolved	*(A9C12DT)* *(mm/dd/yyyy)*	*(A9C12TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C12NME)*	*(A9C12RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #13*(A9C13RPT)* Report	*(A9C13STS)* Pending Resolved	*(A9C13DT)* *(mm/dd/yyyy)*	*(A9C13TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C13NME)*	*(A9C13RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #14*(A9C14RPT)* Report	*(A9C14STS)* Pending Resolved	*(A9C14DT)* *(mm/dd/yyyy)*	*(A9C14TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C14NME)*	*(A9C14RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #15*(A9C15RPT)* Report	*(A9C15STS)* Pending Resolved	*(A9C15DT)* *(mm/dd/yyyy)*	*(A9C15TYP)*	*(A9C15NME)*	*(A9C15RLE)*	

			1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC		1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #16 *(A9C16RPT)* ☐ Report	*(A9C16STS)* Pending Resolved	*(A9C16DT)* *(mm/dd/yyyy)*	*(A9C16TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C16NME)*	*(A9C16RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #17 *(A9C17RPT)* ☐ Report	*(A9C17STS)* Pending Resolved	*(A9C17DT)* *(mm/dd/yyyy)*	*(A9C17TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C17NME)*	*(A9C17RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #18 *(A9C18RPT)* ☐ Report	*(A9C18STS)* Pending Resolved	*(A9C18DT)* *(mm/dd/yyyy)*	*(A9C18TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C18NME)*	*(A9C18RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #19 *(A9C19RPT)* ☐ Report	*(A9C19STS)* Pending Resolved	*(A9C19DT)* *(mm/dd/yyyy)*	*(A9C19TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C19NME)*	*(A9C19RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #20 *(A9C20RPT)* ☐ Report	*(A9C20STS)* Pending Resolved	*(A9C20DT)* *(mm/dd/yyyy)*	*(A9C20TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C20NME)*	*(A9C20RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #21 *(A9C21RPT)* ☐ Report	*(A9C21STS)* Pending Resolved	*(A9C21DT)* *(mm/dd/yyyy)*	*(A9C21TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C21NME)*	*(A9C21RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #22 *(A9C22RPT)* ☐ Report	*(A9C22STS)* Pending Resolved	*(A9C22DT)* *(mm/dd/yyyy)*	*(A9C22TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C22NME)*	*(A9C22RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	

Additional Selection Options for A9C

COM 1 Contact Role
6 - Pharma Rep
99 - Other

Blood and Marrow Transplant Clinical Trials Network

Adverse Event Form (AE1)

Web Version: 1.0; 5.00; 01-28-16

Segment *(PROTSEG)*: 0
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status:*(AVSTATUS)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason

   If Other, specify reason for deactivation:*(AESPEC1)*
2. Record date transplant center became aware of the event:*(AVAWARDT)* *(mm/dd/yyyy)*
3. Indicate weight at time of the event:*(AVWGHTKG)* *(xxx.x)* kg
4. Was this event expected or anticipated?*(AVEXPECT)* ☐ 1 - Yes ☐ 2 - No
5. Record the severity of event:*(AVEVENT)*
   - 1 - Mild
   - 2 - Moderate
   - 3 - Severe
   - 4 - Life Threatening
   - 5 - Fatal
6. What is the relationship to study therapy/intervention:*(AVRELAT)*
   - 1 - Unrelated
   - 2 - Unlikely
   - 3 - Possible
   - 4 - Probable
   - 5 - Definite
7. Is there an alternative etiology:*(AVETIOL)*
   - 0 - None Apparent
   - 1 - Study Disease
   - 2 - Other Pre-Existing Disease or Condition
   - 3 - Accident, Trauma, or External Factors
   - 4 - Concurrent Illness/Condition (Not Pre-Existing)
8. What is the effect on study therapy/intervention schedule:*(AVEFFECT)*
   - 1 - No Change - Completed
   - 2 - No Change - Ongoing
   - 3 - Dose Modified
   - 4 - Temporarily Stopped
   - 5 - Permanently Stopped
9. Record the most severe outcome of the event:*(AVOUTCOM)*
   - 1 - Resolved, No Residual Effects
   - 2 - Resolved with Sequelae
   - 3 - Persistent Condition
   - 4 - Resolved by Death
10. Record the date of resolution:*(AVRESDT)* *(mm/dd/yyyy)*
11. Was this event associated with:*(AVASSOCI)*
    - 0 - None of the Following
    - 1 - Death
    - 2 - Life-Threatening Event
    - 3 - Disability
    - 4 - Congenital Anomaly
    - *Additional Options Listed Below

Comments:*(AE1COMM)*

Additional Selection Options for AE1

Was this event associated with:
5 - Required Intervention to Prevent Permanent Impairment or Damage
6 - Hospitalization (Initial or Prolonged)
9 - Other SAE

Blood and Marrow Transplant Clinical Trials Network

AE Summary Form (AE2)

Web Version: 1.0; 3.12; 10-16-15

Segment *(PROTSEG)*: 0
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status:*(AVSTAT_A)*

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

Relevant Past Medical History

2. Does the patient have any relevant history, including pre-existing medical conditions?*(SEMEDHXS)* ☐ 1 - Yes ☐ 2 - No

If Yes, include any relevant history, including preexisting medical conditions below.

(SEMEDHX)

3. **Event Summary**

Include clinical history of event, associated signs and symptoms, alternative etiologies being considered and medical management below.

(SESUMM)

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4. Initial submitter:*(SEISUBBY)* Name: Date:*(SEISUBDT)* *(mm/dd/yyyy)*

5. Authorized submitter:*(SEASUBBY)* Name: Date:*(SEASUBDT)* *(mm/dd/yyyy)* ?

Blood and Marrow Transplant Clinical Trials Network

AE Therapy Form (AE3)

Web Version: 1.0; 4.05; 10-16-15

Segment *(PROTSEG)*: 0
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status:*(AVSTAT_B)*

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

Study Product/Suspect Medication Data

2. Was the patient receiving any study products/suspect medications?*(RCVSP)* ☐ 1 - Yes ☐ 2 - No

If Yes, list the study product/suspect medications the subject was taking in the grid below.

Study Product Name (Note: If blinded, indicate as such)	Dose of Study Product(s) at SAE Onset	Route of Study Product(s) at SAE Onset	Schedule of Study Product(s) at SAE Onset	Date Study Product First Started *(mm/dd/yyyy)*	Date Study Product Last Taken *(mm/dd/yyyy)*	Reason for Use
(SPNAME1)	*(SP1DOSE)*	*(SP1ROUTE)*	*(SP1SCHED)*	*(SP1STDT)*	*(SP1SPDT)*	*(SP1REASO)*
(SPNAME2)	*(SP2DOSE)*	*(SP2ROUTE)*	*(SP2SCHED)*	*(SP2STDT)*	*(SP2SPDT)*	*(SP2REASO)*
(SPNAME3)	*(SP3DOSE)*	*(SP3ROUTE)*	*(SP3SCHED)*	*(SP3STDT)*	*(SP3SPDT)*	*(SP3REASO)*
(SPNAME4)	*(SP4DOSE)*	*(SP4ROUTE)*	*(SP4SCHED)*	*(SP4STDT)*	*(SP4SPDT)*	*(SP4REASO)*
(SPNAME5)	*(SP5DOSE)*	*(SP5ROUTE)*	*(SP5SCHED)*	*(SP5STDT)*	*(SP5SPDT)*	*(SP5REASO)*

Concomitant Medications

3. Was the patient taking any concomitant medications?*(RCVCONMD)* ☐ 1 - Yes ☐ 2 - No

If Yes, list the concomitant medications the patient was taking up to 1 month prior to SAE onset in the grid below.

Medication	Start Date *(mm/dd/yyyy)*	Stop Date *(mm/dd/yyyy)*	Dose, Route, Schedule	Indication
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*	*(CM1INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*	*(CM2INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*	*(CM3INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*	*(CM4INDIC)*

				1 - Treatment of adverse event 9 - Other
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*	*(CM5INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED6)	*(CM6STDT)*	*(CM6SPDT)*	*(CM6DOSE)*	*(CM6INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED7)	*(CM7STDT)*	*(CM7SPDT)*	*(CM7DOSE)*	*(CM7INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED8)	*(CM8STDT)*	*(CM8SPDT)*	*(CM8DOSE)*	*(CM8INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED9)	*(CM9STDT)*	*(CM9SPDT)*	*(CM9DOSE)*	*(CM9INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED10)	*(CM10STDT)*	*(CM10SPDT)*	*(CM10DOSE)*	*(CM10INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED11)	*(CM11STDT)*	*(CM11SPDT)*	*(CM11DOSE)*	*(CM11INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED12)	*(CM12STDT)*	*(CM12SPDT)*	*(CM12DOSE)*	*(CM12INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED13)	*(CM13STDT)*	*(CM13SPDT)*	*(CM13DOSE)*	*(CM13INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED14)	*(CM14STDT)*	*(CM14SPDT)*	*(CM14DOSE)*	*(CM14INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED15)	*(CM15STDT)*	*(CM15SPDT)*	*(CM15DOSE)*	*(CM15INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED16)	*(CM16STDT)*	*(CM16SPDT)*	*(CM16DOSE)*	*(CM16INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED17)	*(CM17STDT)*	*(CM17SPDT)*	*(CM17DOSE)*	*(CM17INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED18)	*(CM18STDT)*	*(CM18SPDT)*	*(CM18DOSE)*	*(CM18INDI)* 1 - Treatment of adverse event 9 - Other

(CONMED19)	*(CM19STDT)*	*(CM19SPDT)*	*(CM19DOSE)*	*(CM19INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED20)	*(CM20STDT)*	*(CM20SPDT)*	*(CM20DOSE)*	*(CM20INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED21)	*(CM21STDT)*	*(CM21SPDT)*	*(CM21DOSE)*	*(CM21INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED22)	*(CM22STDT)*	*(CM22SPDT)*	*(CM22DOSE)*	*(CM22INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED23)	*(CM23STDT)*	*(CM23SPDT)*	*(CM23DOSE)*	*(CM23INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED24)	*(CM24STDT)*	*(CM24SPDT)*	*(CM24DOSE)*	*(CM24INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED25)	*(CM25STDT)*	*(CM25SPDT)*	*(CM25DOSE)*	*(CM25INDI)* 1 - Treatment of adverse event 9 - Other

Comments:*(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Laboratory/Diagnostics Form (AE4)

Web Version: 1.0; 3.12; 06-16-16

Segment *(PROTSEG)*: 0
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status:*(AVSTAT_C)*

1 - Keep report active
2 - Deactivate - Report filed in error
3 - Deactivate - Key field error
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)	Lab Value Previous to this SAE (Include units)	Collection Date for Previous Lab *(mm/dd/yyyy)*
(ADLTST1)	*(ADL1CD)*	*(ADL1RES)*	*(ADL1NORG)*	*(ADL1PRVL)*	*(ADL1PCD)*
(ADLTST2)	*(ADL2CD)*	*(ADL2RES)*	*(ADL2NORG)*	*(ADL2PRVL)*	*(ADL2PCD)*
(ADLTST3)	*(ADL3CD)*	*(ADL3RES)*	*(ADL3NORG)*	*(ADL3PRVL)*	*(ADL3PCD)*
(ADLTST4)	*(ADL4CD)*	*(ADL4RES)*	*(ADL4NORG)*	*(ADL4PRVL)*	*(ADL4PCD)*
(ADLTST5)	*(ADL5CD)*	*(ADL5RES)*	*(ADL5NORG)*	*(ADL5PRVL)*	*(ADL5PCD)*
(ADLTST6)	*(ADL6CD)*	*(ADL6RES)*	*(ADL6NORG)*	*(ADL6PRVL)*	*(ADL6PCD)*
(ADLTST7)	*(ADL7CD)*	*(ADL7RES)*	*(ADL7NORG)*	*(ADL7PRVL)*	*(ADL7PCD)*
(ADLTST8)	*(ADL8CD)*	*(ADL8RES)*	*(ADL8NORG)*	*(ADL8PRVL)*	*(ADL8PCD)*
(ADLTST9)	*(ADL9CD)*	*(ADL9RES)*	*(ADL9NORG)*	*(ADL9PRVL)*	*(ADL9PCD)*
(ADLTST10)	*(ADL10CD)*	*(ADL10RES)*	*(ADL10NRG)*	*(ADL10PVL)*	*(ADL10PCD)*

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
(ADDTS1)	*(AD1DTDAT)*	*(AD1DTRES)*

(ADDTS2)	*(AD2DTDAT)*	*(AD2DTRES)*
(ADDTS3)	*(AD3DTDAT)*	*(AD3DTRES)*
(ADDTS4)	*(AD4DTDAT)*	*(AD4DTRES)*
(ADDTS5)	*(AD5DTDAT)*	*(AD5DTRES)*
(ADDTS6)	*(AD6DTDAT)*	*(AD6DTRES)*
(ADDTS7)	*(AD7DTDAT)*	*(AD7DTRES)*
(ADDTS8)	*(AD8DTDAT)*	*(AD8DTRES)*
(ADDTS9)	*(AD9DTDAT)*	*(AD9DTRES)*
(ADDTS10)	*(AD10DTDT)*	*(AD10DTRS)*

Comments:*(AE4COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Review Form (AE5)

Web Version: 1.0; 3.12; 10-16-15

Segment *(PROTSEG)*: 0
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status:*(AVSTAT_D)*

1 - Keep report active
2 - Deactivate - Report filed in error
3 - Deactivate - Key field error
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)*

Blood and Marrow Transplant Clinical Trials Network

AE Medical Monitor Reviewer Form (AE6)

Web Version: 1.0; 9.00; 03-06-17

Segment *(PROTSEG)*: 0
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 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 the patient be withdrawn from further protocol therapy? *(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
5. Is the review complete?*(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
6. If **No**, what additional information is required:*(AMREVINF)*
7. Medical Monitor event description:*(AMMMEVDS)*
8. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
   - 1 - Grade 1
   - 2 - Grade 2
   - 3 - Grade 3
   - 4 - Grade 4
   - 5 - Grade 5

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 6.02; 12-02-15

1. Name Code:*(NAMECODE)*
2. IUBMID # (if available):*(IUBMID)*
3. Gender:*(GENDER)* ☐ 1 - Male ☐ 2 - Female
4. Date of Birth:*(DOB)* *(mm/dd/yyyy)*
5. Ethnicity:*(ETHNIC)*
   - 1- Hispanic or Latino
   - 2- Not Hispanic or Latino
   - 8- Unknown
   - 9- Not Answered
6. Race:*(RACE)*
   - White
   - 10 - White (Not Otherwise Specified)
   - 11 - European (Not Otherwise Specified)
   - 13 - Mediterranean
   - 14 - White North American
   - *Additional Options Listed Below

   Specify race:*(RACESP)*
7. Secondary Race:*(RACE2)*
   - White
   - 10 - White (Not Otherwise Specified)
   - 11 - European (Not Otherwise Specified)
   - 13 - Mediterranean
   - 14 - White North American
   - *Additional Options Listed Below

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

Web Version: 1.0; 4.16; 06-16-17

1. Record date of death:*(DTHDT)* *(mm/dd/yyyy)*

2. Was an autopsy performed?*(AUTPERF)* ☐ 1 - Yes ☐ 2 - No

If yes, attach de-identified autopsy report or death summary to the form below.

Enter appropriate cause of death code below. List in order of decreasing severity.

3. Primary cause of death:*(CZDTHPRM)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

?

Specify other:*(DTHSPEC1)*

4. Secondary cause of death:*(SCNDCZ1)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC2)*

5. Secondary cause of death:*(SCNDCZ2)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC3)*

6. Secondary cause of death:*(SCNDCZ3)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC4)*

7. Secondary cause of death:*(SCNDCZ4)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

Additional Selection Options for DTH

Primary cause of death:
2.2 - Fungal
2.3 - Viral
2.4 - Protozoal
2.5 - Other, Specify Below
2.9 - Organism Not Identified
Interstitial Pneumonia
3.1 - Viral, CMV
3.2 - Viral, Other
3.3 - Pneumocystis
3.4 - Other, Specify Below
3.9 - Idiopathic
4.0 - Adult Respiratory Distress Syndrome
5.0 - Acute GVHD
6.0 - Chronic GVHD
7.0 - Recurrence or Persistence of Leukemia/Malignancy/MDS
7.1 - Persistent Disease
Organ Failure (Not Due to GVHD or Infection)
8.1 - Liver
8.2 - Cardiac (Cardiomyopathy)
8.3 - Pulmonary
8.4 - CNS
8.5 - Renal
8.6 - Other, Specify Below
8.7 - Multiple Organ Failure, Specify Below
8.8 - Secondary Graft Failure
9.0 - Secondary Malignancy
9.1 - EBV
9.2 - Other, Specify Below
Hemorrhage
10.1 - Pulmonary
10.2 - Intracranial
10.3 - Gastrointestinal
10.4 - Hemorrhage Not Specified
10.5 - Other, Specify Below
Vascular
11.1 - Thromboembolic
11.2 - Disseminated Intravascular Coagulation (DIC)
11.3 - Gastrointestinal
11.4 - Thrombotic Thrombocytopenic Purpura
11.5 - Vascular Not Specified
11.9 - Other, Specify Below
12.0 - Accidental Death
13.0 - Other, Specify Below

Blood and Marrow Transplant Clinical Trials Network

09030 (ENR)

Web Version: 1.0; 1.00; 10-16-15

Allogeneic HIV Transplant - Segment 0

1. Date informed consent form signed:*(HIVCNSDT)* _____ *(mm/dd/yyyy)*

Comments:*(HIVCMMNT)*

Blood and Marrow Transplant Clinical Trials Network

HIV HLA (Page 1) (HH1)

Web Version: 1.0; 1.01; 10-16-15

Segment *(PROTSEG)*: 0
Visit Number *(VISNO)*:

HLA Typing

Donor type:*(HLARLTD)* ☐ 1 - Related Donor ☐ 2 - Unrelated Donor

Type of HLA Match required by this protocol:*(HT1MATCH)*

Loci A, B: Low Level DNA, Locus DRB1: High Level DNA
Loci A, B: Serologic, Locus DRB1: High Level DNA
Loci A, B: Serologic, Locus DRB1: Low Level DNA
Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA
Loci A, B, C: Serologic, Locus DRB1: High Level DNA
*Additional Options Listed Below

1. Recipient HLA Typing

HLA-A

Typing method:*(HLAAMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLAANUM)*

1 - One
2 - Two

1st:	*(HLAA11X)*		*(HLAA12X)* /		*(HLAA13X)* /		*(HLAA14X)* /
	(HLAA15X)		*(HLAA16X)* /		*(HLAA17X)* /		*(HLAA18X)* /
2nd:	*(HLAA21X)*		*(HLAA22X)* /		*(HLAA23X)* /		*(HLAA24X)* /
	(HLAA25X)		*(HLAA26X)* /		*(HLAA27X)* /		*(HLAA28X)* /

HLA-B

Typing method:*(HLABMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLABNUM)*

1 - One
2 - Two

1st:	*(HLAB11X)*		*(HLAB12X)* /		*(HLAB13X)* /		*(HLAB14X)* /
	(HLAB15X)		*(HLAB16X)* /		*(HLAB17X)* /		*(HLAB18X)* /
2nd:	*(HLAB21X)*		*(HLAB22X)* /		*(HLAB23X)* /		*(HLAB24X)* /
	(HLAB25X)		*(HLAB26X)* /		*(HLAB27X)* /		*(HLAB28X)* /

HLA-C

Typing method:*(HLACMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLACNUM)*

1 - One
2 - Two

1st:	*(HLAC11X)*		*(HLAC12X)* /		*(HLAC13X)* /		*(HLAC14X)* /
	(HLAC15X)		*(HLAC16X)* /		*(HLAC17X)* /		*(HLAC18X)* /
2nd:	*(HLAC21X)*		*(HLAC22X)* /		*(HLAC23X)* /		*(HLAC24X)* /

(HLAC25X) | (HLAC26X) / | (HLAC27X) / | (HLAC28X) /

HLA-DRB1

Typing method:*(HLADMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLADNUM)*

1 - One
2 - Two

1st: (HLAD11X) | (HLAD12X) / | (HLAD13X) / | (HLAD14X) /

(HLAD15X) | (HLAD16X) / | (HLAD17X) / | (HLAD18X) /

2nd: (HLAD21X) | (HLAD22X) / | (HLAD23X) / | (HLAD24X) /

(HLAD25X) | (HLAD26X) / | (HLAD27X) / | (HLAD28X) /

Comments:*(HH1COMM)*

Additional Selection Options for HH1

Type of HLA Match required by this protocol:
Loci A, B, C, DQ: Low Level DNA, Locus DRB1: High Level DNA
High Level DNA
Low Level DNA
Serologic

Blood and Marrow Transplant Clinical Trials Network

HIV HLA (Page 2) (HH2)

Web Version: 1.0; 1.01; 10-16-15

Segment *(PROTSEG)*: 0
Visit Number *(VISNO)*:

HLA Typing

Type of HLA Match required by this protocol:*(HT2MATCH)*

Loci A, B: Low Level DNA, Locus DRB1: High Level DNA
Loci A, B: Serologic, Locus DRB1: High Level DNA
Loci A, B: Serologic, Locus DRB1: Low Level DNA
Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA
Loci A, B, C: Serologic, Locus DRB1: High Level DNA
*Additional Options Listed Below

1. Donor HLA Typing

HLA-A

Typing method:*(HLAAMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLAANUM)*

1 - One
2 - Two

1st:	*(HLAA11X)*		*(HLAA12X)* /		*(HLAA13X)* /		*(HLAA14X)* /
	(HLAA15X)		*(HLAA16X)* /		*(HLAA17X)* /		*(HLAA18X)* /
2nd:	*(HLAA21X)*		*(HLAA22X)* /		*(HLAA23X)* /		*(HLAA24X)* /
	(HLAA25X)		*(HLAA26X)* /		*(HLAA27X)* /		*(HLAA28X)* /

HLA-B

Typing method:*(HLABMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLABNUM)*

1 - One
2 - Two

1st:	*(HLAB11X)*		*(HLAB12X)* /		*(HLAB13X)* /		*(HLAB14X)* /
	(HLAB15X)		*(HLAB16X)* /		*(HLAB17X)* /		*(HLAB18X)* /
2nd:	*(HLAB21X)*		*(HLAB22X)* /		*(HLAB23X)* /		*(HLAB24X)* /
	(HLAB25X)		*(HLAB26X)* /		*(HLAB27X)* /		*(HLAB28X)* /

HLA-C

Typing method:*(HLACMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLACNUM)*

1 - One
2 - Two

1st:	*(HLAC11X)*		*(HLAC12X)* /		*(HLAC13X)* /		*(HLAC14X)* /
	(HLAC15X)		*(HLAC16X)* /		*(HLAC17X)* /		*(HLAC18X)* /
2nd:	*(HLAC21X)*		*(HLAC22X)* /		*(HLAC23X)* /		*(HLAC24X)* /
	(HLAC25X)		*(HLAC26X)* /		*(HLAC27X)* /		*(HLAC28X)* /

HLA-DRB1

Typing method:*(HLADMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLADNUM)*

1 - One
2 - Two

1st:	*(HLAD11X)*		*(HLAD12X)* /		*(HLAD13X)* /		*(HLAD14X)* /
	(HLAD15X)		*(HLAD16X)* /		*(HLAD17X)* /		*(HLAD18X)* /
2nd:	*(HLAD21X)*		*(HLAD22X)* /		*(HLAD23X)* /		*(HLAD24X)* /
	(HLAD25X)		*(HLAD26X)* /		*(HLAD27X)* /		*(HLAD28X)* /

Comments:*(HH2COMM)*

Additional Selection Options for HH2

Type of HLA Match required by this protocol:
Loci A, B, C, DQ: Low Level DNA, Locus DRB1: High Level DNA
High Level DNA
Low Level DNA
Serologic

Blood and Marrow Transplant Clinical Trials Network

BMT AE Tracking Form (A99)

Web Version: 1.0; 1.02; 12-08-16

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

AE1 | AE2 | AE3 | AE4 | AE5 | AE6

1. Date event initially reported in AdvantageEDC:*(EVENTDT)* _____ *(mm/dd/yyyy)*
2. Overall event status:*(OVSTATUS)*
   - 1 - Open
   - 2 - Closed
   - 3 - De-activated; Did Not Qualify for Expedited Reporting to Any Entity
3. Is there enough information to send to the Medical Monitor?*(INFOTOMM)* ☐ 1 - Yes ☐ 2 - No
4. If 'Yes', date event initially sent to Medical Monitor:*(DATETOMM)* _____ *(mm/dd/yyyy)*
5. Indicate whether the Medical Monitor's review is complete:*(MMREVCMP)* ☐ 1 - Yes ☐ 2 - No
6. If the Medical Monitor's review is not complete, indicate the event's review status:*(MMREVSTS)*
   - 1 - With Medical Monitor for Review
   - 2 - Pending Additional Info From Transplant Center
   - 3 - With EMMES AE Coordinator
   - 9 - Other
7. If 'Other', specify:*(MMREVSPC)* _____
8. Does the event need to be reported on other Case Report Forms (CRFs)? *(OTHRCRF)* ☐ 1 - Yes ☐ 2 - No
9. If 'Yes', specify other CRFs on which the event should be reported and whether this has been completed by the transplant center:*(OTHCRFSP)* _____

Reporting to DSMB

10. Does the event require expedited reporting to the DSMB?*(DSMBEX)* ☐ 1 - Yes ☐ 2 - No
11. If 'Yes', date initial report must be circulated to the DSMB:*(DSMBIRDT)* _____ *(mm/dd/yyyy)*
12. If 'Yes', date initial report circulated to the DSMB:*(DSMBSNDT)* _____ *(mm/dd/yyyy)*
13. Overall event reporting status to the DSMB:*(DSMBSTTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below
14. If 'Other', specify:*(DSMBSTSP)* _____
15. DSMB report reviewer status:*(DSMBREVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other
16. If 'Other', specify:*(DSMBROTH)* _____

Reporting to FDA

17. Does the event require expedited reporting to the FDA?*(FDAEX)* ☐ 1 - Yes ☐ 2 - No
18. If 'Yes', date FDA must be notified:*(FDANOTDT)* _____ *(mm/dd/yyyy)*
19. If 'Yes', date initial safety report must be circulated to the FDA:*(FDAIRDT)* _____ *(mm/dd/yyyy)*
20. If 'Yes', date initial safety report circulated to the FDA:*(FDASNTDT)* _____ *(mm/dd/yyyy)*

21. Overall event reporting status to the FDA:*(FDASTTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

22. If 'Other', specify:*(FDASTSP)*

23. FDA report reviewer status:*(FDAREVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

24. If 'Other', specify:*(FDAROTH)*

Reporting to Pharma Company #1

25. Name of pharma company #1:*(PC1NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

26. Does the event required expedited reporting to pharma company #1?*(PC1EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

27. If 'Yes', date initial report must be circulated to pharma company #1:*(PC1IRDT)* *(mm/dd/yyyy)*

28. If 'Yes', date initial report circulated to pharma company #1:*(PC1SNTDT)* *(mm/dd/yyyy)*

29. Overall event reporting status to pharma company #1:*(PC1STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

30. If 'Other', specify:*(PC1STSP)*

31. Pharma company #1 report reviewer status:*(PC1REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

32. If 'Other', specify:*(PC1ROTH)*

Reporting to Pharma Company #2

33. Name of pharma company #2:*(PC2NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

34. Does the event require expedited reporting to pharma company #2?*(PC2EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

35. If 'Yes', date initial report must be circulated to pharma company #2:*(PC2IRDT)* *(mm/dd/yyyy)*

36. If 'Yes', date initial report circulated to pharma company #2:*(PC2SNTDT)* *(mm/dd/yyyy)*

37. Overall event reporting status to pharma company #2:*(PC2STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

38. If 'Other', specify:*(PC2STSP)*

39. Pharma company #2 report reviewer status:*(PC2REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

40. If 'Other', specify:*(PC2ROTH)*

Reporting to Pharma Company #3

41. Name of pharma company #3:*(PC3NAME)*
    - 1 - Celgene
    - 2 - Millennium
    - 3 - Pfizer
    - 4 - Miltenyi
    - 5 - Novartis

42. Does the event require expedited reporting to pharma company #3?*(PC3EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

43. If 'Yes', date initial report must be circulated to pharma company #3:*(PC3IRDT)* *(mm/dd/yyyy)*

44. If 'Yes', date initial report circulated to pharma company #3:*(PC3SNTDT)* *(mm/dd/yyyy)*

45. Overall event reporting status to pharma company #3:*(PC3STTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below

46. If 'Other', specify:*(PC3STSP)*

47. Pharma company #3 report reviewer status:*(PC3REVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other

48. If 'Other', specify:*(PC3ROTH)*

Reporting to Pharma Company #4

49. Name of pharma company #4:*(PC4NAME)*
    - 1 - Celgene
    - 2 - Millennium
    - 3 - Pfizer
    - 4 - Miltenyi
    - 5 - Novartis

50. Does the event require expedited reporting to pharma company #4?*(PC4EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

51. If 'Yes' date initial report must be circulated to pharma company #4:*(PC4IRDT)* *(mm/dd/yyyy)*

52. If 'Yes', date initial report circulated to pharma company #4:*(PC4SNTDT)* *(mm/dd/yyyy)*

53. Overall event reporting status to pharma company #4:*(PC4STTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below

54. If 'Other', specify:*(PC4STSP)*

55. Pharma company #4 report reviewer status:*(PC4REVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other

56. If 'Other', specify:*(PC4ROTH)*

Comments:*(A99COMM)*

Additional Selection Options for A99

Overall event reporting status to the DSMB:
6 - Pending Circulation of Quaternary Follow-Up Report
7 - Closed; Reporting Complete
9 - Other

Blood and Marrow Transplant Clinical Trials Network

BMT AE Tracking Communications Form (A9C)

Web Version: 1.0; 1.01; 12-08-16

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

	Status	Communication Date	Communication Type	Contact Name	Contact Role
Communication #1*(A9C1RPT)* ☐ Report	*(A9C1STS)* Pending Resolved	*(A9C1DT)* *(mm/dd/yyyy)*	*(A9C1TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C1NME)*	*(A9C1RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #2*(A9C2RPT)* ☐ Report	*(A9C2STS)* Pending Resolved	*(A9C2DT)* *(mm/dd/yyyy)*	*(A9C2TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C2NME)*	*(A9C2RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #3*(A9C3RPT)* ☐ Report	*(A9C3STS)* Pending Resolved	*(A9C3DT)* *(mm/dd/yyyy)*	*(A9C3TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C3NME)*	*(A9C3RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #4*(A9C4RPT)* ☐ Report	*(A9C4STS)* Pending Resolved	*(A9C4DT)* *(mm/dd/yyyy)*	*(A9C4TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C4NME)*	*(A9C4RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #5*(A9C5RPT)* ☐ Report	*(A9C5STS)* Pending Resolved	*(A9C5DT)* *(mm/dd/yyyy)*	*(A9C5TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C5NME)*	*(A9C5RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #6*(A9C6RPT)* ☐ Report	*(A9C6STS)* Pending Resolved	*(A9C6DT)* *(mm/dd/yyyy)*	*(A9C6TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C6NME)*	*(A9C6RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below
Communication #7*(A9C7RPT)* ☐ Report	*(A9C7STS)*	*(A9C7DT)* *(mm/dd/yyyy)*	*(A9C7TYP)*	*(A9C7NME)*	*(A9C7RLE)*

	Pending Resolved		1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC		1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #8*(A9C8RPT)* Report	*(A9C8STS)* Pending Resolved	*(A9C8DT)* *(mm/dd/yyyy)*	*(A9C8TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C8NME)*	*(A9C8RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #9*(A9C9RPT)* Report	*(A9C9STS)* Pending Resolved	*(A9C9DT)* *(mm/dd/yyyy)*	*(A9C9TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C9NME)*	*(A9C9RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #10*(A9C10RPT)* Report	*(A9C10STS)* Pending Resolved	*(A9C10DT)* *(mm/dd/yyyy)*	*(A9C10TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C10NME)*	*(A9C10RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #11*(A9C11RPT)* Report	*(A9C11STS)* Pending Resolved	*(A9C11DT)* *(mm/dd/yyyy)*	*(A9C11TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C11NME)*	*(A9C11RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #12*(A9C12RPT)* Report	*(A9C12STS)* Pending Resolved	*(A9C12DT)* *(mm/dd/yyyy)*	*(A9C12TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C12NME)*	*(A9C12RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #13*(A9C13RPT)* Report	*(A9C13STS)* Pending Resolved	*(A9C13DT)* *(mm/dd/yyyy)*	*(A9C13TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C13NME)*	*(A9C13RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #14*(A9C14RPT)* Report	*(A9C14STS)* Pending Resolved	*(A9C14DT)* *(mm/dd/yyyy)*	*(A9C14TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C14NME)*	*(A9C14RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #15*(A9C15RPT)* Report	*(A9C15STS)* Pending Resolved	*(A9C15DT)* *(mm/dd/yyyy)*	*(A9C15TYP)*	*(A9C15NME)*	*(A9C15RLE)*	

			1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC		1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #16 *(A9C16RPT)* ☐ Report	*(A9C16STS)* Pending Resolved	*(A9C16DT)* *(mm/dd/yyyy)*	*(A9C16TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C16NME)*	*(A9C16RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #17 *(A9C17RPT)* ☐ Report	*(A9C17STS)* Pending Resolved	*(A9C17DT)* *(mm/dd/yyyy)*	*(A9C17TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C17NME)*	*(A9C17RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #18 *(A9C18RPT)* ☐ Report	*(A9C18STS)* Pending Resolved	*(A9C18DT)* *(mm/dd/yyyy)*	*(A9C18TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C18NME)*	*(A9C18RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #19 *(A9C19RPT)* ☐ Report	*(A9C19STS)* Pending Resolved	*(A9C19DT)* *(mm/dd/yyyy)*	*(A9C19TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C19NME)*	*(A9C19RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #20 *(A9C20RPT)* ☐ Report	*(A9C20STS)* Pending Resolved	*(A9C20DT)* *(mm/dd/yyyy)*	*(A9C20TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C20NME)*	*(A9C20RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #21 *(A9C21RPT)* ☐ Report	*(A9C21STS)* Pending Resolved	*(A9C21DT)* *(mm/dd/yyyy)*	*(A9C21TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C21NME)*	*(A9C21RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #22 *(A9C22RPT)* ☐ Report	*(A9C22STS)* Pending Resolved	*(A9C22DT)* *(mm/dd/yyyy)*	*(A9C22TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C22NME)*	*(A9C22RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	

Additional Selection Options for A9C

COM 1 Contact Role
6 - Pharma Rep
99 - Other

Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 5.00; 06-05-17

Segment *(PROTSEG)*: A

Date of Admission *(ADMITDT)*:

1. Date of discharge:*(DISCHDT)* _____ *(mm/dd/yyyy)*

2. Patient discharge status:*(DISCPTST)* ☐ 1 - Alive ☐ 2 - Dead

If Dead, a Death Form must be submitted.

3. Record PRIMARY discharge diagnosis:*(PHSPREAS)*

01 - GVHD
02 - Relapse/Progression
03 - Graft Failure
04 - Infection
05 - Fungal Infection
*Additional Options Listed Below

?

Specify organ:(ADM4SPEC)* _____

**Specify other:*(ADM1SPEC)* _____

4. Record secondary discharge diagnoses:

a. GVHD:*(REASGVHD)* ☐ 1 - Contributory ☐ 2 - Noncontributory ?

b. Relapse/progression:*(REASRLPS)* ☐ 1 - Contributory ☐ 2 - Noncontributory

c. Graft failure:*(REASGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory

d. Infection:*(REASINF)* ☐ 1 - Contributory ☐ 2 - Noncontributory

e. Fever:*(REASFVR)* ☐ 1 - Contributory ☐ 2 - Noncontributory

f. Seizure:*(REASSZR)* ☐ 1 - Contributory ☐ 2 - Noncontributory

g. Bleeding/hemorrhage:*(REASGIBL)* ☐ 1 - Contributory ☐ 2 - Noncontributory

h. Diarrhea:*(REASDRH)* ☐ 1 - Contributory ☐ 2 - Noncontributory

i. Nausea/vomiting:*(REASNV)* ☐ 1 - Contributory ☐ 2 - Noncontributory

j. Organ failure:*(REASORGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory

Specify organ:*(ADM3SPEC)* _____

k. Trauma:*(REASTRAM)* ☐ 1 - Contributory ☐ 2 - Noncontributory

l. Psychiatric:*(REASPSYC)* ☐ 1 - Contributory ☐ 2 - Noncontributory

m. Secondary malignancy:*(REASMALG)* ☐ 1 - Contributory ☐ 2 - Noncontributory

n. Scheduled procedure/treatment:*(REASPROC)* ☐ 1 - Contributory ☐ 2 - Noncontributory

o. Thrombosis/thrombus/embolism:*(REASTRMB)* ☐ 1 - Contributory ☐ 2 - Noncontributory

p. Other:*(REASOTHR)* ☐ 1 - Contributory ☐ 2 - Noncontributory

Specify other:*(ADM2SPEC)* _____

5. Record re-admission institution:*(ADMCENTR)*

1 - Original Transplant Center
2 - Other Transplant Center
3 - Other Hospital

Comments:*(ADMCOMM1)* _____

Additional Selection Options for ADM

Record PRIMARY discharge diagnosis:
06 - Non-Fungal Infection
07 - Fever
08 - Seizure
09 - Bleeding/Hemorrhage
10 - Diarrhea
11 - Nausea/Vomiting
12 - Organ Failure (specify organ)*
13 - Trauma
14 - Psychiatric
15 - Secondary Malignancy
16 - Transplant
17 - Scheduled Procedure/Treatment
18 - Thrombosis/Thrombus/Embolism
99 - Other (specify)**

Blood and Marrow Transplant Clinical Trials Network

Adverse Event Form (AE1)

Web Version: 1.0; 5.00; 01-28-16

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

1. Report activation status:*(AVSTATUS)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason

   If Other, specify reason for deactivation:*(AESPEC1)*
2. Record date transplant center became aware of the event:*(AVAWARDT)* *(mm/dd/yyyy)*
3. Indicate weight at time of the event:*(AVWGHTKG)* *(xxx.x)* kg
4. Was this event expected or anticipated?*(AVEXPECT)* ☐ 1 - Yes ☐ 2 - No
5. Record the severity of event:*(AVEVENT)*
   - 1 - Mild
   - 2 - Moderate
   - 3 - Severe
   - 4 - Life Threatening
   - 5 - Fatal
6. What is the relationship to study therapy/intervention:*(AVRELAT)*
   - 1 - Unrelated
   - 2 - Unlikely
   - 3 - Possible
   - 4 - Probable
   - 5 - Definite
7. Is there an alternative etiology:*(AVETIOL)*
   - 0 - None Apparent
   - 1 - Study Disease
   - 2 - Other Pre-Existing Disease or Condition
   - 3 - Accident, Trauma, or External Factors
   - 4 - Concurrent Illness/Condition (Not Pre-Existing)
8. What is the effect on study therapy/intervention schedule:*(AVEFFECT)*
   - 1 - No Change - Completed
   - 2 - No Change - Ongoing
   - 3 - Dose Modified
   - 4 - Temporarily Stopped
   - 5 - Permanently Stopped
9. Record the most severe outcome of the event:*(AVOUTCOM)*
   - 1 - Resolved, No Residual Effects
   - 2 - Resolved with Sequelae
   - 3 - Persistent Condition
   - 4 - Resolved by Death
10. Record the date of resolution:*(AVRESDT)* *(mm/dd/yyyy)*
11. Was this event associated with:*(AVASSOCI)*
    - 0 - None of the Following
    - 1 - Death
    - 2 - Life-Threatening Event
    - 3 - Disability
    - 4 - Congenital Anomaly
    - *Additional Options Listed Below

Comments:*(AE1COMM)*

Additional Selection Options for AE1

Was this event associated with:
5 - Required Intervention to Prevent Permanent Impairment or Damage
6 - Hospitalization (Initial or Prolonged)
9 - Other SAE

Blood and Marrow Transplant Clinical Trials Network

AE Summary Form (AE2)

Web Version: 1.0; 3.12; 10-16-15

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

1. Report activation status:*(AVSTAT_A)*

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

Relevant Past Medical History

2. Does the patient have any relevant history, including pre-existing medical conditions?*(SEMEDHXS)* ☐ 1 - Yes ☐ 2 - No

If Yes, include any relevant history, including preexisting medical conditions below.

(SEMEDHX)

3. **Event Summary**

Include clinical history of event, associated signs and symptoms, alternative etiologies being considered and medical management below.

(SESUMM)

---

4. Initial submitter:*(SEISUBBY)* Name: Date:*(SEISUBDT)* *(mm/dd/yyyy)*

5. Authorized submitter:*(SEASUBBY)* Name: Date:*(SEASUBDT)* *(mm/dd/yyyy)* ?

Blood and Marrow Transplant Clinical Trials Network

AE Therapy Form (AE3)

Web Version: 1.0; 4.05; 10-16-15

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

1. Report activation status:*(AVSTAT_B)*

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

Study Product/Suspect Medication Data

2. Was the patient receiving any study products/suspect medications?*(RCVSP)* ☐ 1 - Yes ☐ 2 - No

If Yes, list the study product/suspect medications the subject was taking in the grid below.

Study Product Name (Note: If blinded, indicate as such)	Dose of Study Product(s) at SAE Onset	Route of Study Product(s) at SAE Onset	Schedule of Study Product(s) at SAE Onset	Date Study Product First Started *(mm/dd/yyyy)*	Date Study Product Last Taken *(mm/dd/yyyy)*	Reason for Use
(SPNAME1)	*(SP1DOSE)*	*(SP1ROUTE)*	*(SP1SCHED)*	*(SP1STDT)*	*(SP1SPDT)*	*(SP1REASO)*
(SPNAME2)	*(SP2DOSE)*	*(SP2ROUTE)*	*(SP2SCHED)*	*(SP2STDT)*	*(SP2SPDT)*	*(SP2REASO)*
(SPNAME3)	*(SP3DOSE)*	*(SP3ROUTE)*	*(SP3SCHED)*	*(SP3STDT)*	*(SP3SPDT)*	*(SP3REASO)*
(SPNAME4)	*(SP4DOSE)*	*(SP4ROUTE)*	*(SP4SCHED)*	*(SP4STDT)*	*(SP4SPDT)*	*(SP4REASO)*
(SPNAME5)	*(SP5DOSE)*	*(SP5ROUTE)*	*(SP5SCHED)*	*(SP5STDT)*	*(SP5SPDT)*	*(SP5REASO)*

Concomitant Medications

3. Was the patient taking any concomitant medications?*(RCVCONMD)* ☐ 1 - Yes ☐ 2 - No

If Yes, list the concomitant medications the patient was taking up to 1 month prior to SAE onset in the grid below.

Medication	Start Date *(mm/dd/yyyy)*	Stop Date *(mm/dd/yyyy)*	Dose, Route, Schedule	Indication
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*	*(CM1INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*	*(CM2INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*	*(CM3INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*	*(CM4INDIC)*

				1 - Treatment of adverse event 9 - Other
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*	*(CM5INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED6)	*(CM6STDT)*	*(CM6SPDT)*	*(CM6DOSE)*	*(CM6INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED7)	*(CM7STDT)*	*(CM7SPDT)*	*(CM7DOSE)*	*(CM7INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED8)	*(CM8STDT)*	*(CM8SPDT)*	*(CM8DOSE)*	*(CM8INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED9)	*(CM9STDT)*	*(CM9SPDT)*	*(CM9DOSE)*	*(CM9INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED10)	*(CM10STDT)*	*(CM10SPDT)*	*(CM10DOSE)*	*(CM10INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED11)	*(CM11STDT)*	*(CM11SPDT)*	*(CM11DOSE)*	*(CM11INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED12)	*(CM12STDT)*	*(CM12SPDT)*	*(CM12DOSE)*	*(CM12INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED13)	*(CM13STDT)*	*(CM13SPDT)*	*(CM13DOSE)*	*(CM13INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED14)	*(CM14STDT)*	*(CM14SPDT)*	*(CM14DOSE)*	*(CM14INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED15)	*(CM15STDT)*	*(CM15SPDT)*	*(CM15DOSE)*	*(CM15INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED16)	*(CM16STDT)*	*(CM16SPDT)*	*(CM16DOSE)*	*(CM16INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED17)	*(CM17STDT)*	*(CM17SPDT)*	*(CM17DOSE)*	*(CM17INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED18)	*(CM18STDT)*	*(CM18SPDT)*	*(CM18DOSE)*	*(CM18INDI)* 1 - Treatment of adverse event 9 - Other

(CONMED19)	*(CM19STDT)*	*(CM19SPDT)*	*(CM19DOSE)*	*(CM19INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED20)	*(CM20STDT)*	*(CM20SPDT)*	*(CM20DOSE)*	*(CM20INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED21)	*(CM21STDT)*	*(CM21SPDT)*	*(CM21DOSE)*	*(CM21INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED22)	*(CM22STDT)*	*(CM22SPDT)*	*(CM22DOSE)*	*(CM22INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED23)	*(CM23STDT)*	*(CM23SPDT)*	*(CM23DOSE)*	*(CM23INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED24)	*(CM24STDT)*	*(CM24SPDT)*	*(CM24DOSE)*	*(CM24INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED25)	*(CM25STDT)*	*(CM25SPDT)*	*(CM25DOSE)*	*(CM25INDI)* 1 - Treatment of adverse event 9 - Other

Comments:*(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Laboratory/Diagnostics Form (AE4)

Web Version: 1.0; 3.12; 06-16-16

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

1. Report activation status:*(AVSTAT_C)*

1 - Keep report active
2 - Deactivate - Report filed in error
3 - Deactivate - Key field error
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)	Lab Value Previous to this SAE (Include units)	Collection Date for Previous Lab *(mm/dd/yyyy)*
(ADLTST1)	*(ADL1CD)*	*(ADL1RES)*	*(ADL1NORG)*	*(ADL1PRVL)*	*(ADL1PCD)*
(ADLTST2)	*(ADL2CD)*	*(ADL2RES)*	*(ADL2NORG)*	*(ADL2PRVL)*	*(ADL2PCD)*
(ADLTST3)	*(ADL3CD)*	*(ADL3RES)*	*(ADL3NORG)*	*(ADL3PRVL)*	*(ADL3PCD)*
(ADLTST4)	*(ADL4CD)*	*(ADL4RES)*	*(ADL4NORG)*	*(ADL4PRVL)*	*(ADL4PCD)*
(ADLTST5)	*(ADL5CD)*	*(ADL5RES)*	*(ADL5NORG)*	*(ADL5PRVL)*	*(ADL5PCD)*
(ADLTST6)	*(ADL6CD)*	*(ADL6RES)*	*(ADL6NORG)*	*(ADL6PRVL)*	*(ADL6PCD)*
(ADLTST7)	*(ADL7CD)*	*(ADL7RES)*	*(ADL7NORG)*	*(ADL7PRVL)*	*(ADL7PCD)*
(ADLTST8)	*(ADL8CD)*	*(ADL8RES)*	*(ADL8NORG)*	*(ADL8PRVL)*	*(ADL8PCD)*
(ADLTST9)	*(ADL9CD)*	*(ADL9RES)*	*(ADL9NORG)*	*(ADL9PRVL)*	*(ADL9PCD)*
(ADLTST10)	*(ADL10CD)*	*(ADL10RES)*	*(ADL10NRG)*	*(ADL10PVL)*	*(ADL10PCD)*

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
(ADDTS1)	*(AD1DTDAT)*	*(AD1DTRES)*

(ADDTS2)	*(AD2DTDAT)*	*(AD2DTRES)*
(ADDTS3)	*(AD3DTDAT)*	*(AD3DTRES)*
(ADDTS4)	*(AD4DTDAT)*	*(AD4DTRES)*
(ADDTS5)	*(AD5DTDAT)*	*(AD5DTRES)*
(ADDTS6)	*(AD6DTDAT)*	*(AD6DTRES)*
(ADDTS7)	*(AD7DTDAT)*	*(AD7DTRES)*
(ADDTS8)	*(AD8DTDAT)*	*(AD8DTRES)*
(ADDTS9)	*(AD9DTDAT)*	*(AD9DTRES)*
(ADDTS10)	*(AD10DTDT)*	*(AD10DTRS)*

Comments:*(AE4COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Review Form (AE5)

Web Version: 1.0; 3.12; 10-16-15

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

1. Report activation status:*(AVSTAT_D)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 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)*

Blood and Marrow Transplant Clinical Trials Network

AE Medical Monitor Reviewer Form (AE6)

Web Version: 1.0; 9.00; 03-06-17

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

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 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 the patient be withdrawn from further protocol therapy? *(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
5. Is the review complete?*(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
6. If **No**, what additional information is required:*(AMREVINF)*
7. Medical Monitor event description:*(AMMMEVDS)*
8. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
   - 1 - Grade 1
   - 2 - Grade 2
   - 3 - Grade 3
   - 4 - Grade 4
   - 5 - Grade 5

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up GVHD Form (CGV)

Web Version: 1.0; 7.04; 10-16-15

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Start of assessment period:*(DTPRVAST)* _____ *(mm/dd/yyyy)*
2. End of assessment period:*(DTASSESS)* _____ *(mm/dd/yyyy)*

Answer questions 3-9 relating to acute GVHD.

3. Maximum overall grade of acute GVHD during this assessment period:*(GRDAGVHD)*
   - 0 - No Symptoms of Acute GVHD
   - 1 - I
   - 2 - II
   - 3 - III
   - 4 - IV
4. Did clinical signs and/or symptoms of acute GVHD develop during this assessment period?*(AGVDVLP)* ☐ 1 - Yes ☐ 2 - No ?
   5. Record method used to diagnose acute GVHD:*(DGNSAGVH)*
      - 1 - Histologic Evidence
      - 2 - Clinical Evidence
      - 3 - Both
   6. Date of diagnosis of acute GVHD:*(DTDGNAGV)* _____ *(mm/dd/yyyy)* ?
7. Was prophylaxis for GVHD given during this assessment period?*(PROPHIMM)*
   - 1 - Yes
   - 2 - No
   - 3 - Discontinued During This Assessment Period
   8. If yes, specify all immunosuppressants used for GVHD prophylaxis:
      a. Cyclosporine:*(PROPHCY)* ☐ 1 - Yes ☐ 2 - No
      b. Tacrolimus:*(PROPHTAC)* ☐ 1 - Yes ☐ 2 - No
      c. Sirolimus:*(PROPHSIR)* ☐ 1 - Yes ☐ 2 - No
      d. MMF:*(PROPHMMF)* ☐ 1 - Yes ☐ 2 - No
      e. Prednisone:*(PROPHPRD)* ☐ 1 - Yes ☐ 2 - No
      f. Other:*(PROPHOTH)* ☐ 1 - Yes ☐ 2 - No
      Specify other agent used:*(PRPHOTSP)* _____
   9. If GVHD prophylaxis was discontinued during this assessment, record the date:*(PRPHDISC)* _____ *(mm/dd/yyyy)*

Answer questions 10-20 relating to chronic GVHD.

10. Maximum overall severity of chronic GVHD during this assessment period:*(SEVCGVHD)*
    - 0 - No Symptoms of Chronic GVHD
    - 1 - Mild
    - 2 - Moderate
    - 3 - Severe
11. Maximum overall grade of chronic GVHD during this assessment period:*(GRDCGVHD)* ☐ 1 - Limited ☐ 2 - Extensive ?
12. Did clinical signs and/or symptoms of chronic GVHD develop during this assessment period?*(CGVDVLP)* ☐ 1 - Yes ☐ 2 - No ?
    13. Record method used to diagnose chronic GVHD:*(DGNSCGVH)*
        - 1 - Histologic Evidence
        - 2 - Clinical Evidence
        - 3 - Both
    14. Date of diagnosis of chronic GVHD:*(DTDGNCGV)* _____ *(mm/dd/yyyy)* ?

15. Minimum Karnofsky/Lansky Score at time of diagnosis: *(CGVKRNLN)*

- 01 - 100 (Normal; No Complaints/Fully Active)
- 02 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
- 03 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
- 04 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
- 05 - 60 (Requires Occasional Assistance/Minimal Active Play)
- *Additional Options Listed Below

16. Minimum platelet count at time of diagnosis: *(PLTLTCNT)* _____ *(xxx.x)* x 10^9/L

17. Alkaline phosphatase at time of diagnosis: *(ALKPHOSP)* _____ *(xxxx)* U/L

18. Weight at time of diagnosis: *(CGVWEIGH)* _____ *(xxx.x)* kg

19. Total bilirubin at time of diagnosis: *(BILIRUBN)* _____ *(xx.x)* mg/dL

20. Body surface area involved with rash at time of diagnosis: *(BSA)* _____ *(xxx)* % ?

Indicate the maximum severity of involvement for the following organ systems during this assessment period.

Skin/Hair

21. Extent of skin involvement: *(CGVRASH)*

- 0 - No Rash
- 1 - <25% of BSA Involvement
- 2 - 25-50% of BSA Involvement
- 3 - >50% of BSA Involvement
- 4 - Generalized Involvement

?

If there is skin involvement, indicate the type of rash:

a. Lichenoid: *(RASHLICH)* ☐ 1 - Yes ☐ 2 - No

b. Maculopapular: *(RASHMACU)* ☐ 1 - Yes ☐ 2 - No

c. Sclerodermatous: *(RASHSCLR)* ☐ 1 - Yes ☐ 2 - No

Ocular

22. Xerophthalmia: *(DRYEYES)*

- 0 - No Symptoms
- 1 - Dry Eyes but Not Requiring Therapy
- 2 - Dryness of Eyes or Inflammation Requiring Therapy

Oral

23. Mucositis/ulcers (functional): *(MUCOFXN)*

- 0 - No Symptoms
- 1 - Minimal Symptoms, Normal Diet
- 2 - Symptomatic but Can Eat and Swallow Modified Diet
- 3 - Symptomatic and Unable to Adequately Aliment or Hydrate Orally

Pulmonary

24. Dyspnea: *(CGVDYSPN)*

- 0 - Asymptomatic
- 1 - Dyspnea with Exertion
- 2 - Dyspnea with Normal Activities
- 3 - Dyspnea at Rest

25. Pulmonary fibrosis: *(PULMFIBR)*

- 0 - None
- 1 - Minimal Radiographic Findings
- 2 - Patchy or Bi-basilar Radiographic Findings
- 3 - Extensive Radiographic Findings
- 9 - Not Done

26. Bronchiolitis obliterans: *(BRNCOBLT)*

- 1 - Yes, Histologic diagnosis
- 2 - Yes, Clinical diagnosis
- 3 - No
- 4 - Unknown

27. FEV1:*(CGVFEV1)*

0 - 100-90%
1 - <90-75%
2 - <75-50%
3 - <50-25%
4 - <25%

28. Oxygen saturation:*(O2SAT)*

0 - No Symptoms
1 - Desaturation with Exercise
2 - Requires Supplemental Oxygen

Gastrointestinal

29. Esophagus:*(ESOPHAGS)*

0 - No Changes
1 - Symptomatic but Can Eat Regular Diet
2 - Dysphagia or Odynophagia Requiring Dietary Changes
3 - Need for Parenteral Nutrition

30. Nausea and vomiting:*(NAUSVOMT)*

0 - No Protracted Nausea and Vomiting
1 - Persistent Nausea, Vomiting or Anorexia

31. Diarrhea:*(CGVDIARH)*

0 - None
1 - Persisting Less Than 2 Weeks
2 - Persisting More Than 2 Weeks

32. Was diarrhea measured as number of stools or volume of stools?*(DIARHMSR)*

1 - Number of Stools
2 - Volume of Stools
3 - Both Number and Volume

33. Diarrhea (number of stools):*(DIARHEA1)*

1 - Increase of <4 Stools/day Over Baseline; Mild Increase in Ostomy Output Compared to Baseline
2 - Increase of 4-6 stools/day; IV Fluids Indicated <24 Hrs; Moderate Increase in Ostomy Output
3 - Increase of 7 or More Stools/day, IV Fluids for 24 or More Hrs; Hospitalization
4 - Life-threatening Consequences (e.g. Hemodynamic Collapse)
5 - Death

Use mL/day for adult recipients and mL/m^2 for pediatric recipients.

34. Diarrhea (volume of stools):*(DIARHEA2)*

1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m^2
2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m^2
3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m^2
4 - Diarrhea >1500 mL/day or >833 mL/m^2
5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

35. Malabsorption:*(MALABSRP)*

0 - No Symptoms
2 - Altered Diet; Oral Therapies Indicated (e.g. Enzymes, Medications, Dietary Supplements)
3 - Inability to Aliment Adequately via GI Tract (e.g. TPN Indicated)
4 - Life-threatening Consequences
5 - Death

Hepatic

36. Bilirubin level:*(LIVERBIL)*

0 - Bilirubin <2.0 mg/dL
1 - Bilirubin 2.0-3.0 mg/dL
2 - Bilirubin 3.1-6.0 mg/dL
3 - Bilirubin 6.1-15.0 mg/dL
4 - Bilirubin >15.0 mg/dL

Genitourinary

37. Vaginitis:*(VAGNITIS)*

0 - No Symptoms or Not Applicable
1 - Mild, Intervention Not Indicated
2 - Moderate, Intervention Indicated
3 - Severe, Not Relieved with Treatment; Ulceration

Musculoskeletal

38. Contractures:*(CONTRCTR)*
0 - No Symptoms
2 - Mild Joint Contractures (Does not Affect ADL)
3 - Severe Joint Contractures (Interferes with ADL)

39. Myositis:*(MYOSITIS)* ☐ 1 - Yes ☐ 2 - No

Hematologic

40. Eosinophilia:*(EOSINPHL)* ☐ 1 - Yes ☐ 2 - No

Other

41. Serositis:*(SEROSITS)* ☐ 1 - Yes ☐ 2 - No

42. Fascitis:*(FASCITIS)* ☐ 1 - Yes ☐ 2 - No

43. Was there other organ involvement?*(ORGNOTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other organ:*(ORGSPEC)*

Answer questions 44-50 relating to biopsies performed during this assessment period.

44. Were any biopsies performed during this assessment period for suspected GVHD?*(BIOPSY)* ☐ 1 - Yes ☐ 2 - No

If yes, record the type, date, and result of any biopsies performed for suspected GVHD below.

Type of Biopsy:	If Other, Specify:	Date of Biopsy:	Result of Biopsy:
45. *(BIOTYP1)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP1OSPE)*	*(BIODT1)* *(mm/dd/yyyy)*	*(BIORSLT1)* 1 - Positive 2 - Negative 3 - Equivocal
46. *(BIOTYP2)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP2OSPE)*	*(BIODT2)* *(mm/dd/yyyy)*	*(BIORSLT2)* 1 - Positive 2 - Negative 3 - Equivocal
47. *(BIOTYP3)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP3OSPE)*	*(BIODT3)* *(mm/dd/yyyy)*	*(BIORSLT3)* 1 - Positive 2 - Negative 3 - Equivocal
48. *(BIOTYP4)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP4OSPE)*	*(BIODT4)* *(mm/dd/yyyy)*	*(BIORSLT4)* 1 - Positive 2 - Negative 3 - Equivocal
49. *(BIOTYP5)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP5OSPE)*	*(BIODT5)* *(mm/dd/yyyy)*	*(BIORSLT5)* 1 - Positive 2 - Negative 3 - Equivocal

50. *(BIOTYP6)*	*(TYP6OSPE)*	*(BIODT6)* (mm/dd/yyyy)	*(BIORSLT6)*
1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below			1 - Positive 2 - Negative 3 - Equivocal

Answer questions 51-54 relating to GVHD therapy.

51. Was a specific therapy used to **treat** GVHD during this assessment period?*(THRPYUSD)*

1 - Yes, Initiated this Assessment Period
2 - Yes, Continuing from Previous Assessment Period
3 - No

If yes, indicate whether or not the agents listed below were used to **treat** GVHD during this assessment period:

a. ALS, ALG, ATS, ATG:*(THRPYATG)*

b. Azathioprine:*(THRPYAZA)*

c. Cyclosporine:*(THRPYCYC)*

d. Systemic Corticosteroids:*(THRPYSCO)*

e. Topical Corticosteroids:*(THRPYTCO)*

f. Thalidomide:*(THRPYTHA)*

g. Tacrolimus (FK 506, Prograf):*(THRPYTAC)*

h. Mycophenolate Mofetil (MMF, Cellcept):*(THRPYMMF)*

i. PUVA (Psoralen and UVA):*(THRPYPUV)*

j. ECP (Extra-corporeal Photopheresis):*(THRPYECP)*

k. Sirolimus (Rapamycin):*(THRPYSIR)*

l. Etretinate:*(THRPYETR)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

m. Lamprene:*(THRPYLAM)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

n. Etanercept:*(THRPYETA)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

o. Zenapax (Daclizumab):*(THRPYZEN)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

p. Chloroquine Phosphate:*(THRPYCPH)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

q. In Vivo Anti T-lymphocyte Monoclonal Antibody: *(THRPYMAB)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

Specify in vivo anti T-lymphocyte monoclonal antibody used:*(MABAGNT)*

r. In Vivo Immunotoxin:*(THRPYIMM)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

Specify in vivo immunotoxin used:*(IMMAGNT)*

s. Other:*(THRPYOTH)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
3 - No, Drug Not Given

Specify other agent used:*(OTHAGNT)*

52. Has treatment been discontinued?*(ONGTRT)* ☐ 1 - Yes ☐ 2 - No

53. If yes, enter date of discontinuation:*(TRTSTOP)* *(mm/dd/yyyy)*

54. Indicate the best response to GVHD therapy during this assessment period:*(THRPYRSP)*

1 - Complete Resolution of Symptoms
2 - Partial Resolution of Symptoms
3 - Stable Symptoms
4 - Progression of Symptoms

?

Answer questions 55-58 relating to current patient status.

55. Are symptoms of GVHD still present?*(GVHDSYMP)* ☐ 1 - Yes ☐ 2 - No

56. Current Karnofsky/Lansky Score:*(CURKRNLN)*

01 - 100 (Normal; No Complaints/Fully Active)
02 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
03 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
04 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
05 - 60 (Requires Occasional Assistance/Minimal Active Play)
*Additional Options Listed Below

57. Current platelet count:*(CURPLTCT)* *(xxx.x)* $x10^9/L$

58. Current weight:*(CURWGHT)* *(xxx.x)* kg

Comments:*(CGVCOMM)*

Additional Selection Options for CGV

Minimum Karnofsky/Lansky Score at time of diagnosis:
06 - 50 (Requires Considerable Assistance/No Active Play)
07 - 40 (Disabled/Able to Initiate Quiet Activities)
08 - 30 (Severely Disabled/Needs Assistance for Quiet Play)
09 - 20 (Very Sick/Limited to Very Passive Activity)
10 - 10 (Moribund; Completely Disabled)

Biopsy Type 1
6 - Lung Biopsy
7 - Other, Specify

Current Karnofsky/Lansky Score:
06 - 50 (Requires Considerable Assistance/No Active Play)
07 - 40 (Disabled/Able to Initiate Quiet Activities)
08 - 30 (Severly Disabled/Needs Assistance for Quiet Play)
09 - 20 (Very Sick/Limited to Very Passive Activity)
10 - 10 (Moribund; Completely Disabled)
11 - 0 (Dead)

Blood and Marrow Transplant Clinical Trials Network

CIBMTR Recipient ID (CID)

Web Version: 1.0; 1.06; 10-16-15

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. CRID # (CIBMTR Recipient ID):*(CRIDNM)* *(xxxxxxxxxx)*

Comments:*(CIDCOMM)*

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CMV Specimen Form (CMV)

Web Version: 1.0; 1.00; 10-16-15

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Was a sample collected for CMV testing?*(HIVBLCMV)* ☐ 1 - Yes ☐ 2 - No

2. If yes, record date sample for CMV testing was obtained:*(HIVCMVDT)* _____ *(mm/dd/yyyy)*

3. Result of CMV test:*(HIVCMVRS)*

1 - Positive
2 - Negative
3 - Below level of detection

4. CMV viral load:*(HIVCMVLD)* _____ *(xxxxxx)* copies/mL

Comments:*(HIVCMVCM)*

Blood and Marrow Transplant Clinical Trials Network

Conditioning Regimen Form - 0903 (CR4)

Web Version: 1.0; 1.00; 10-16-15

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Record the patient's weight prior to initiation of conditioning: *(CR4WGHT)* _____ *(xxx.x)* kg
2. Record the date the weight was determined: *(CR4WGHDT)* _____ *(mm/dd/yyyy)*
3. Record the patient's body surface area (BSA) prior to initiation of conditioning: *(CR4BSA)* _____ *(x.xx)* m^2
4. Record the date the BSA was determined: *(CR4BSADT)* _____ *(mm/dd/yyyy)*
5. Did the patient receive a myeloablative or reduced intensity conditioning regimen? *(CR4CNDIN)* ☐ 1 - Myeloablative ☐ 2 - Reduced Intensity
6. Indicate the myeloablative conditioning regimen the patient received: *(CR4MYABL)*
   - 1 - Busulfan/Fludarabine (Bu/Flu)
   - 2 - Cyclophosphamide/Total Body Irradiation (Cy/TBI)
   - 3 - Other, specify
7. Indicate the reduced intensity conditioning regimen the patient received: *(CR4REDIN)*
   - 1 - Fludarabine/Busulfan (Flu/Bu)
   - 2 - Fludarabine/Melphalan (Flu/Mel)
   - 3 - Other, specify
8. If other conditioning regimen was received, specify the drugs received and the dosing schedule: *(CR4OTCON)* _____

Record the dates the patient received the following drugs and the total dose received:

	Start Date	Stop Date	Total Dose
9. Fludarabine:	*(CR4FSTDT)* _____ *(mm/dd/yyyy)*	*(CR4FSPDT)* _____ *(mm/dd/yyyy)*	*(CR4FLDS)* _____ *(xxxx)* mg
10. Busulfan:	*(CR4BSTDT)* _____ *(mm/dd/yyyy)*	*(CR4BSPDT)* _____ *(mm/dd/yyyy)*	*(CR4BUDS)* _____ *(xxxx)* mg
11. Melphalan:	*(CR4MSTDT)* _____ *(mm/dd/yyyy)*	*(CR4MSPDT)* _____ *(mm/dd/yyyy)*	*(CR4MPTD)* _____ *(xxxx)* mg
12. Cyclophosphamide:	*(CR4CSTDT)* _____ *(mm/dd/yyyy)*	*(CR4CSPDT)* _____ *(mm/dd/yyyy)*	*(CR4CYDS)* _____ *(xxxx)* mg
13. Total Body Irradiation:	*(CR4TSTDT)* _____ *(mm/dd/yyyy)*	*(CR4TSPDT)* _____ *(mm/dd/yyyy)*	*(CR4TBIDS)* _____ *(xxxx)* cGy

14. Indicate the GVHD prophylaxis regimen the patient received: *(CR4GVHDP)*
    - 1 - Tacrolimus/Methotrexate (Tac/MTX)
    - 2 - Tacrolimus/Sirolimus (Tac/Sir)
    - 3 - Post-Transplant Cyclophosphamide (Post-TXP Cy)
    - 4 - Post-Transplant Cyclophosphamide/Tacrolimus/ Mycophenolate Mofetil (Post-TXP Cy/Tac/MMF)

Comments: *(CR4CMMNT)* _____

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Demographics (DEM)

Web Version: 1.0; 6.02; 12-02-15

1. Name Code:*(NAMECODE)*
2. IUBMID # (if available):*(IUBMID)*
3. Gender:*(GENDER)* ☐ 1 - Male ☐ 2 - Female
4. Date of Birth:*(DOB)* *(mm/dd/yyyy)*
5. Ethnicity:*(ETHNIC)*
   - 1- Hispanic or Latino
   - 2- Not Hispanic or Latino
   - 8- Unknown
   - 9- Not Answered
6. Race:*(RACE)*
   - White
   - 10 - White (Not Otherwise Specified)
   - 11 - European (Not Otherwise Specified)
   - 13 - Mediterranean
   - 14 - White North American
   - *Additional Options Listed Below

   Specify race:*(RACESP)*
7. Secondary Race:*(RACE2)*
   - White
   - 10 - White (Not Otherwise Specified)
   - 11 - European (Not Otherwise Specified)
   - 13 - Mediterranean
   - 14 - White North American
   - *Additional Options Listed Below

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

Web Version: 1.0; 4.16; 06-16-17

1. Record date of death:*(DTHDT)* *(mm/dd/yyyy)*

2. Was an autopsy performed?*(AUTPERF)* ☐ 1 - Yes ☐ 2 - No

If yes, attach de-identified autopsy report or death summary to the form below.

Enter appropriate cause of death code below. List in order of decreasing severity.

3. Primary cause of death:*(CZDTHPRM)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

?

Specify other:*(DTHSPEC1)*

4. Secondary cause of death:*(SCNDCZ1)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC2)*

5. Secondary cause of death:*(SCNDCZ2)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC3)*

6. Secondary cause of death:*(SCNDCZ3)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC4)*

7. Secondary cause of death:*(SCNDCZ4)*

1.0 - Graft Rejection or Failure
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

Additional Selection Options for DTH

Primary cause of death:
2.2 - Fungal
2.3 - Viral
2.4 - Protozoal
2.5 - Other, Specify Below
2.9 - Organism Not Identified
Interstitial Pneumonia
3.1 - Viral, CMV
3.2 - Viral, Other
3.3 - Pneumocystis
3.4 - Other, Specify Below
3.9 - Idiopathic
4.0 - Adult Respiratory Distress Syndrome
5.0 - Acute GVHD
6.0 - Chronic GVHD
7.0 - Recurrence or Persistence of Leukemia/Malignancy/MDS
7.1 - Persistent Disease
Organ Failure (Not Due to GVHD or Infection)
8.1 - Liver
8.2 - Cardiac (Cardiomyopathy)
8.3 - Pulmonary
8.4 - CNS
8.5 - Renal
8.6 - Other, Specify Below
8.7 - Multiple Organ Failure, Specify Below
8.8 - Secondary Graft Failure
9.0 - Secondary Malignancy
9.1 - EBV
9.2 - Other, Specify Below
Hemorrhage
10.1 - Pulmonary
10.2 - Intracranial
10.3 - Gastrointestinal
10.4 - Hemorrhage Not Specified
10.5 - Other, Specify Below
Vascular
11.1 - Thromboembolic
11.2 - Disseminated Intravascular Coagulation (DIC)
11.3 - Gastrointestinal
11.4 - Thrombotic Thrombocytopenic Purpura
11.5 - Vascular Not Specified
11.9 - Other, Specify Below
12.0 - Accidental Death
13.0 - Other, Specify Below

Blood and Marrow Transplant Clinical Trials Network

Endpoint Review Form - 0903 (E11)

Web Version: 1.0; 1.00; 06-28-16

Case ID *(CASEID)*:

Site:*(EXXSITE)* *(xxxxx)*

Patient ID:*(EXXPATID)*

1. Review Date:*(REVIEWDT)* *(mm/dd/yyyy)*
2. Primary Reviewer Name:*(REVNAME)*
   - Joe Alvarnas
   - Richard Ambinder
   - Uday Popat
   - Willis Navarro
3. Case Status:*(CASESTAT)*
   - 1- Complete (C)
   - 2- Query (Q)
   - 3- Ready for Review (R)
   - 4- Secondary Review (S)
4. Review Committee Comments:*(REVCOMM)*
5. EMMES Comments:*(EMMCOMM)*

Reviewer Adjudicated Fields

6. Did the patient die?*(PATDIED)* ☐ 1 - Yes ☐ 2 - No
   a. Primary cause of death:*(REVCOD)*
   - 1.0 - Graft Rejection or Failure
   - 1.1 - Autologous Recovery
   - Infection (Other than Interstitial Pneumonia)
   - 1.2 - Rejection
   - 2.1 - Bacterial
   - *Additional Options Listed Below

   b. Specify other COD:*(REVCODSP)*
7. Acute GVHD maximum grade:*(MAXAGVHD)*
   - 0- Grade 0
   - 1- Grade I
   - 2- Grade II
   - 3- Grade III
   - 4- Grade IV

   a. Grade II- IV acute GVHD onset date:*(AGVH24DT)* *(mm/dd/yyyy)*

   b. Grade III- IV acute GVHD onset date:*(AGVH34DT)* *(mm/dd/yyyy)*
8. Chronic GVHD maximum grade:*(MAXCGVHD)*
   - 0- None
   - 1- Limited
   - 2- Extensive

   a. Chronic GVHD onset date:*(CGVHDT)* *(mm/dd/yyyy)*

   b. Chronic GVHD maximum severity:*(CGMAXSEV)*
   - 1 - None
   - 2 - Mild
   - 3 - Moderate
   - 4 - Severe
9. Progression or relapse:*(PRGRLP)* ☐ 1 - Yes ☐ 2 - No
   a. Date of progression or relapse:*(PRGRLPDT)* *(mm/dd/yyyy)*

10. Disease Status at Study Entry:*(ENTRYDS)*

1- Complete Remission
2- Partial Remission
3- Stable Disease
4- Relapsed or Progressive Disease
5- Not Evaluable

11. Disease Status at Day 100:*(D0100DR)*

1- Complete Remission
2- Partial Remission
3- Stable Disease
4- Relapsed or Progressive Disease
5- Not Evaluable

a. Date of Day 100 Disease Status:*(D0100DT)* *(mm/dd/yyyy)*

12. Exclude patient from the primary analysis population?*(EXCLUDE)* ☐ 1 - Yes ☐ 2 - No

a. Specify reason for exclusion:*(EXCLUDSP)*

13. Was the patient eligible?*(ELIGIBLE)* ☐ 1 - Yes ☐ 2 - No

a. Specify reason for ineligibility:*(ELIGIBSP)*

14. Were treatment compliance issues identified?*(TRTCMPLY)* ☐ 1 - Yes ☐ 2 - No

a. Specify compliance issues:*(TRTCMPSP)*

15. Number of Queries:*(QUERYNUM)*

00- Its A Miracle!
01
02
03
04
*Additional Options Listed Below

Number of queries indicated will determine how many queries are captured on the query form.

Comments:*(EXXCOMM)*

Additional Selection Options for E11

Primary cause of death:
2.2 - Fungal
2.3 - Viral
2.4 - Protozoal
2.5 - Other, Specify Below
2.9 - Organism Not Identified
Interstitial Pneumonia
3.1 - Viral, CMV
3.2 - Viral, Other
3.3 - Pneumocystis
3.4 - Other, Specify Below
3.9 - Idiopathic
4.0 - Adult Respiratory Distress Syndrome
5.0 - Acute GVHD
6.0 - Chronic GVHD
7.0 - Recurrence or Persistence of Leukemia/Malignancy/MDS
7.1 - Persistent Disease
Organ Failure (Not Due to GVHD or Infection)
8.1 - Liver
8.2 - Cardiac (Cardiomyopathy)
8.3 - Pulmonary
8.4 - CNS
8.5 - Renal
8.6 - Other, Specify Below
8.7 - Multiple Organ Failure, Specify Below
8.8 - Secondary Graft Failure
9.0 - Secondary Malignancy
9.1 - EBV
9.2 - Other, Specify Below
Hemorrhage
10.1 - Pulmonary
10.2 - Intracranial
10.3 - Gastrointestinal
10.4 - Hemorrhage Not Specified
10.5 - Other, Specify Below
Vascular
11.1 - Thromboembolic
11.2 - Disseminated Intravascular Coagulation (DIC)
11.3 - Gastrointestinal
11.4 - Thrombotic Thrombocytopenic Purpura
11.5 - Vascular Not Specified
11.9 - Other, Specify Below
12.0 - Accidental Death
13.0 - Other, Specify Below

Number of Queries:
05 - Could Be Worse
06
07
08
09
10 - Just Start Over

Blood and Marrow Transplant Clinical Trials Network

0903A (ENR)

Web Version: 1.0; 3.01; 10-16-15

Allogeneic HIV Transplant - Segment A

1. Patient's date of birth:*(PATIDOB)* 12/07/1977 *(mm/dd/yyyy)*
2. Proposed date of initiation of conditioning:*(HIVCONDT)* *(mm/dd/yyyy)*

Inclusion Criteria

3. Patient diagnosis:*(HIVDIS)*
   - 1 - Acute Myeloid Leukemia (AML)
   - 2 - Acute Lymphocytic Leukemia (ALL)
   - 3 - Myelodysplastic Syndromes (MDS)
   - 4 - Hodgkin Lymphoma
   - 5 - Non-Hodgkin Lymphoma
4. Patient's current leukemia status:*(LEUKSTAG)*
   - 1 - First Complete Remission
   - 2 - First Relapse
   - 3 - Second Complete Remission
   - 4 - Second Relapse
   - 5 - 3rd or Greater Complete Remission
   - *Additional Options Listed Below
5. Patient's current lymphoma status:*(LYMPSTAG)*
   - 1 - Complete Remission
   - 2 - Partial Remission
   - 3 - Stable Disease
   - 4 - Relapsed or Progressive Disease
6. Number of regimens of induction chemotherapy the patient has received: *(INDCHEMO)* *(x)*
7. Number of regimens of salvage chemotherapy the patient has received: *(SALCHEMO)* *(x)*
8. Does the patient have chemosensitive disease as demonstrated by at least a partial response to most recent therapy?*(PARTRESP)* ☐ 1 - Yes ☐ 2 - No
9. Percent of blasts in the bone marrow:*(PTBONMW)* *(xx)* %
10. Date of bone marrow biopsy:*(BONMWDT)* *(mm/dd/yyyy)*
11. Does the patient have cardiac disease?*(CARDISEA)* ☐ 1 - Yes ☐ 2 - No
12. American Heart Association (AHA) classification for the patient's cardiac disease:*(AHACLAS)*
    - 1 - Class I
    - 2 - Class II
    - 3 - Class III
    - 4 - Class IV

	Most Recent Value	ULN for Your Institution	Date of Assessment
13. LVEF:	*(HIVLVEF)* *(xxx)* %		*(HIVEFDT)* *(mm/dd/yyyy)*
14. Bilirubin:	*(BILIRUBI)* *(x.x)* mg/dL		*(HIVBILDT)* *(mm/dd/yyyy)*
15. ALT:	*(HIVALTV)* *(xxx)* Units/L	*(HIVALULN)* *(xxx)* Units/L	*(HIVALTDT)* *(mm/dd/yyyy)*
16. AST:	*(HIVASTV)* *(xxx)* Units/L	*(HIVASULN)* *(xxx)* Units/L	*(HIVASTDT)* *(mm/dd/yyyy)*
17. Creatinine Clearance:	*(HIVCCLEA)* *(xxx)* mL/min		*(HIVCCLDT)* *(mm/dd/yyyy)*
18. DLCO:	*(HIVDLCOV)* *(xxx)* % pred		*(HIVDLCDT)* *(mm/dd/yyyy)*
19. FEV1:	*(HIVFEV1V)* *(xxx)* % pred		*(HIVFEVDT)* *(mm/dd/yyyy)*

20. FVC:	*(HIVFVCV)* ☐ *(xxx)* % pred	*(HIVFVCDT)* ☐ *(mm/dd/yyyy)*

21. If the patient has a bilirubin >2.0 mg/dL, is it attributed to Gilbert Syndrome or antiretroviral therapy?*(GILBARV)* ☐ 1 - Yes ☐ 2 - No

22. Does the patient have an undetectable HIV viral load?*(UNDVIRAL)* ☐ 1 - Yes ☐ 2 - No

23. Patient's viral load:*(HIVVIRAL)* ☐ *(xxxxx)* copies/mL

24. Was the patient evaluated with HIV drug resistance testing?*(ARVRSTST)* ☐ 1 - Yes ☐ 2 - No

25. Date of approval from the Review Committee:*(REVAPPDT)* ☐ *(mm/dd/yyyy)*

26. Is the patient willing to comply with effective antiretroviral therapy?*(ARVCMPLY)* ☐ 1 - Yes ☐ 2 - No

27. Is the patient willing to use contraceptive techniques from the time of initiation of conditioning until six months post-transplant?*(USECONT)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

Exclusion Criteria

28. Patient's Karnofsky performance score:*(HIVKALAN)*

- 01 - 100 (Normal; No Complaints/Fully Active)
- 02 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
- 03 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
- 04 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
- 05 - 60 (Requires Occasional Assistance/Minimal Active Play)
- *Additional Options Listed Below

29. Does the patient have an active CNS malignancy?*(CNSMALIG)* ☐ 1 - Yes ☐ 2 - No

30. Does the patient have a history of positive CSF cytology that has become negative with intrathecal chemotherapy?*(CSFCTYOL)* ☐ 1 - Yes ☐ 2 - No

31. Does the patient have an uncontrolled bacterial, viral, or fungal infection (currently taking medication and with progression or no clinical improvement)? *(HIVINFEC)* ☐ 1 - Yes ☐ 2 - No

32. Does the patient have active CMV retinitis or other CMV-related organ dysfunction?*(HIVCMV)* ☐ 1 - Yes ☐ 2 - No

33. Does the patient have any AIDS related syndromes or symptoms that pose a perceived excessive risk for transplantation-related morbidity as determined by the principal investigator?*(AIDSYNDR)* ☐ 1 - Yes ☐ 2 - No

34. Does the patient have chronic hepatitis B or C?*(HEPBC)* ☐ 1 - Yes ☐ 2 - No

35. Does the patient have an undetectable hepatitis viral load (<500 copies/mL) by PCR?*(HEPVIRL)* ☐ 1 - Yes ☐ 2 - No

36. Does the patient have clinical or pathologic evidence of irreversible chronic liver disease?*(CHLVDIS)* ☐ 1 - Yes ☐ 2 - No

37. Is the patient pregnant (positive ß-HCG) or breastfeeding? (PREGBFBX)*(PTPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

38. Is the patient pregnant (positive ß-HCG) or breastfeeding? (PREGBFBX)*(PTPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

39. Has the patient had a previous allogeneic hematopoietic stem cell transplant? *(PRIORALL)* ☐ 1 - Yes ☐ 2 - No

40. Does the patient have any psychosocial conditions that would prevent study compliance and follow-up, as determined by the principal investigator? *(HIVPSYCH)* ☐ 1 - Yes ☐ 2 - No

Consent for Use of Biological Specimens for Research

41. Did the patient agree to provide blood for future research?*(PTRSCHSM)* ☐ 1 - Yes ☐ 2 - No

Comments:*(HIVCOMM)*

Additional Selection Options for ENR

Patient's current leukemia status:
6 - 3rd or Greater Relapse

Patient's Karnofsky performance score:
06 - 50 (Requires Considerable Assistance/No Active Play)
07 - 40 (Disabled/Able to Initiate Quiet Activities)
08 - 30 (Severely Disabled/Needs Assistance for Quiet Play)
09 - 20 (Very Sick/Limited to Very Passive Activity)
10 - 10 (Moribund; Completely Disabled)

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form - 0903 (F11)

Web Version: 1.0; 1.01; 10-16-15

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Date of last contact:*(F11CONDT)* _____ *(mm/dd/yyyy)*

Since the date of the last visit indicate if any of the following have occurred:

2. Has the patient died?*(F11PTDIE)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Death Form must be submitted.
   3. Date of patient death:*(F11DTHDT)* _____ *(mm/dd/yyyy)*
4. Has the patient relapsed or experienced disease progression?*(F11RELPR)* ☐ 1 - Yes ☐ 2 - No
   If Yes, de-identified source documentation of the relapse or progression should be attached to this form.
   5. Date of relapse or progression:*(F11RELDT)* _____ *(mm/dd/yyyy)*
6. Has the patient been treated for relapse or progression?*(F11RELTR)* ☐ 1 - Yes ☐ 2 - No
   7. Date treatment administered:*(F11TRTDT)* _____ *(mm/dd/yyyy)*
   8. Indicate type of treatment:*(F11TRTYP)*
      - 1 - DLI
      - 2 - Chemotherapy
      - 3 - Radiation
      - 4 - Second Transplant
      - 5 - Other Cellular Therapy
      - *Additional Options Listed Below
   9. Specify other treatment:*(F11SPOTH)* _____
10. Has the patient experienced any new clinically significant infections?*(F11NEWIN)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Infection Form must be submitted.
    11. Date of infection:*(F11INFDT)* _____ *(mm/dd/yyyy)*
12. Has the patient been hospitalized?*(F11HOSP)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Re-Admission Form must be submitted.
    13. Date of hospitalization:*(F11HOSDT)* _____ *(mm/dd/yyyy)*
14. Has the patient experienced any Unexpected, Grade 3-5 Adverse Events? *(F11UAE)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Unexpected, Grade 3-5 Adverse Event Form must be submitted.
    15. Date of onset of Unexpected, Grade 3-5 Adverse Event:*(F11UAEDT)* _____ *(mm/dd/yyyy)*

Comments:*(F11COMM)*

Additional Selection Options for F11

Indicate type of treatment:
6 - Other

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Web Version: 1.0; 10.14; 12-09-16

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Date of staging:*(STAGEDT)* _____ *(mm/dd/yyyy)*

   Start of GVHD Assessment Period:*(GVASSTDT)* _____ *(mm/dd/yyyy)*

   End of GVHD Assessment Period:*(GVASENDT)* _____ *(mm/dd/yyyy)*

   The assessment for which you are entering data must have taken place within the above dates. If the patient was not seen during the assessment period specified above, please exit the form and request an exception for this form.

2. Immunosuppressant (prophylaxis) received:*(IMMUNORC)*

   0 - Prednisone
   1 - Cyclosporine
   2 - Tacrolimus
   3 - Not taken during assessment

3. Record most recent blood level of immunosuppressant (prophylaxis): *(TROUGHLV)* _____ *(xxxx.x)* ng/mL

4. Record date blood sample obtained:*(TROUGHDT)* _____ *(mm/dd/yyyy)*

Record the highest level of organ abnormalities, the etiologies contributing to the abnormalities and any biopsy results during the assessment period.

5. Skin abnormalities:*(GVHSKINA)*

   0 - No Rash
   1 - Maculopapular Rash, <25% of Body Surface
   2 - Maculopapular Rash, 25-50% of Body Surface
   3 - Generalized Erythroderma
   4 - Generalized Erythroderma with Bullus Formation and Desquamation

6. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SETGVHD) ☐ 1 - Yes ☐ 2 - No	*(SETDRGRX)* ☐ 1 - Yes ☐ 2 - No	*(SETCRTOX)* ☐ 1 - Yes ☐ 2 - No

Infection	Other
(SETINFCT) ☐ 1 - Yes ☐ 2 - No	*(SETOTHER)* ☐ 1 - Yes ☐ 2 - No

Specify other skin etiologies:*(GVHSKNSP)* _____

7. Skin biopsy for GVHD:*(GVHSKINB)*

   1 - Positive
   2 - Negative
   3 - Equivocal
   4 - Not Done

8. Upper GI abnormalities:*(GVHUPGIA)*

   0 - No Protracted Nausea and Vomiting
   1 - Persistent Nausea, Vomiting or Anorexia

9. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(UGIETGVH) ☐ 1 - Yes ☐ 2 - No	*(UGIETDRG)* ☐ 1 - Yes ☐ 2 - No	*(UGIETCON)* ☐ 1 - Yes ☐ 2 - No

TPN	Infection	Other
(UGIETTPN) ☐ 1 - Yes ☐ 2 - No	*(UGIETINF)* ☐ 1 - Yes ☐ 2 - No	*(UGIETOTH)* ☐ 1 - Yes ☐ 2 - No

Specify other upper intestinal tract etiologies:*(UGIETSPC)*

10. Upper intestinal tract biopsy for GVHD:*(UGIBIORS)*

1 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

11. Lower GI abnormalities:*(GVHINTA)*

0 - No Diarrhea
1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m^2
2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m^2
3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m^2
4 - Diarrhea >1500 mL/day or >833 mL/m^2
*Additional Options Listed Below

Use mL/day for adult patients and mL/m^2 for pediatric patients

12. Lower intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(LGIETGVH) ☐ 1 - Yes ☐ 2 - No	*(LGIETDRG)* ☐ 1 - Yes ☐ 2 - No	*(LGIETCON)* ☐ 1 - Yes ☐ 2 - No
TPN	**Infection**	**Other**
(LGIETTPN) ☐ 1 - Yes ☐ 2 - No	*(LGIETINF)* ☐ 1 - Yes ☐ 2 - No	*(LGIETOTH)* ☐ 1 - Yes ☐ 2 - No

Specify other lower intestinal tract etiologies:*(LGIETSPC)*

13. Lower intestinal tract biopsy for GVHD:*(LGIBIORS)*

1 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

14. Liver abnormalities:*(GVHLIVRA)*

0 - Bilirubin <2.0 mg/dL
1 - Bilirubin 2.0-3.0 mg/dL
2 - Bilirubin 3.1-6.0 mg/dL
3 - Bilirubin 6.1-15.0 mg/dL
4 - Bilirubin >15.0 mg/dL

15. Liver etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity	TPN
(LIVETGVH) ☐ 1 - Yes ☐ 2 - No	*(LIVETDRG)* ☐ 1 - Yes ☐ 2 - No	*(LIVETCND)* ☐ 1 - Yes ☐ 2 - No	*(LIVETTPN)* ☐ 1 - Yes ☐ 2 - No
Infection	**VOD**	**Other**	
(LIVETINF) ☐ 1 - Yes ☐ 2 - No	*(LIVETVOD)* ☐ 1 - Yes ☐ 2 - No	*(LIVETOTH)* ☐ 1 - Yes ☐ 2 - No	

Specify other liver etiologies:*(GVHLIVRS)*

16. Liver biopsy for GVHD:*(GVHLIVRB)*

1 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

17. Was any treatment of GVHD modified during this assessment period? ☐ 1 - Yes ☐ 2 - No
(GVHTHERP)

This only applies to TREATMENT for GVHD. If GVHD prophylaxis was the only modification during this assessment period, this question should be answered "2 - No".

18. If yes, specify agent name:*(GVHAGENT)*

- 1 - CSA
- 2 - FK506
- 3 - Topical Steroids
- 4 - Prednisone
- 5 - ATG
- *Additional Options Listed Below

Specify other agent:*(GVHAGNSP)*

19. Indicate treatment modification:*(GVHTRMOD)*

- 1 - Started
- 2 - Stopped
- 4 - Tapered
- 5 - Increased

Comments:*(GVHCOMM)*

Additional Selection Options for GVH

Lower GI abnormalities:
5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

If yes, specify agent name:
6 - MMF
7 - Daclizumab
8 - Methylprednisolone
9 - Other

Blood and Marrow Transplant Clinical Trials Network

Hematopoiesis Form (HF1)

Web Version: 1.0; 3.00; 10-16-15

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Did the patient's ANC drop below 500/mm^3 after the initiation of the conditioning regimen?*(ANCDRP)* ☐ 1 - Yes ☐ 2 - No
   2. Did the patient achieve ANC ≥ 500/mm^3 for three consecutive measurements obtained on different days?*(ANCREC)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Previously Reported
      3. Record absolute neutrophil counts and dates obtained:

Day 1:	*(D1ANC)*	*(xxxxx)* /mm^3	*(D1ANCDT)*	*(mm/dd/yyyy)*	
Day 2:	*(D2ANC)*	*(xxxxx)* /mm^3	*(D2ANCDT)*	*(mm/dd/yyyy)*	
Day 3:	*(D3ANC)*	*(xxxxx)* /mm^3	*(D3ANCDT)*	*(mm/dd/yyyy)*	

4. If 'No', record the most recent absolute neutrophil count:*(RECNTANC)* *(xxxxx)* /mm^3
5. Date most recent absolute neutrophil count obtained:*(RCTANCDT)* *(mm/dd/yyyy)*

Record Chimerism Assay Data for Marrow and/or Blood

Upload source documents for all chimerism results during the assessment period.

Marrow:

6. Was a chimerism assay performed on a marrow sample during this assessment period?*(MRWCHIM)* ☐ 1 - Yes ☐ 2 - No
   7. Record date specimen collected:*(MRWCHIDT)* *(mm/dd/yyyy)*
   8. Record method of evaluation:*(MRWMTHD)*

1 - Standard Cytogenetics
2 - Fluorescent In Situ Hybridization (FISH)
3 - Restriction Fragment-Length Polymorphisms (RFLP)
4 - Polymerase Chain Reaction (PCR) [VNTR, STR, micro or mini satellite]
5 - HLA Serotyping
*Additional Options Listed Below

      9. Specify other method of evaluation:*(MRWMTHSP)*
   10. Record marrow chimerism cell type:*(MRWTYPE)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
   11. Record marrow assay results:*(MRWRSLT)*

1 - All Host Cells
2 - All Donor Cells
3 - Host and Donor

   12. Record % donor:*(MRWPCTD)* *(xx)* %

Blood:

13. Was a chimerism assay performed on a blood sample during this assessment period?*(BLDCHIM)* ☐ 1 - Yes ☐ 2 - No
   14. Record date specimen collected:*(BLDCHIDT)* *(mm/dd/yyyy)*
   15. Record method of evaluation:*(BLDMTHD)*

1 - Standard Cytogenetics
2 - Fluorescent In Situ Hybridization (FISH)
3 - Restriction Fragment-Length Polymorphisms (RFLP)
4 - Polymerase Chain Reaction (PCR) [VNTR, STR, micro or mini satellite]
5 - HLA Serotyping
*Additional Options Listed Below

      16. Specify other method of evaluation:*(BLDMTHSP)*
   17. Record blood chimerism cell type:*(BLDTYPE)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes

18. Record blood assay results:*(BLDRSLT)*

1 - All Host Cells
2 - All Donor Cells
3 - Host and Donor

19. Record % donor:*(BLDPCTD)*

(xx) %

T Cell (CD3+):

20. Was a chimerism assay performed on a T cell sample during this assessment period?*(TCLCHIM)*

☐ 1 - Yes ☐ 2 - No

21. Record date specimen collected:*(TCLCHIDT)*

(mm/dd/yyyy)

22. Record method of evaluation:*(TCLMTHD)*

1 - Standard Cytogenetics
2 - Fluorescent In Situ Hybridization (FISH)
3 - Restriction Fragment-Length Polymorphisms (RFLP)
4 - Polymerase Chain Reaction (PCR) [VNTR, STR, micro or mini satellite]
5 - HLA Serotyping
*Additional Options Listed Below

23. Specify other method of evaluation:*(TCLMTHSP)*

24. Record the type of T cell sample:*(TCLTYPE)*

☐ 1 - Blood ☐ 2 - Marrow

25. Record T cell assay results:*(TCLRSLT)*

1 - All Host Cells
2 - All Donor Cells
3 - Host and Donor

26. Record % donor:*(TCLPCTD)*

(xx) %

Comments:*(HTPCOMM)*

Additional Selection Options for HF1

Record method of evaluation:
9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Infection Form (IFN)

Web Version: 1.0; 3.00; 06-05-17

Segment *(PROTSEG)*: A
Infection Site *(INFSITE)*:
Infection Start Date *(INFSTDT)*:

INFECTION I

1. Is Infection I a nonmicrobiologically defined infection?*(IFN1NMCR)* ☐ 1 - Yes ☐ 2 - No ?
   2. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection?*(IFN1PTPN)* ☐ 1 - Yes ☐ 2 - No
      3. Did the patient require mechanical ventilation?*(IFN1PTVT)* ☐ 1 - Yes ☐ 2 - No
   4. Did the patient have typhlitis?*(IFN1PTTY)* ☐ 1 - Yes ☐ 2 - No
   5. Did the patient have severe sepsis without an identified organism?*(IFN1PSEP)* ☐ 1 - Yes ☐ 2 - No
   6. Type of infection:*(IFN1TYPE)*
      B - Bacteria
      V - Viral
      F - Fungal
      P - Protozoal
      O - Other
   7. Organism I:*(IFN1ORGN)*
      B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
      B02 - Agrobacterium radiobacter
      B03 - Alcaligenes xylosoxidans
      B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
      B05 - Bacillus (cereus, other species)
      *Additional Options Listed Below
      Specify other organism:*(IFN1OTSP)*
   8. Severity of infection:*(IFN1SVRT)*
      2 - Grade 2
      3 - Grade 3
9. Was there evidence of sepsis?*(IFN1EVSP)* ☐ 1 - Yes ☐ 2 - No
10. Was there evidence of new or worsening infiltrates at the time of the infection? *(IFN1EVIN)* ☐ 1 - Yes ☐ 2 - No

INFECTION II

11. Is Infection II a nonmicrobiologically defined infection?*(IFN2NMCR)* ☐ 1 - Yes ☐ 2 - No ?
    12. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection?*(IFN2PTPN)* ☐ 1 - Yes ☐ 2 - No
        13. Did the patient require mechanical ventilation?*(IFN2PTVT)* ☐ 1 - Yes ☐ 2 - No
    14. Did the patient have typhlitis?*(IFN2PTTY)* ☐ 1 - Yes ☐ 2 - No
    15. Did the patient have severe sepsis without an identified organism?*(IFN2PSEP)* ☐ 1 - Yes ☐ 2 - No
    16. Type of infection:*(IFN2TYPE)*
        B - Bacteria
        V - Viral
        F - Fungal
        P - Protozoal
        O - Other
    17. Organism II:*(IFN2ORGN)*
        B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
        B02 - Agrobacterium radiobacter
        B03 - Alcaligenes xylosoxidans
        B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
        B05 - Bacillus (cereus, other species)
        *Additional Options Listed Below
        Specify other organism:*(IFN2OTSP)*

18. Severity of infection:*(IFN2SVRT)*

2 - Grade 2
3 - Grade 3

19. Was there evidence of sepsis?*(IFN2EVSP)* ☐ 1 - Yes ☐ 2 - No

20. Was there evidence of new or worsening infiltrates at the time of the infection? *(IFN2EVIN)* ☐ 1 - Yes ☐ 2 - No

INFECTION III

21. Is Infection III a nonmicrobiologically defined infection?*(IFN3NMCR)* ☐ 1 - Yes ☐ 2 - No ?

22. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection?*(IFN3PTPN)* ☐ 1 - Yes ☐ 2 - No

23. Did the patient require mechanical ventilation?*(IFN3PTVT)* ☐ 1 - Yes ☐ 2 - No

24. Did the patient have typhlitis?*(IFN3PTTY)* ☐ 1 - Yes ☐ 2 - No

25. Did the patient have severe sepsis without an identified organism?*(IFN3PSEP)* ☐ 1 - Yes ☐ 2 - No

26. Type of infection:*(IFN3TYPE)*

B - Bacteria
V - Viral
F - Fungal
P - Protozoal
O - Other

27. Organism III:*(IFN3ORGN)*

B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
B02 - Agrobacterium radiobacter
B03 - Alcaligenes xylosoxidans
B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
B05 - Bacillus (cereus, other species)
*Additional Options Listed Below

Specify other organism:*(IFN3OTSP)*

28. Severity of infection:*(IFN3SVRT)*

2 - Grade 2
3 - Grade 3

29. Was there evidence of sepsis?*(IFN3EVSP)* ☐ 1 - Yes ☐ 2 - No

30. Was there evidence of new or worsening infiltrates at the time of the infection? *(IFN3EVIN)* ☐ 1 - Yes ☐ 2 - No

31. Was an agent(s) administered to treat the infection(s)?*(IFNAGTRT)* ☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for the infection(s):

Agents administered for prophylaxis should not be reported.

32. 1st agent:*(IFN1AGNT)*

abacavir (Ziagen)
acyclovir (Zovirax)
albendazole (Albenza)
amantadine (Symmetrel, Symadine)
amikacin (Amikin)
*Additional Options Listed Below

Specify other agent:*(IFN1AGSP)*

33. 2nd agent:*(IFN2AGNT)*

abacavir (Ziagen)
acyclovir (Zovirax)
albendazole (Albenza)
amantadine (Symmetrel, Symadine)
amikacin (Amikin)
*Additional Options Listed Below

Specify other agent:*(IFN2AGSP)*

34. 3rd agent:*(IFN3AGNT)*

abacavir (Ziagen)
acyclovir (Zovirax)
albendazole (Albenza)
amantadine (Symmetrel, Symadine)
amikacin (Amikin)
*Additional Options Listed Below

Specify other agent:*(IFN3AGSP)*

35. Were additional agents administered for the infection(s)?*(IFNADDAG)* ☐ 1 - Yes ☐ 2 - No

If yes, specify additional agents administered:*(IFNADDSP)*

Comments: *(IFNCOMM)*

Additional Selection Options for IFN

Infection Site *(INFSITE)* (key field):
01 - Blood/Buffy Coat
02 - Disseminated - Generalized, Isolated at 2 or More Distinct Sites
03 - Brain
04 - Spinal Cord
05 - Meninges and CSF
06 - Central Nervous System Unspecified
07 - Lips
08 - Tongue, Oral Cavity, and Oro-Pharynx
09 - Esophagus
10 - Stomach
11 - Gallbladder and Biliary Tree (Not Hepatitis), Pancreas
12 - Small Intestine
13 - Large Intestine
14 - Feces/Stool
15 - Peritoneum
16 - Liver
17 - Gastrointestinal Tract Unspecified
18 - Upper Airway and Nasopharynx
19 - Larynx
20 - Lower Respiratory Tract (Lung)
21 - Pleural Cavity, Pleural Fluid
22 - Sinuses
23 - Respiratory Tract Unspecified
24 - Kidneys, Renal Pelvis, Ureters and Bladder
25 - Prostate
26 - Testes
27 - Fallopian Tubes, Uterus, Cervix
28 - Vagina
29 - Genito-Urinary Tract Unspecified
30 - Genital Area
31 - Rash, Pustules, or Abscesses Not Typical of Any of the Above
32 - Skin Unspecified
33 - Woundsite
34 - Catheter Tip
35 - Eyes
36 - Ears
37 - Joints
38 - Bone Marrow
39 - Bone Cortex (Osteomyelitis)
40 - Muscle (Excluding Cardiac)
41 - Cardiac (Endocardium, Myocardium, Pericardium)
42 - Lymph Nodes
43 - Spleen
99 - Other Unspecified

Organism I:
B06 - Bacteroides (gracillis, uniformis, vulgaris, other species)
B07 - Borrelia (Lyme disease)
B08 - Branhamelia or Moraxella catarrhalis (other species)
B09 - Campylobacter (all species)
B11 - Chlamydia
B12 - Citrobacter (freundii, other species)
B13 - Clostridium (all species except difficile)
B14 - Clostridium difficile
B15 - Corynebacterium (all non-diptheria species)
B16 - Coxiella
B17 - Enterobacter
B18 - Enterococcus (all species)
B19 - Escherichia (also E. coli)
B20 - Flavimonas oryzihabitans
B21 - Flavobacterium
B22 - Fusobacterium nucleatum
B23 - Gram Negative Diplococci (NOS)
B24 - Gram Negative Rod (NOS)
B25 - Gram Positive Cocci (NOS)
B26 - Gram Positive Rod (NOS)
B27 - Haemophilus (all species including influenzae)
B28 - Helicobacter pylori
B29 - Klebsiella
B30 - Lactobacillus (bulgaricus, acidophilus, other species)
B31 - Legionella
B32 - Leptospira
B33 - Leptotrichia buccalis
B34 - Leuconostoc (all species)
B35 - Listeria
B36 - Methylobacterium
B37 - Micrococcus (NOS)
B38 - Mycobacteria (avium, bovium, haemophilum, intercellulare)
B39 - Mycoplasma
B40 - Neisseria (gonorrhoea, meningitidis, other species)
B41 - Nocardia
B42 - Pharyngeal/Respiratory Flora
B43 - Propionibacterium (acnes, avidum,

granulosum, other species)
B44 - Pseudomonas (all species except
cepacia and maltophilia)
B45 - Pseudomonas or Burkholderia cepacia
B46 - Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia
B47 - Rhodococcus
B48 - Rickettsia
B49 - Salmonella (all species)
B50 - Serratia marcescens
B51 - Shigella
B52 - Staphylococcus (coag -)
B53 - Staphylococcus (coag +)
B54 - Staphylococcus (NOS)
B55 - Stomatococcus mucilaginosis
B56 - Streptococcus (all species except Enterococcus)
B57 - Treponema (syphilis)
B58 - Tuberculosis (NOS, AFB, acid fast bacillus, Koch bacillus)
B59 - Typical Tuberculosis (TB, Tuberculosis)
B60 - Vibrio (all species)
B99 - Other Bacteria
V01 - Herpes Simplex (HSV1, HSV2)
V02 - Herpes Zoster (Chicken pox, Varicella)
V03 - Cytomegalovirus (CMV)
V04 - Adenovirus
V05 - Enterovirus (Coxsackie, Echo, Polio)
V06 - Hepatitis A (HAV)
V07 - Hepatitis B (HBV, Australian antigen)
V08 - Hepatitis C (includes non-A and non-B, HCV)
V09 - HIV-1, HITLV-III
V10 - Influenza (Flu)
V11 - Measles (Rubeola)
V12 - Mumps
V13 - Papovavirus
V14 - Respiratory Syncytial virus (RSV)
V15 - Rubella (German Measles)
V16 - Parainfluenza
V17 - HHV-6 (Human Herpes Virus)
V18 - Epstein-Barr Virus (EBV)
V19 - Polyomavirus
V20 - Rotavirus
V21 - Rhinovirus (Common Cold)
V22 - Other Viral
P1 - Pneumoncystis (PCP)
P2 - Toxoplasma
P3 - Giardia
P4 - Cryptosporidium
P5 - Amebiasis
P6 - Echinocoocalcyst
P7 - Trichomonas (either vaginal or gingivitis)
P8 - Other Protozoal (Parasite)
O1 - Mycobacterium Tuberculosis
O2 - Other Mycobacterium
O3 - Mycoplasma
O4 - Other Organism
F01 - Candida Albicans
F02 - Candida Krusei
F03 - Candida Parasilosis
F04 - Candida Tropicalis
F05 - Torulopsis Galbrata (a subspecies of Candida)
F06 - Candida (NOS)
F07 - Asperguillus Flavus
F08 - Asperguillus Fumigatus
F09 - Asperguillus Niger
F10 - Asperguillus (NOS)
F11 - Cryptococcus Species
F12 - Fusarium Species
F13 - Mucormycosis (Zygomycetes, Rhizopus)
F14 - Yeast (NOS)
F15 - Other Fungus

1st agent:
amoxicillin / clavulanate (Augmentin)
amphotericin b (Abelcet, Amphotec, Fungizone)
ampicillin (Omnipen, Polycillin)
ampicillin / sulbactam (Unasyn)
amprenavir (Agenerase)
atovaquone (Meprone)
azithromycin (Zithromax, Z-Pack)
cefaclor (Ceclor)
cefadroxil (Duricef, Ultracef)
cefazolin (Ancef, Kefzol)
cefdinir (Omnicef)
cefepime (Maxipime)
cefixime (Suprax)
cefoperazone (Cefobid)
cefotaxime (Claforan)
cefotetan (Cefotan)

cefoxitin (Mefoxin)
cefpodoxime (Vantin)
cefprozil (Cefzil)
ceftazidime (Fortaz, Tazicef)
ceftriaxone (Rocephin)
cefuroxime (Ceftin, Kefurox, Zinacef)
cephalexin (Keflet, Keflex, Keftab)
chloramphenicol (Chloromycetin)
cidofovir (Vistide)
ciprofloxacin (Cipro)
clarithromycin (Biaxin)
clindamycin (Cleocin)
clotrimazole (Mycelex, Lotrimin)
clotrimoxazole / betamethasone (Lotrisone)
co-trimoxazole (Bactrim, Septra, Sulfamethoprim)
dapsone (DDS)
dicloxacillin (Dycill, Dynapen, Pathocil)
didanosine (Videx, ddI)
doxycycline (Vibramycin)
efavirenz (Sustiva)
erythromycin (Ery-Tab, Ilosone, Pediamycin)
erythromycin ethyl/sulfisoxazole (Pediazole)
erythromycin topical (Akne-mycin, Eryderm)
ethambutol (Myambutol)
famciclovir (Famvir)
fluconazole (Diflucan)
flucytosine (Ancobon)
foscarnet (Foscavir)
ganciclovir (Cytovene)
gatifloxacin (Tequin)
gentamicin (Garamycin, Gentacidin)
grepafloxacin (Raxar)
hepatitis a vaccine (Havrix, Vaqta)
hepatitis b vaccine (Recombivax HB, Engerix-B)
hepatitis c vaccine
imipenem / cilastatin (Primaxin)
imiquimod (Aldara)
indinavir (Crixivan)
interferon alfacon-1 (Infergen)
interferon beta-1a (Avonex)
interferon beta-1b (Betaseron)
isoniazid (INH, Lanizid, Nydrazid)
itraconazole (Sporonox)
ivermectin (Stromectol)
kanamycin (Kantrex)
ketoconazole (Nizoral)
lamivudine (Epivir, 3TC)
levofloxacin (Levaquin)
linezolid (Zyvox)
lopinavir/ritonavir (Kaletra)
mefloquine (Larium)
meropenem (Merrem I.V.)
metronidazole (Flagyl, Protostat)
minocycline (Arestin)
moxifloxacin hydrochloride (Avelox)
mupirocin (Bactroban)
nafcillin (Nallpen, Unipen)
nelfinavir (Viracept)
neomycin (Mycifradin, Myciguent)
neomycin / polymxin / hydrocortisone (Cortisporin)
nevirapine (Viramune)
nitrofurantoin (Macrobid)
nystatin (Mycostatin)
oseltamivir (Tamiflu)
oxacillin (Bactocill)
palivizumab (Synagis)
penicillin g (Bicillin)
penicillin vk (V-Cillin K, Veetids)
pentamidine (Pentam 300)
piperacillin (Pipracil)
piperacillin/tazobactam (Zosyn)
podofilox (Condylox)
polymyxin (Ak-Spore H.C., Cortisporin Ophthalmic Suspension)
PPD skin test (Mantoux Test, Tine Test)
pyrazinamide (Rifater)
pyrimethamine (Daraprim)
quinidine gluconate (Duraquin, Cardioqiuin)
quinupristin/dalfopristin (Synercid)
respiratory syncytial immune globulin (Respigam)
ribavirin (Virazole)
rifampin (Rifadin, Rimactane)
rifampin/isoniazid (Rifamate, Rimactane/INH)
rifampin/isoniazid/pyrazinamide (Rifater)
rimantadine (Flumadine)
ritonavir (Norvir)
saquinavir mesylate (Fortovase, Invirase)
stavudine (d4T, Zerit)

streptomycin (Streptomycin sulfate)
sulfamethoxazole / trimethoprim (Bactrim)
terbinafine (Lamisil)
terconazole (Terazol)
tetracycline (Achromycin)
ticarcillin / clavulanate (Ticar, Timentin)
tobramycin (Nebcin, Tobrex, TobraDex)
trimethoprim / sulfamethoxazole (Bactrim, Septra, Co-trimoxazole)
valacyclovir (Valtrex)
valganciclovir (Valcyte)
vancomycin (Vancocin)
zidovudine (AZT, Retrovir)
other

Blood and Marrow Transplant Clinical Trials Network

Laboratory Assessment Form - 0903 (LA8)

Web Version: 1.0; 3.01; 10-16-15

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

Hemoglobin

1. Enter the patient's most recent hemoglobin value without transfusion support: *(LA8HGVAL)* _____ *(xx.x)* g/dL
2. Enter the date the hemoglobin level was obtained:*(LA8HGDT)* _____ *(mm/dd/yyyy)*

Flow Cytometry

3. Record the patient's most recent WBC:*(LA8WBC)* _____ *(xxxxxx)* /µL
4. Enter the date the WBC was obtained:*(LA8WBCDT)* _____ *(mm/dd/yyyy)*
5. Record the date the flow cytometry was performed:*(LA8FLCDT)* _____ *(mm/dd/yyyy)*
6. CD2:*(LA8CD2VL)* _____ *(xxxxx)* cells/?L
7. CD3:*(LA8CD3VL)* _____ *(xxxxx)* cells/?L
8. CD4:*(LA8CD4VL)* _____ *(xxxxx)* cells/µL
9. CD8:*(LA8CD8VL)* _____ *(xxxxx)* cells/?L
10. CD19:*(LA8CD19V)* _____ *(xxxxx)* cells/?L
11. CD3+/CD25+:*(LA8CD25V)* _____ *(xxxxx)* cells/?L
12. CD45 RA/RO:*(LA8CD45V)* _____ *(xxxxx)* cells/?L
13. CD56+/CD3-:*(LA8CD56V)* _____ *(xxxxx)* cells/?L

Quantitative Immunoglobulins

14. IgA:*(LA8IGA)* _____ *(xxxxx.xx)* *(LA8IGAUN)* [1 - g/dL / 2 - mg/dL]
15. Date:*(LA8IGADT)* _____ *(mm/dd/yyyy)*
16. IgG:*(LA8IGG)* _____ *(xxxxx.xx)* *(LA8IGGUN)* [1 - g/dL / 2 - mg/dL]
17. Date:*(LA8IGGDT)* _____ *(mm/dd/yyyy)*
18. IgM:*(LA8IGM)* _____ *(xxxxx.xx)* *(LA8IGMUN)* [1 - g/dL / 2 - mg/dL]
19. Date:*(LA8IGMDT)* _____ *(mm/dd/yyyy)*

HIV Viral Copy

20. Record the patient's HIV viral copy number:*(LA8HIVCP)* _____ *(xxxxx)* copies/mL
21. Record the date the patient's HIV viral copy number was obtained: *(LA8CPYDT)* _____ *(mm/dd/yyyy)*

Platelets

22. Record the most recent platelet count:*(LA8RCPLT)* _____ *(xxxxxx)* /µL
23. Record the date of the most recent platelet count:*(LA8PLTDT)* _____ *(mm/dd/yyyy)*

Neutrophils

24. Record the most recent ANC count:*(LA8RCANC)* _____ *(xxxxx)* /µL

25. Record the date of the most recent ANC count:*(LA8ANCDT)* _____ *(mm/dd/yyyy)*

26. Were growth factors given during the assessment period?*(LA8GWTFC)* ☐ 1 - Yes ☐ 2 - No

27. Record the date growth factors were last given:*(LA8GFCDT)* _____ *(mm/dd/yyyy)*

Comments:*(LA8CMMTS)*

Blood and Marrow Transplant Clinical Trials Network

Endpoint Review Query Form - 0903 (Q11)

Web Version: 1.0; 1.00; 06-28-16

Case ID *(CASEID)*:

Site:*(QXXSITE)*

Patient ID:*(QXXPATID)*

Number of Queries Indicated:*(QRYNUM)*

Queries

Query Status	Date Query Sent	Query	Date Response Received	
(QSTAT01) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT01)* *(mm/dd/yyyy)*	*(QDESC01)*	*(QRSPDT01)* *(mm/dd/yyyy)*	*(QRSPNS01)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT02) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT02)* *(mm/dd/yyyy)*	*(QDESC02)*	*(QRSPDT02)* *(mm/dd/yyyy)*	*(QRSPNS02)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT03) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT03)* *(mm/dd/yyyy)*	*(QDESC03)*	*(QRSPDT03)* *(mm/dd/yyyy)*	*(QRSPNS03)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT04) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT04)* *(mm/dd/yyyy)*	*(QDESC04)*	*(QRSPDT04)* *(mm/dd/yyyy)*	*(QRSPNS04)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT05)	*(QSNTDT05)* *(mm/dd/yyyy)*	*(QDESC05)*	*(QRSPDT05)* *(mm/dd/yyyy)*	*(QRSPNS05)*

1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved				

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT06) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT06)* *(mm/dd/yyyy)*	*(QDESC06)*	*(QRSPDT06)* *(mm/dd/yyyy)*	*(QRSPNS06)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT07) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT07)* *(mm/dd/yyyy)*	*(QDESC07)*	*(QRSPDT07)* *(mm/dd/yyyy)*	*(QRSPNS07)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT08) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT08)* *(mm/dd/yyyy)*	*(QDESC08)*	*(QRSPDT08)* *(mm/dd/yyyy)*	*(QRSPNS08)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT09) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT09)* *(mm/dd/yyyy)*	*(QDESC09)*	*(QRSPDT09)* *(mm/dd/yyyy)*	*(QRSPNS09)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT10) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT10)* *(mm/dd/yyyy)*	*(QDESC10)*	*(QRSPDT10)* *(mm/dd/yyyy)*	*(QRSPNS10)*

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 0903 (SA7)

Web Version: 1.0; 1.00; 10-16-15

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

Microbial Translocation Markers

1. Was a peripheral blood sample collected for microbial translocation markers? *(SA7MICTR)* ☐ 1 - Yes ☐ 2 - No
   2. Record the date the peripheral blood sample for microbial translocation markers testing was collected:*(SA7MTRDT)* _____ *(mm/dd/yyyy)*

HIV Reservoir

3. Does the patient have negative HIV viral loads?*(SA7NEGVI)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
4. Was a peripheral blood sample collected for latent HIV reservoir testing? *(SA7LATHI)* ☐ 1 - Yes ☐ 2 - No
   5. Record the date the peripheral blood sample for latent HIV reservoir testing was collected:*(SA7LATDT)* _____ *(mm/dd/yyyy)*
6. Was a peripheral blood sample collected for HIV single copy PCR testing? *(SA7HIVSI)* ☐ 1 - Yes ☐ 2 - No
   7. Record the date the peripheral blood sample for HIV single copy PCR testing was collected:*(SA7HIVDT)* _____ *(mm/dd/yyyy)*

Immune Reconstitution Studies

8. Was a peripheral blood sample collected for immune reconstitution testing? *(SA7IMMRE)* ☐ 1 - Yes ☐ 2 - No
   9. Record the date the peripheral blood sample for immune reconstitution testing was collected:*(SA7IMMDT)* _____ *(mm/dd/yyyy)*

Future Research

10. Was a peripheral blood sample for future research collected?*(SA7FUTUR)* ☐ 1 - Yes ☐ 2 - No
    11. Record the date the peripheral blood sample for future research was collected:*(SA7FUTDT)* _____ *(mm/dd/yyyy)*

Comments:*(SA7COMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0903 (T20)

Web Version: 1.0; 1.00; 10-16-15

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Record date of evaluation:*(TXYEVLDT)* _____ *(mm/dd/yyyy)*

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 4.02.

GI Disorders

2. Oral mucositis:*(ORLMUCOS)*
   - 0 - Grades 0-2
   - 3 - Severe pain; interfering with oral intake
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

Renal Disorders

3. Cystitis noninfective:*(CYSTNINF)*
   - 0 - Grades 0-2
   - 3 - Gross hematuria; transfusion, IV meds or hosp indicated;
   - 4 - Life-threatening consequences; urgent radiologic or operative intervention indicated
   - 5 - Death

4. Acute kidney injury:*(ACKIDINJ)*
   - 0 - Grades 0-2
   - 3 - Creatinine >3x baseline; >4.0 mg/dL; hospitalization indicated
   - 4 - Life-threatening consequences; dialysis indicated
   - 5 - Death

5. Chronic kidney disease:*(CHKIDDIS)*
   - 0 - Grades 0-2
   - 3 - eGFR or CrCl 29-15 ml/min/1.73 m^2
   - 4 - eGFR <15 ml/min/1.73 m^2; dialysis or renal transplant indicated
   - 5 - Death

6. Did the patient receive dialysis?*(RCVDIALY)* ☐ 1 - Yes ☐ 2 - No

7. If yes, were laboratory values corrected?*(LBVALCOR)* ☐ 1 - Yes ☐ 2 - No

Hemorrhagic Disorders

8. Hemorrhage:*(HEMORRHG)*
   - 0 - Grades 0-2
   - 3 - Transfusion, radiologic, endoscopic, or elective operative intervention indicated
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

9. Which organ system was the hemorrhage associated with?*(ORGSYHEM)*
   - 1 - CNS
   - 2 - Gastrointestinal
   - 3 - Genitourinary
   - 4 - Pulmonary, Upper Respiratory
   - 5 - Other

Specify other organ system:*(ORGSYHSP)* _____

Cardiac Disorders

10. Cardiac arrhythmia:*(CRDARRHY)*
    - 0 - Grades 0-2
    - 3 - Severe, medically significant; medical intervention indicated
    - 4 - Life-threatening consequences; hemodynamic compromise; urgent intervention indicated
    - 5 - Death

11. Specify arrhythmia:*(CRDARRSP)* _____

12. Left ventricular systolic dysfunction:*(LFVTSYDF)*

0 - Grades 0-2
3 - Symptomatic due to drop in ejection fraction responsive to intervention
4 - Refractory or poorly controlled HF; ventricular device, iv vaso, or heart transplant indicated
5 - Death

13. Pericardial effusion:*(PERCRDEF)*

0 - Grades 0-2
3 - Effusion with physiologic consequences
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

Nervous System Disorders

14. Somnolence:*(SOMNOLN)*

0 - Grades 0-2
3 - Obtundation or Stupor
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

15. Seizure:*(TXSEIZR)*

0 - Grades 0-2
3 - Multiple seizures despite medical intervention
4 - Life-threatening; prolonged repetitive seizures
5 - Death

16. Neuropathy:*(NEURPTHY)*

0 - Grades 0-2
3 - Severe symptoms; limiting self care ADL
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

17. Specify neuropathy type:*(NEURTYSP)*

1 - Motor
2 - Sensory
3 - Both motor and sensory

Blood and Lymphatic Disorders

18. Thrombotic thrombocytopenic purpura:*(THRMBPUR)*

0 - Grades 0-2
3 - Laboratory findings with clinical consequences [e.g., renal insufficiency, petechiae]
4 - Life-threatening consequences [e.g., CNS hemorrhage or thrombosis/embolism or renal failure]
5 - Death

Vascular Disorders

19. Hypotension:*(HYPOTEN)*

0 - Grades 0-2
3 - Medical intervention or hospitalization indicated
4 - Life-threatening and urgent intervention indicated
5 - Death

20. Hypertension:*(HYPERTSN)*

0 - Grades 0-2
3 - Stage 2 [SBP 160+ mmHg or DBP 100+ mmHg]; medical intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

21. Capillary leak syndrome:*(CAPLKSYN)*

0 - Grades 0-2
3 - Severe symptoms; intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

22. Thromboembolic event:*(THROMBEV)*

0 - Grades 0-2
3 - Thrombosis; medical intervention indicated
4 - Life-threatening; urgent intervention indicated
5 - Death

Respiratory, Thoracic and Mediastinal Disorders

23. Hypoxia:*(TXHYPXIA)*

0 - Grades 0-2
3 - Decreased oxygen saturation at rest (e.g. pulse oximeter <88% or PaO2 <= 55 mm Hg)
4 - Life-threatening airway compromise; urgent intervention indicated
5 - Death

24. Dyspnea:*(TXDYSPNA)*

0 - Grades 0-2
3 - Shortness of breath at rest; limiting self care ADL
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

Metabolism and Nutrition Disorders

25. Hyperglycemia:*(HYPRGLYC)*

0 - Grades 0-2
3 - >250-500 mg/dL; >13.9-27.8 mmol/L; hospitalization indicated
4 - >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5 - Death

Chemistry/Investigations

26. Cholesterol:*(CHOLESTR)*

0 - Grades 0-2
3 - >400-500 mg/dL; >10.34-12.92 mmol/L
4 - >500 mg/dL; >12.92 mmol/L

27. Triglycerides:*(TRIGLYCR)*

0 - Grades 0-2
3 - >500-1000 mg/dL; >5.7-11.4 mmol/L
4 - >1000 mg/dL; >11.4 mmol/L; life-threatening consequences
5 - Death

Hepatic Disorders

28. ALT:*(TXALT)*

0 - Grades 0-2
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

29. AST:*(TXAST)*

0 - Grade 0-2
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

30. Bilirubin:*(TXBILIRB)*

0 - Grades 0-2
3 - >3.0-10.0 x ULN
4 - >10.0 x ULN

31. Alkaline Phosphatase:*(TXALKPH)*

0 - Grades 0-2
3 - >5.0-20.0 x ULN
4 - >20.0 ULN

32. Did the patient develop any clinical signs/symptoms of abnormal liver function during this assessment period?*(SYMABNLF)* ☐ 1 - Yes ☐ 2 - No

Indicate all clinical signs/symptoms of abnormal liver functioning:

33. Jaundice:*(TXJAUND)* ☐ 1 - Yes ☐ 2 - No
34. Hepatomegaly:*(HEPTMGLY)* ☐ 1 - Yes ☐ 2 - No
35. Right upper quadrant pain:*(RTQUADPN)* ☐ 1 - Yes ☐ 2 - No
36. Weight gain (>5%) from baseline:*(TXWGHTGN)* ☐ 1 - Yes ☐ 2 - No
37. Other clinical signs/symptoms:*(OTLVABN)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms of abnormal liver function:*(OTLVABSP)*

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
38. VOD:	*(VODETIOL)* 1 - Yes; 2 - No	*(VODBIOP)* 1 - Positive; 2 - Negative; 3 - Equivocal; 4 - Not Done	*(VODDOPP)* 1 - Confirmed; 2 - Not Confirmed; 3 - Not Done
39. GVHD:	*(GVHETIOL)* 1 - Yes; 2 - No	*(GVHBIOP)* 1 - Positive; 2 - Negative; 3 - Equivocal; 4 - Not Done	*(GVHDOPP)* 1 - Confirmed; 2 - Not Confirmed; 3 - Not Done

40. Infection:	*(INFETIOL)* 1 - Yes 2 - No	*(INFBIOP)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(INFDOPP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
41. Other:	*(OTHETIOL)* 1 - Yes 2 - No	*(OTHBIOP)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(OTHDOPP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
42. Unknown:	*(UNKETIOL)* 1 - Yes 2 - No	N/A	N/A

Specify other etiology:*(OTHETSP)*

Comments:*(T20COMM)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 17.01; 11-17-17

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Record date of initiation of conditioning regimen:*(CONDNGDT)* _____ *(mm/dd/yyyy)*
2. Record date of hematopoietic stem cell infusion:*(TXDTTXP)* _____ *(mm/dd/yyyy)*
3. Record the patient's pre-transplant CMV antibody (IgG) status:*(CMVSTAT)* ☐ 1 - Positive ☐ 2 - Negative
4. Record the stem cell source:*(TXPSTMSR)*
   - 1 - Peripheral Blood
   - 2 - Bone Marrow
5. IUBMID for this patient (if available):*(T_IUBMID)* _____

Comments:*(COMMTXP1)* _____